Consolidated Technical Specifications of COVID-19 Medicines, Supplies and Equipment

Depart of Health Services
Ministry of Health and Population
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This report on the **"Consolidated Technical Specifications of COVID-19 Medicines, Supplies and Equipment"** ***produced within the agreed timeframe, incorporating relevant information from all procurement centres of MoHP (2020)*** has been prepared by the Department of Health Services (DoHS)/Ministry of Health and Population (MoHP) with the technical and financial assistance of the UKaid and the Nepal Health Sector Support Programme (NHSSP).

Contributors: Dr. Dipendra Raman Singh, Dr. Ramesh Kharel, Mr. Chudamani Bhandari, Dr. Suresh Tiwari, and Baburam Humagain

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EXECUTIVE SUMMARY

This report is concerned with the development and compilation of technical specifications required for the management of Coronavirus Disease (COVID-19) cases. This report includes four different category items, viz: Personal Protective Equipment (PPE), laboratory kits and reagents, Intensive Care Unit (ICU) medicines and major equipment. The purpose of this task was to contribute to the improvement of procurement processes by developing a consolidated list of technical specifications for COVID-19 commodities, approved by the Ministry of Health and Population (MoHP). It is important to ensure that required medical goods and services work efficiently, are of high quality and are within the estimated cost range to assure procurement integrity. While preparing these specifications, several sets of guidelines and protocols were taken as major references: the World Health Organization (WHO) specifications, Centers for Disease Control and Prevention (CDC) protocols, guidelines created by the Incident Command System (ICS) and national protocols developed by the Health Emergency Operation Centre (HEOC). As a result of the COVID-19 pandemic and subsequent lockdown, a wider consultation between stakeholders, including Sub-national Governments (SNGs), could not be carried out: this is a limitation of this report. Detailed technical specifications of the following items have been prepared:

SN	Item type	Number
1	PPE	12
2	Laboratory kits and reagents	4
3	ICU medicines	71
4	COVID-19-specific equipment	18

These specifications are designed to provide the requirements to be followed by Procuring Entities (PEs) for the assurance of the quality of goods procured and to ensure wider participation of bidders. This document will help potential suppliers to understand the quality specification of commodities. Additionally it helps ensure efficiency, assure quality, maintain transparency and ensure effective procurement management functions.

ABBREVIATIONS

AED	Automated External Defibrillator
BIPAP	Bi-level Positive Airway Pressure
BP	British Pharmacopoeia
CDC	Centers for Disease Control and Prevention
COVID-19	Coronavirus Disease
CPAP	Continuous Positive Airway Pressure
DFID	UK Department for International Development
DoHS	Department of Health Services
ECG	Electrocardiogram
EDP	External Development Partner
ET	Endotracheal
FMIP	Financial Management Improvement Plan
GoN	Government of Nepal
HEOC	Health Emergency Operation Centre
HME	Heat and Moisture Exchanger
HSERP	Health Sector Emergency Response Plan
ICS	Incident Command System
ICU	Intensive Care Unit
IP	Indian Pharmacopoeia
LMD	Logistics Management Division
MD	Management Division
MoHP	Ministry of Health and Population
NHSS	Nepal Health Sector Strategy
NHSSP	Nepal Health Sector Support Programme
NPHL	National Public Health Laboratory
PAHO	Pan American Health Organization
PDI	Post-delivery Inspection

PE	Procuring Entity
PIP	Procurement Improvement Plan
PPA	Public Procurement Act
PPE	Personal Protective Equipment
PPR	Public Procurement Regulation
RT-PCR	Reverse Transcription Polymerase Chain Reaction
SNG	Sub-national Government
TA	Technical Assistance
ToR	Terms of Reference
TSB	Technical Specification Bank
USG	Ultrasonography
USP	United States Pharmacopoeia
VfM	Value for Money
VTM	Virus Transport Medium
WHO	World Health Organization
W/V	Weight/Volume

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CHAPTER 1 – INTRODUCTION

1.1 Background

The Nepal Health Sector Strategy (NHSS) 2015–20 addresses the health challenges of Nepal to ensure access to free basic health care services that are quality assured, transparent and accountable to the people. In order to implement this strategy, the Federal Ministry of Health and Population (MoHP) must develop the capacity of its departments, councils, academies, centres, hospitals and Procuring Entities (PEs) to be involved in procurement proceedings. Under this strategy, the MoHP has endorsed the Financial Management Improvement Plan (FMIP) 2016–21 and the Procurement Improvement Plan (PIP) 2017–21. Both of these documents outline the importance of improving procurement practices in the health sector by implementing reform initiatives that will contribute to resolving the current issues related to the procurement cycle.

NHSS 2015/16-21/22 addresses the health challenges of Nepal to ensure universal access to free and high-quality basic health care services that are transparent and accountable to the people. Ensuring the quality of services includes the provision of high-quality equipment, medicines and other supplies. The MoHP has therefore mandated its departments, centres, councils, hospitals, academies and several PEs to be an essential part of procurement proceedings.

The UK-funded Nepal Health Sector Programme 3 (NHSP3)/ Nepal Health Sector Support Programme (NHSSP) is committed to supporting the MoHP to achieve this strategic goal of the NHSS, to deliver the highest-quality services while ensuring Value for Money (VfM) in expenditures. A core area of work within the NHSSP's Leadership and Governance thematic area is to support the MoHP to develop a streamlined, efficient, accountable and transparent procurement system that is built on good procurement management practices. This includes helping to develop strategies, set up protocols, define standards and improve existing structures and mechanisms so that equipment, medicines and supplies at the point of delivery are safe to use and make services efficient.

In the Coronavirus Disease (COVID-19) pandemic, the Management Division (MD) within the Department of Health Services (DoHS) is responsible for procuring a large number of specific goods and services for the management of COVID-19 cases. At the same time, the division has responsibility for managing various goods and services for regular functions, including medicines, vaccines, contraceptives, equipment, instruments and accessories. Initially, the MD adopted an "emergency management" approach to implementing the Health Sector Emergency Response Plan (HSERP) for the COVID-19 pandemic. The division, which had been assigned the responsibility of managing procurement and related logistics for this purpose, adopted technical specifications of the items procured that were based on World Health Organization (WHO) and other international/national references. However, this "emergency management" approach now has to be regularised for the continuing COVID-19 context.

1.2 Rationale

A technical specification is a legal document mandatorily required for procurement management initiation as per the Public Procurement Act (PPA) and Public Procurement Regulation (PPR). Without this document, procurement proceedings cannot be started. A technical specification provides the detailed qualitative requirements of the procurement process. It should cover material composition, physical, dimensional, and performance parameters. The preparation of specifications has the greatest impact on quality and VfM in procurement. One of the key indicators of procurement integrity is specification of procurement items in the

planning process. The process is more efficient, fair and transparent when clearly defined technical specifications of the various commodities are in place and are used.

Certain COVID-19-related commodities do not appear on existing lists of regularly used items: for example, Personal Protective Equipment (PPE) related to COVID-19 was not in regular demand or use before the pandemic. A separate and consolidated list of COVID-19-related commodities, complete with technical specifications, was urgently required to ensure quality consistency in procured items and to elicit participation from a wider pool of bidders. The prepared specifications shall be referred to by all levels of government, from Federal to Sub-national Government (SNG), as well as hospitals. Technical specifications of COVID-19-related commodities are even more significant in the federal context: procurement processes are decentralised and each sphere of government procures commodities based on their needs. In addition, since autonomous agencies and private sector providers also procure COVID-19-related items, robust specifications are necessary not only to ensure quality but also to elicit participation from a wider pool of bidders.

1.3 Technical Specification Bank (TSB)

A Technical Specification Bank (TSB) is a bank, operated through software, containing the technical specifications of pharmaceuticals and medical equipment. In 2015/16, a TSB was designed and put into operation with the support of UKaid; it was updated with standard coding of pharmaceuticals and equipment in 2017/18. The TSB is available on the MD website (***www.dohslmd.gov.np***) and is open to use for all users, even those outside the health sector. A guideline for the use of the TSB was prepared and in 2017/18, orientation training on using the TSB effectively was given to the staff of the DoHS. All specifications are provided with a unique code, by which required goods can be identified.

At present, the technical specifications of drugs and equipment required for the bidding process in the DoHS are almost all drawn from the TSB. The TSB has significantly helped PEs in all spheres of government by reducing the time spent preparing technical specifications for medical equipment and pharmaceuticals and seeking the input of technical experts. The specifications downloaded from the TSB have also helped PEs to estimate the costs of procurement. To date, more than 1000 TSB users (individuals/institutions, including all users from local to federal level) have been registered. Similarly, more than 27,000 downloads and more than 19,000 searches for different specifications have been recorded.

The specifications developed for COVID-19 commodities, once uploaded onto the system and approved, will also automatically be provided with separate unique codes by the system. This will allow anyone, especially PEs, to refer only to a code for a particular item with standard approved technical specification to be procured.

1.4 Purpose

The purpose of this task was to contribute to the improvement of procurement processes by developing a consolidated list of technical specifications for COVID-19 commodities, approved by the MoHP. The specific tasks included:

- Prepare draft specifications of COVID-19-related commodities (supplies, reagents, medicines and equipment);
- Share and seek feedback on the draft specifications of COVID-19-related commodities from technical experts;
- Validate the consolidated technical specifications of COVID-19 commodities through a high-level stakeholders' workshop;

- Present consolidated technical specifications of COVID-19 commodities to the Consolidated Annual Procurement Plan Monitoring Committee, and seek recommendation for their approval;
- Ensure the approval of consolidated technical specifications of COVID-19 commodities, from the MD, DoHS.

1.5 Methodology

A draft of specifications of COVID-19 commodities was prepared, which included the following:

- PPE;
- Laboratory reagents, kits and Virus Transport Medium (VTM) employed in Coronavirus tests using Reverse Transcription Polymerase Chain Reaction (RT-PCR) technology;
- Equipment used in COVID testing and COVID case management; and
- Major ICU/ventilator consumables.

In preparing specifications, those recommended by the WHO were taken as the major reference for COVID-19-specific items; recommendations from the Centers for Disease Control and Prevention (CDC) and other international practices were also reviewed. Medicines and consumables were selected in line with the national protocol developed by the Health Emergency Operation Centre (HEOC), while laboratory reagents and kits were based on the technologies used by laboratories in testing. Equipment was selected according to the protocol and decisions made by the Incident Command System (ICS) under the MoHP.

1.6 Limitations

The COVID-19 pandemic has led to restrictions in movement and gathering. Formal meetings and workshops could not be organised and a wider consultation could therefore not be carried out: consultation with provinces and local levels was not possible. It would have been better if a wider consultation with users and suppliers had been carried out. Further, certain specifications could not be imported into the TSB because of issues with compatibility between the specification format and the current software layout. There was insufficient time to align these elements; however, the process has been harmonised by restructuring the TSB software.

CHAPTER 2 – CONSOLIDATION OF SPECIFICATIONS

2.1 Existing Status

At present, there are 121 technical specifications of pharmaceuticals and 1109 specifications of medical equipment recorded in the TSB; these are referred to by MD and SNGs in their procurement processes. The current specifications are periodically updated and new specifications of medicines and consumables are developed and added to the TSB. In the current procurements, the updated specifications are being used. Although several specifications recorded in the TSB have been used in COVID-19 cases, these need to be updated as per the changes in technology and market dynamics. Several COVID-19-related items are not recorded in the TSB and were not developed. The initiative to create consolidated technical specifications of COVID-19 commodities will not only improve the capacity of federal PEs but also facilitate the strengthening of procurement functions in all spheres of government, including hospitals.

2.2 Review of Literature/References

Item identification

A list of key items required for COVID-19 case management was prepared based on the national protocol for COVID management and WHO recommendations for COVID-19 management. The list of items was verified by experts in each respective area, who were identified by the Incident Command System (ICS)/HEOC. Medicines used for Intensive Care Units (ICUs) and ICU consumables were verified by clinicians with expertise in this area.

Specification development

The following references were used to develop the draft specifications of selected items.

SN	Item type	References
1	PPE	Requirements and technical specifications of personal protective equipment (PPE) for the novel coronavirus (2019-ncov) in healthcare settings (interim recommendations, 2/6/2020). Pan American Health Organization (PAHO); Health Emergencies (Washington, D.C., PAHO, 2020-02-06) Laboratory BIOSAFETY MANUAL THIRD EDITION, file:///C:/Users/User/Baburam's%20Working%20Folder/COVID%20Specs%20references/Bio-saftey%20laboratory%20standard.pdf Comparison of FFP2, KN95, and N95 and Other Filtering Facepiece Respirator Classes. 3M Personal Safety Division. Technical Bulletin, May, 2020, Revision 4 Guidance for the Selection and Use of Personal Protective Equipment (PPE) in Healthcare Settings. file:///C:/Users/User/Baburam's%20Working%20Folder/COVID%20Specs%20references/PPE%20guidelines.pdf

2	Laboratory kits and reagents	2019 Novel Coronavirus, Wuhan, China – Guidelines for Clinical specimens. CDC, 2020. Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases: interim guidance. WHO, 2020. What COVID-19 rapid tests are available in the EU? https://akrnconsulting.com/what-is-the-status-of-the-covid-19-rapid-tests-in-the-eu-eea/ cro BEE ® NA16 NUCLEIC ACID EXTRACTION SYSTEM. file:///C:/Users/User/Baburam's%20Working%20Folder/COVID%20Specs%20references/gp-crobee-brochure-2016-en.pdf
3	Medicines, including ICU	Indian Pharmacopoeia (IP), British Pharmacopoeia (BP) and United States Pharmacopoeia (USP)
4	Equipment used in COVID testing and COVID case management	WHO technical specification for medical devices Version 1.1 , 2014 https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/covid-19-critical-items
5	Major ICU/ventilator consumables	Core medical equipment – Information. Ventilator, Intensive Care. WHO, 2011 https://www.who.int/medical_devices/innovation/ventilator_intensive_care.pdf?ua=1

2.3 Stakeholder/Expert Consultation

Following a literature review, including references listed for respective items above, a draft of COVID-related specifications was prepared. The draft document was shared with related experts and authorities and updated as per their suggestions to ensure that it was tailored to the context in Nepal.

SN	Item type	Process
1	PPE	Expert consultation with users, suppliers and biomedical engineers
2	Laboratory kits and reagents	Expert consultation with laboratory technologists, microbiologists and users of the National Public Health Laboratory (NPHL)
3	Medicines, including ICU	A meeting of suppliers' and manufacturers' representatives was organised to gain their feedback
4	Equipment used in COVID testing and COVID cases management	Expert consultation with laboratory testing and users at NPHL; feedback received from potential suppliers

5	Major ICU/ventilator consumables	WHO-recommended specifications were taken as the major reference point; these are also currently being used by the MD for COVID-19 procurement. Experts in ICU, pathology laboratories and others were consulted by telephone during the development of the Nepal-specific COVID-19-related technical specifications of medical equipment and other commodities. Current TSB specifications were also modified as required for COVID-19

All feedback and comments were critically analysed and verified for rationality and validity to ensure their appropriateness.

2.4 High-level Meeting

Several informal meetings were organised so to ensure that the technical specifications were more widely understood and accepted. Participants at these workshops included high-level MoHP officials, high-level DoHS officials, technical experts and staff of MD involved in procurement processes. The inputs from the meeting were incorporated to give the document its final shape.

2.5 Summary List of Consolidated Technical Specifications of COVID-19 Medicines, Supplies and Equipment

The following make up the list of items included in the approved "Consolidated technical specifications of COVID-19 Medicines, Supplies and Equipment."

A. List of PPE (Refer to Annex I for detailed specification)

SN	Item	SN	Item
1	Particulate-filtering face piece respirator	2	Face shields/visor
3	Nitrile gloves (no-sterile)	4	Goggles (reusable)
5	Goggles (disposable)	6	Gown level IV
7	Medical/surgical mask	8	Biohazard bag
9	Body bag (for dead body packing)	10	Apron (COVID), Coverall Protection
11	Bouffant cap	12	Hand sanitiser (disinfectant)

B. List of laboratory kits and reagents (Refer to Annex II for detailed specification)

SN	Item	SN	Item
1	Real-time RT-PCR kits for Severe Acute Respiratory Syndrome (SARS) Cov-2	2	Ribonucleic Acid (RNA) extraction reagent for manual extraction
3	VTM	4	Rapid diagnostic test kit for COVID-19

C. List of ICU medicines (Refer to Annex III for detailed specification)

SN	Item	SN	Item
1	0.9% W/V SODIUM CHLORIDE INJECTION 500ML	2	5% W/V DEXTROSE INJECTION
3	ADENSOINE 3MG/ML INJECTION	4	ADRENALINE INJECTION
5	AMIODARONE 50MG/ML INJECTION	6	AMOXYCILLIN+POTASSIUM CLAVULANATE INJECTION 1.2 GM
7	ATRACURIUM 2.5 ML INJECTION	8	ATROPINE SULPHATE 0.06% W/V INJECTION
9	AZITHROMYCIN 500MG/ML INJECTION	10	AZITHROMYCIN TABLET 500 MG
11	CALCIUM GLUCONATE INJECTION	12	CEFTRIAXONE 500MG INJECTION
13	CEFTRIAXONE 1G INJECTION	14	CHLORPROMAZINE 25MG/2ML INJECTION
15	CLINDAMYCIN INJECTION 600MG	16	DEXMEDITOMIDINE INJECTION
17	DEXAMETHASONE INJECTION	18	DEXTROSE 50% W/V
19	DIAZEPAM INJECTION 2 MG/ML, 5 ML	20	DIGOXIN 0.25MG/ML
21	DOBUTAMINE 250MG INJECTION	22	DOPAMINE 200MG TABLET
23	ENOXAPARIN 40IU INJECTION	24	ENOXAPARIN 60IU INJECTION
25	FENTANYL INJECTION	26	FRUSEMIDE INJECTION 20 MG/ML, 2 ML
27	GLYCERYL TRINITRATE 50MG/10ML INJ	28	GLYCOPYROLATE 0.2MG/ML INJECTION
29	HEPARIN 5000IU INJECTION	30	HYDRALAZINE 20MG INJECTION
31	HYDROCORTISONE POWDER FOR INJECTION	32	IMIPENEM+CILASTATIN 500MG INJECTION
33	INSULIN INJECTION SOLUBLE	34	INSULIN MIXED
35	KETOROLAC 30MG INJECTION	36	LABETALOL 5MG/ML INJECTION
37	LEVOFLOXACIN 100ML INJECTION	38	LIGNOCAINE 2% W/W OINTMENT
39	LIGNOCAINE 1% INJECTION	40	LIGNOCAINE 2% INJECTION
41	MAGNESIUM SULPHATE INJECTION	42	MEROPENEM INJECTION
43	METOPROLOL 1MG/ML INJECTION	44	METHYLPREDNISOLONE INJECTION
45	METRONIDAZOLE INJECTION	46	MIDAZOLAM 1MG/ML INJECTION
47	MORPHINE 10MG/ML INJECTION	48	NALOXONE 0.4MG INJECTION
49	NORADRENALINE 1MG/ML INJECTION	50	ONDANDTERON 2ML INJECTION
51	PANTOPRAZOLE 40MG INJECTION	52	PARACETAMOL INJECTION 150 MG/ML, 2 ML
53	PHENIRAMINE 22.75 MG/ML, 2 ML	54	PHENTYOIN SODIUM 30MG INJECTION
55	PIPERACILLIN + TAZOBACTAM INJECTION	56	PLASMA-LYTE INJECTION
57	POTASSIUM CHLORIDE 10ML INJECTION	58	PROPOFOL 10MG/ML INJECTION
59	RANITIDINE INJECTION 25 MG/ML, 2 ML	60	RINGER LACTATE 500ML INJECTION
61	ROCURONIUM 50MG INJECTION	62	SALBUTAMOL/IPRATROPIUM INHALER
63	SODIUM BICARBONATE INJECTION VIAL	64	THIOPENTAL 500MG INJECTION
65	SUXAMETHONIUM CHLORIDE 50MG INJ	66	TECIOPLANIN 400MG INJECTION
67	THIAMINE INJECTION 100 MG/ML	68	VANCOMYCIN 500MG INJECTION
69	TECIOPLANIN 400MG INJECTION	70	THIAMINE INJECTION 100 MG/ML
71	VANCOMYCIN 500MG INJECTION		

D. List of major ICU/ventilator consumables (Refer to Annex IV for detailed specification)

SN	Item	SN	Item
1	Ventilator circuit	2	Heat and Moisture Exchanger (HME) filter
3	Catheter mount	4	Suction catheter FG10
5	Endotracheal (ET) Tube 7 and 7.5	6	Yankauer Suction Tube
7	Ambu bag	8	Gudals airways 3.0 and 4.0

E. List of Equipment (Refer to Annex V for detailed specification)

SN	Item	SN	Item
1	Automated nucleic acid extraction machine	2	Automated External Defibrillator (AED)
3	Bi-level Positive Airway Pressure(BIPAP)	4	Continuous Positive Airway Pressure (CPAP)
5	Electrocardiogram (ECG) machine, portable (12 channel)	6	ICU Bed, (Fowler's Bed)
7	Infusion pump	8	Oxygen concentrator (10L)
9	Patient monitor, portable	10	Portable x-ray machine (mobile, 10KW)
11	Portable blood gas analyser	12	Pulse oximeter with ECG monitor
13	Resuscitation set, emergency	14	Electric suction pump (surgical aspirator)
15	Syringe infusion pump	16	Ultrasonography (USG) portable colour doppler with 3 probes
17	Ventilator, invasive	18	Ventilator, portable

CHAPTER 3 – CONCLUSION, CHALLENGES AND WAY FORWARD

3.1 Conclusion

These specifications are designed to fulfil the requirements to be followed by PEs for the assurance of quality of goods procured and ensure wider participation of bidders. This document will help potential suppliers to understand the quality specification of commodities. Additionally, it helps ensure efficiency, assure quality, maintain transparency and ensure effective procurement management functions.

3.2 Challenges

The major challenge in implementing these approved specifications concerns the limited capacity of SNGs to verify/evaluate the defined quality parameters in the specifications: this might be explained by a lack of technical experts at the time of bid evaluation and Post-delivery Inspection (PDI). SNGs and hospitals have been preparing their own specifications and procuring specific COVID-19 items; it may prove challenging to persuade them to adopt the specifications detailed in this document if they differ from those that they have been using.

3.3 Way Forward

- Formulate a technical committee with a responsibility to update specifications for new COVID-19-related medicines, supplies and equipment
- Develop a brief user manual and provide training to officials working at federal, provincial and local levels
- The Government of Nepal (GoN)/MoHP/DoHS should emphasise the mandatory use of prescribed specifications to SNGs and other PEs
- Develop an electronic technical specification for COVID-19 medicines, supplies and equipment

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Annex I: List of PPE and their detailed technical specifications

1. Particulate-filtering face piece respirator

Item name	**Particulate-filtering face piece respirator**
Purpose	Protection of mouth from pathogenic microbes
Type	Face piece respirator
Purpose	Protection from the Corona virus while in contact with COVID 19 cases
Requirements	Should have performance equivalent to filter performance at least ≥95%, flow rate 85 to 95L/min Good breathability with design that does not collapse against the mouth (e.g. duckbill, cup shaped)
Equivalent standards	N95/KN95/FFP2
Compliance/certification required	At least WHO COVID specification for face respirator and/CE/USFDA requirements

2. Face shields/visor

Item name	**Face shields/visor**
Purpose	Protection of face including eye from microbial contamination
Material	Made of clear plastic and provides good visibility to both the wearer and the patient,
Requirements	Adjustable band to attach firmly around the head and fit snuggly against the forehead, Fog resistant (preferable), Completely cover the sides and length of the face, May be re-usable (made of robust material which can be cleaned and disinfected) or disposable.
Compliance/certification required	EU standard directive 86/686/EEC, EN 166/2002, ANSI/ISEA Z87.1-2010, or equivalent

3. Nitrile Gloves (Non-sterile)

Item name	**Gloves, non-sterile**
Purpose	Protection of hand from microbial contamination
Description	Comfortable, super soft flexible powder free nitrile gloves provide added safety applications.
Requirements	Designed with special nitrile formulation and fit like latex and allow full range of motion and excellent flexibility to minimize stress and fatigue. powder-free, Cuff length preferably reach mid-forearm (e.g. minimum 280mm total length. Should not contain natural rubber latex
Size	Different size
Compliance/certification required	EU standard directive 93/42/EEC Class I, EN 455, EU standard directive 89/686/EEC Category III, EN 374 ANSI/ISEA 105-2011, ASTM D6319-10 or equivalent

4. Goggles (reusable)

Item name	**Safety Goggles**
Purpose	Use for biohazard (Virus) protection
Requirements	Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure, Enclose eyes and the surrounding areas, Accommodate wearers with prescription glasses, Clear plastic lens with fog and scratch resistant treatments,

	Adjustable band to secure firmly so as not to become loose during clinical activity, Indirect venting to avoid fogging,
Type	Reusable after decontamination
Compliance/certification required	EU standard directive 86/686/EEC, EN 166/2002, ANSI/ISEA Z87.1-2010, or equivalent

5. Goggles (disposable)

Item name	**Safety Goggles**
Purpose	Use for biohazard (Virus) protection
Requirements	Good seal with the skin of the face, Flexible PVC frame to easily fit with all face contours with even pressure, Enclose eyes and the surrounding areas, Accommodate wearers with prescription glasses, Clear plastic lens with fog and scratch resistant treatments, Adjustable band to secure firmly so as not to become loose during clinical activity, Indirect venting to avoid fogging,
Type	Disposable
Compliance/certification required	EU standard directive 86/686/EEC, EN 166/2002, ANSI/ISEA Z87.1-2010, or equivalent

6. Gown Level IV

Item name	**Gown for COVID**
Purpose	Virus protection barrier
Type	Blood borne pathogens penetration resistant:
Descriptions	Single use, fluid resistant, disposable, length mid-calf to cover the top of the boots, thumb/finger loops or elastic cuff to anchor sleeves in place.
Requirements	To be used in high risk situations which prevents all fluid penetration at least for up to 1 hour Must have tested the barrier level barrier level performance
Colour	Preferably light
Compliance/certification required	AAMI PB70 level 4 performance, or (EN 14126-B) and partial body protection (EN 13034 or EN 14605), or equivalent

7. Medical/surgical mask

Item	**Medical/surgical mask**
Purpose	Protection from bio hazard
	Medical/surgical mask, high fluid resistance, good breathability, internal and external faces should be clearly identified, structured design that does not collapse against the mouth (e.g. duckbill, cup shaped) Fluid resistance at minimum 120 mmHg pressure
Filtration efficiency	ASTM F2101, EN14683 annex B, or equivalent
Breathability	MIL–M-36945C, EN 14683 annex C, or equivalent
Compliance/certification required	EN 14683 Type IIR performance ASTM F2100 level 2 or level 3 or equivalent; based on ASTM F1862-07, ISO 22609, or equivalent

8. Biohazard bag

Item name	**Biohazard bag**
Purpose	Personnel protection from biohazard

Requirements	Disposal bag for bio-hazardous waste, 30x50cm, with "Biohazard" print, autoclavable polypropylene. Not less than micron thickness
Basic unit	one
Packing	Not more than 50 units per cartoon

9. Body bag (for dead body packing)

Item type	**Body bag (for dead body packing)**
Purpose	Infected dead body packing
Requirements	Made of linear enforced, U-shape zipper and 2 zipper pulls with tie ribs. Adult size 250x120cm Protector Body Bag specifications: 6 handles Impermeable, linear reinforced LLDPE, LDPE, EVA, PEVA, (avoid PVC), minimum thickness 400 microns; Should be able to hold 100-125 kilos (200-250 lbs), Should contain no chlorides: burning of chlorides pollute the environment and can cause damage to retort chambers. Should be non-carcinogenic to health of funeral workers when used for cremations. At least 6 handles included in the body bag to allow burial team to hand carry it safely Heat-sealed: ensure superior strength and safety, Provide full containment of blood borne pathogens Cracking point of 25 - 32 degrees below zero
Self-life	Minimum 10 years
Colour	White

10. Apron (COVID), Coverall Protection

Item name	**Apron (COVID), Coverall Protection**
Purpose	Protection from microbes in the body
Item description (Single Use, disposable)	Spray/aerosol-penetration resistant, biohazard-protective coverall, for use in COVID 19 patient-isolation units for infection prevention and control against viral penetration
Material used	Polyester with PVC coating or 100% PVC or 100% rubber. Waterproof. Minimum basis weight: 250g/m2.
Requirements	Elasticated hood around face, Elasticated cuffs and ankles, Elasticated sleeves with bound seams. Zipper with re-sealable flap protecting leakage through seams, Stitched-in neck label indicating the type and performance of the suit against the below mentioned standards.
Colour	White
Compliance/certification required	At least WHO COVID apron specification and/USFDA requirements

Acronyms: EVA: ethylene-vinyl acetate; LDPE: Low-density polyethylene; LLDPE: Linear Low-Density Polyethylene; PEVA - polyethylene vinyl acetate); PVC: polyvinyl chloride

11. Bouffant cap

Item type	Bouffant cap
Purpose	Protection from dirt
Item description	Single use disposable stretchable
Material used	Made of strong, light weight and breathable spun bonded polypropylene (SPP) fabric
Requirements	Dimensions Relaxed 8” and stretched 21” for small and relaxed 8.5” and 24” in stretched condition

Color	Blue/white
Compliance/certification required	CE or USFDA

12. Hand Sanitizer (Disinfectant)

Item name	**Hand sanitizer**
Purpose	Protection from the Corona virus while in contact with COVID 19 causing virus in hand
Composition	Isopropyl alcohol Not less than 75%v/v or Ethyl alcohol Not less than 80% v/v Glycerol 1.45% v/v Hydrogen peroxide 0.125% v/v The product may be in liquid or gel form with or without *colouring agent and/or flavouring agent in permissible limits*
Other requirements	Shall have an acceptable odour, shall not have any disagreeable odour or smell.
Quality requirement *(to have been tested from government approved laboratory)*	• pH: 6 to 8 • Alcohol/IPA content • Bacterial efficacy
Packaging	The content must have been packed in the suitable polyethylene terephthalate (PET) bottle fitted with ejection/pumping cap,
Compliance/certification required	Must have been approved and permitted by Drug Regulatory Authority of Nepal.

Annex II: List of laboratory kits and reagents and their detailed technical specifications

1. Real Time RT-PCR Kits for SARS Cov-2

Name of item	**Real Time RT-PCR Kits for SARS Cov-2**
Purpose	**RT-PCR testing (COVID 19)**
Description	Must target at least two genes (E, RdRP, N, ORF 1ab.) should include positive control and internal control for both targets, should be compatible with ABI 7500, Biorad (CFX 96) and rotorgene platforms The kit should include RT PCR enzyme and Buffer Sensitivity at least 95% The detection limit should be at least 500 copies per ml
Other requirements	The manufacturer should be certified by WHO or USFDA or CE or should have been listed by USFDA/CDC or WHO for emergency use

2. RNA extraction reagent for manual extraction

Item name	**RNA extraction reagent for manual extraction**
Purpose	RNA extraction from swab sample
Description	Spin column based Suitable for manual extraction of bodily fluids, oro- and nasopharyngeal swab, blood samples serum or plasma samples. **Sample input:** Up to 400 microliters **Elution volume:** more than 30 microliters with RNA ready for Real Time PCR Should not require heating step. Extraction steps should not take more than thirty minutes. The number of collection tubes should be provided in sufficient number Should contain reagents for RNA binding, nonenzymatic lysis (washing and elusion)
Other requirements	The manufacturer should be certified by WHO or USFDA or CE or should have been listed by USFDA/CDC or WHO for emergency use

3. Virus Transport Medium (VTM)

Item name	**Virus Transport Medium (VTM)**
Purpose	Swab collection (COVID 19)
Tube Requirements	Suitably prepared sterile media for use in collecting throat and nasal swabs from human. Should contain virus inactivator, should stabilize virus RNA. Should be contained in airtight plastic tubes with cap. There must be sticker for labelling
Media volume	1ml to 3ml
Swab collection sticks	- Along with the tubes there should be two swab sticks (one for oropharyngeal swab and another for nasopharyngeal swab). - There should be provision of break lines to allow to fit into the container. - Both the sticks should have fibre acrylic swab. The stick for nasopharyngeal swab should be flexible enough for ease the collection of swab sample from nasopharynx. - The swabs sticks should be contained in blisters
Others	The item should be at least CE approved

4. Rapid Diagnostic Test Kit for COVID-19

PURPOSE	Aid in diagnosis of patient with suspected SARS- COV-2 infection
PRINCIPLE	Immunochromatographic test for qualitative detection and differentiation of IgM and IgG against SARS COV-2
SAMPLE	whole blood/serum/ plasma
CERTIFICATION	CE (European) approved or Approval by US- FDA or National Medical Products Administration (NMPA) of China approval
S**ENSITIVITY**	>90%
SPECIFICITY	>90%
SHELF LIFE	Not less than 12 months
READING TIME	Not more than 30 min
Cross reactivity	The device should not show cross reactivity with the antibodies against following agents: HBV/ HCV/ HIV I/II/ Adenovirus/ Parainfluenza virus 1-4/ influenza virus A and B/ Enterovirus 71/ Respiratory syncytial virus/ Rhino virus

Annex III: Intensive Care Unit (ICU) medicines and their detailed technical specifications

1. 0.9% W/V SODIUM CHLORIDE INJECTION 500ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Sodium chloride
Dosage Form	Sterile solution of NaCL in water for injection. 500ml
Strength	Each ml contains 9 mg sodium chloride
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
Ph	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Plastic Pouch or plastic (PET) bottle
Primary Packaging	The bags known as Viaflo composed of polyolefin/polyamide co-extruded plastic (PL-2442). The bags are overwrapped with a protective plastic pouch composed of polyamide/polypropylene. The plastic packing should be made from BFS technology.
Tertiary Packaging	Plastic pouch/bottle corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

2. 5% W/V DEXTROSE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dextrose
Dosage Form	Infusion
Strength	5% w/v 500ml bottle
Route of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
5-Hydroxymethylfurfural and Related Substances	
Heavy Metals	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	500 ml plastic bottle.
Primary Packaging	Dextrose injection packed in a plastic bottle made from single stage Form Fill Seal (FFS)/Blow Fill Seal (BFS) technology from Polypropylene or Polyethylene polymer.
Secondary Packaging	Each bottle is over-wrapped with transparent plastic of 250 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 5 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

3. ADENSOINE 3MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Adenosine
Dosage Form	Sterile solution of adenosine in water for injection.
Strength	Each 1ml of solution contains 3mg of adenosine. Each vial contains 6mg of adenosine per 2ml of solution (3mg/ml).
Route of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	100 ml plastic bottle.
Primary Packaging	100 ml is packed in bottle made from single stage FFS/BFS technology from a virgin polyethylene polymer.
Tertiary Packaging	50 bottles packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

4. ADRENALINE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Adrenaline Bitartarate/Adrenaline Acid Tartarate/Adrenaline Tartarate/Epinephrine Tartarate
Dosage Form	Injection
Strength	0.1% w/v.
Route of Administration	IM/SC
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Appearance of Solution	
pH	
Noradrenaline	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	1 ml type I glass ampoule.
Primary Packaging	1 ml of adrenaline injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 ampoules in a PVC tray are packed in a duplex NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 3 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 1 year from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

5. AMIODARONE 50mg/ml Injection

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Amiodarone
Dosage Form	Sterile solution of amiodarone in water for injection.
Strength	Each ampoule with 3 ml of Amiodarone Hydrochloride 50 mg/ml concentrate for solution for Injection/Infusion contains 150 mg amiodarone hydrochloride.
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Dissolution	
Assay	
Uniformity of dosage form	
Dissolution	
PACKAGING SPECIFICATIONS	
Basic Unit	3 ml type I amber coloured OPC glass ampoule.
Primary Packaging	3ml of amiodarone injection packed in type I amber coloured OPC ampoule
Tertiary Packaging	10 PVC blistered trays each containing 5 ampoules are packed together in a duplex with complete labelling and NLT 350 gsm.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

6. AMOXYCILLIN+POTASSIUM CLAVULANATE INJECTION 1.2 GM

ITEM IDENTITY	
INN/Generic Name	Amoxycillin + Potassium Clavulanate
Dosage Form	Powder for injection
Strength	Each vial contains 1000mg amoxicillin (as sodium salt) and 200mg clavulanic acid (as potassium salt).(i.e. Each 1.2g vial of co-amoxiclav contains 1.0mmol of potassium and 3.1 mmol of sodium)
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Water	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Powder for injection in type I Glass Vial. Water for injection/diluents in polypropylene/polyethylene containers.
Primary Packaging	The powder is packed in glass vial that is either teflonised elastomer closure of type I butyl stopper sealed with an aluminium over cap or Type I flint glass vial with bromo-butyl rubber plug and metal seal.
Secondary Packaging	Each vial along with the water for injection is packed together in a duplex NLT 350 gsm. 100 such duplexes in supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

7. ATRACURIUM 2.5 ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Atracurium
Dosage Form	Parenteral
Strength	2.5 ml of solution contains 25 mg Atracurium besilate.
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Other Tests	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule in packs of 5 ampoules.
Primary Packaging	2.5 ml of Atracurium injection packed in a type I glass vial with compatible elastomer closure and crimp-on aluminium seal and PE plastic over-cap or Type I clear glass ampoule fusion sealed..
Secondary Packaging	10 vials in a PVC tray are packed in a duplex NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 3 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

8. ATROPINE SULPHATE 0.06% W/V INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Atropine Sulphate
Dosage Form	Injection Vial
Strength	0.06% w/v
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Uniformity of content	
Bacterial Endotoxins	
Residual solvents	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	0.06 ml glass vials.(type I)
Primary Packaging	0.06 ml of atropine sulphate injection packed in an amber coloured USP type I glass vials.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 vials is packed in a cardboard carton NLT 350 gsm. 100 vials in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 5 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

9. AZITHROMYCIN 500MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Azithromycin
Dosage Form	Powder for solution for infusion
Strength	Each vial contains 500 mg of azithromycin (equivalent to 524.1 mg of azithromycin dehydrate.)
Route Of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Susceptibility test	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial
Primary Packaging	Glass (type I) vials with bromobutyl rubber stopper and sealed with aluminium/plastic flip-off cap.
Secondary Packaging	Vials packed in a cardboard carton NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated cartons at least 5 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

10. AZITHROMYCIN TABLET 500 mg

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Azithromycin Dihydrate
Dosage Form	Uncoated/Film-coated tablets
Strength	Each tablet contains azithromycin dihydrate equivalent to 500 mg of azithromycin.
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related Substances	
Dissolution	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Blister/strip pack containing 3 or 6 or 10 tablets.
Primary Packaging	Tablets packed in an aluminium-PVC blister pack. Printed aluminium foil thickness must be NLT 0.025 mm and PVC thickness must be NLT 0.25 mm. or Tablets packed in an aluminium-aluminium strip or blister pack of total thickness of NLT 0.15mm or Strip tablets packed in foil must not be less than 0.065mm
Secondary Packaging	Not more than 100 labelling in one duplex box having NLT 350 gsm thick
Tertiary Packaging	Packed in at least 3 ply thick corrugated cartons. The number of secondary packing units in one carton shall be not more than 50 boxes or as specified in the bid document.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at normal room temperature.

11. CALCIUM GLUCONATE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Calcium gluconate
Dosage Form	Parenteral
Strength	Each ml of calcium gluconate injection contains calcium 8.9mg equivalent to 0.44 mEq of calcium ion.
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Other Tests	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	10 ml type I glass vial.
Primary Packaging	10 ml of calcium gluconate injection packed in a type I glass vial with compatible elastomer closure and crimp-on aluminium seal and PE plastic over-cap or Type I clear glass ampoule fusion sealed..
Secondary Packaging	10 vials in a PVC tray are packed in a duplex NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 3 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

12. CEFTRIAXONE 500MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Ceftriaxone
Dosage Form	Sterile solution of ceftriaxone in water for injection.
Strength	Each vial contains ceftriaxone sodium equivalent to 500 mg
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Melting point	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type glass vial.
Primary Packaging	Type II clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

13. CEFTRIAXONE 1G INJECTION

ITEM IDENTITY	
INN/Generic Name	Ceftriaxone sodium
Dosage Form	Powder for injection
Strength	Each vial contains Ceftriaxone 1gm Constituted with sterile water for injection immediately before use. (*The constituted material complies with the requirements for Clarity of solution and Particulate matter stated under Parenteral Preparations (Injections)*).
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Water	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Powder for injection in type I Glass Vial. Water for injection/diluents in polypropylene/polyethylene containers.
Primary Packaging	The powder is packed in glass vial that is either teflonised elastomer closure of type I butyl stopper sealed with an aluminium over cap or Type I flint glass vial with bromo-butyl rubber plug and metal seal.
Secondary Packaging	Each vial along with the water for injection is packed together in a duplex NLT 350 gsm. 100 such duplexes in supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

14. CHLORPROMAZINE 25MG/2ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Chlorpromazine
Dosage Form	Sterile solution of chlorpromazine in water for injection.
Strength	Each vial contains Chlorpromazine Hydrochloride 25mg/2ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type II glass vial.
Primary Packaging	Type II clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

15. CLINDAMYCIN INJECTION 600MG

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Clindamycin
Dosage Form	Sterile solution of clindamycin in water for injection.
Strength	Each 4ml vial contains 600mg clindamycin.
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Specific optical rotation	
Assay	
Sterility	
Water content	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I flint glass ampoule
Primary Packaging	Type 1 flint glass ampoule containing 4ml sterile, aqueous solution, packed in cardboard carton, together with a leaflet. 1 or 5 ampoules in each pack.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.

16. DEXMEDITOMIDINE Injection

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dexmedetomidine
Dosage Form	Sterile solution of dexmedetomidine in water for injection.
Strength	Each 1 ml of concentrate contains dexmedetomidine hydrochloride equivalent to 100 micrograms dexmedetomidine
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Content uniformity	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampule..
Primary Packaging	2 ml Type I glass ampoule, grey bromobutyl rubber closure with fluoropolymer coating.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

17. DEXAMETHASONE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dexamethasone
Dosage Form	Sterile solution of Dexamethasone in water for injection.
Strength	Each ml of solution contains 3.3 mg dexamethasone (as sodium phosphate) which is equivalent to 4 mg dexamethasone phosphate.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Assay	
Impurities	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I amber glass vial.
Primary Packaging	2 ml Type I amber glass vial with 13 mm chlorobutyl-based rubber stopper and spun on aluminium cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

18. DEXTROSE 50% W/V

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dextrose
Dosage Form	Infusion
Strength	50% w/v
Route of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Ph	
5-Hydroxymethylfurfural and Related Substances	
Heavy Metals	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	100 ml plastic bottle.
Primary Packaging	Dextrose injection packed in a plastic bottle made from single stage Form Fill Seal (FFS)/Blow Fill Seal (BFS) technology from Polypropylene or Polyethylene polymer.
Secondary Packaging	Each bottle is over-wrapped with transparent plastic of 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 5 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

19. DIAZEPAM INJECTION 2 mg/ml, 5 ml

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Diazepam
Dosage Form	Injection (Ampoule)
Strength	2 mg/ml
Route of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	5 ml solution in type I glass ampoule.
Primary Packaging	5 ml of diazepam injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 ampoules in a PVC tray are packed in a duplex NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 5 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

20. DIGOXIN 0.25MG/ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Digoxin
Dosage Form	Sterile solution of digoxin in water for injection.
Strength	0.25mg/ml
Route Of Administration	IM/IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type I glass ampoule.
Primary Packaging	2 ml of Digoxin injection packed in a neutral coloured type I glass ampoule.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 5 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

21. DOBUTAMINE 250MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dobutamine
Dosage Form	Sterile solution of Dobutamine in water for injection.
Strength	Each vial of Dobutamine contains dobutamine hydrochloride corresponding to 250 mg dobutamine
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Ph.Eur.
Primary Packaging	Dobutamine 5 mg/ml (250 mg in 50 ml) ampoules made of colourless, neutral glass, type I Ph.Eur.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

22. DOPAMINE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Dopamine
Dosage Form	Sterile solution of Dopamine in water for injection
Strength	Each ml of concentrate contains 40 mg dopamine hydrochloride. Each 5 ml ampoule of concentrate contains 200 mg dopamine hydrochloride.
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoules
Primary Packaging	Clear, type I, glass ampoules sealed with bromo-butyl rubber plugs with aluminium overseals or plastic 'flip-top' caps.
Tertiary Packaging	Bottles packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

23. ENOXAPARIN 40IU Injection

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Enoxaparin
Dosage Form	Sterile solution of Enoxaparin in water for injection.
Strength	Each prefilled syringe contains enoxaparin sodium 4,000 IU anti-Xa activity (equivalent to 40 mg) in 0.4 mL water for injections.
Route Of Administration	SC/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass pre-filled syringes.
Primary Packaging	Solution for injection in Type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and with or without an automatic safety device.
Tertiary Packaging	Prefilled syringes are stored in plastic trays and carton boxes. Packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

24. ENOXAPARIN 60IU INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Enoxaparin
Dosage Form	Sterile solution of Enoxaparin in water for injection.
Strength	Each prefilled syringe contains enoxaparin sodium 6,000 IU anti-Xa activity (equivalent to 60 mg) in 0.6 mL water for injections.
Route Of Administration	SC/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass pre-filled syringe
Primary Packaging	Solution for injection in Type I glass pre-filled syringes with chlorobutyl rubber stopper fitted with injection needle and with or without an automatic safety device.
Tertiary Packaging	Prefilled syringes are stored in plastic trays and carton boxes. Packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

25. FENTANYL INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Fentanyl
Dosage Form	Sterile solution of Fentanyl in water for injection with the aid of sodium hydroxide.
Strength	Each 2ml ampoule contains 100 micrograms of fentanyl as fentanyl citrate
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Glass type I Ph Eur
Primary Packaging	Glass type I Ph. Eur., closed with bromobutyl rubber stopper packed in a cardboard carton containing one vial.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.

26. FRUSEMIDE INJECTION 20 MG/ML, 2 ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Frusemide/Furosemide
Dosage Form	Sterile solution of frusemide in water for injection with the aid of sodium hydroxide.
Strength	10 mg/ml
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type I glass ampoule.
Primary Packaging	2 ml of frusemide injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

27. GLYCERYL TRINITRATE 50MG/10ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Glyceryl Trinitrate
Dosage Form	Sterile solution of Glyceryl Trinitrate in water for injection with the aid of sodium hydroxide.
Strength	50mg/10ml
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	Clear, Type I glass ampoules 10 ml in packs of 5 ampoules. Injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

28. GLYCOPYROLATE 0.2MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Glycopyrrolate
Dosage Form	Sterile solution of Glycopyrrolate in water for injection with the aid of sodium hydroxide.
Strength	0.2 mg/ml
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	Injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

29. HEPARIN 5000IU INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Heparin
Dosage Form	Sterile solution of heparin in water for injection with the aid of sodium hydroxide.
Strength	Heparin sodium 5,000 I.U./ml
Route Of Administration	SC/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type 1 glass, Ph Eur
Primary Packaging	5ml multidose neutral glass (Type 1, Ph Eur) vial.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

30. HYDRALAZINE 20MG INJECTION

Item Identity	
PARAMETER	**STANDARD**
INN/Generic Name	Hydralazine
Dosage Form	Sterile solution of Hydralazine in water for injection with the aid of sodium hydroxide.
Strength	Each 2 ml ampoule contains 20mg hydralazine hydrochloride.
Route Of Administration	IV/IM
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	Colourless Type I glass 2ml ampoule. Five ampoules are packed in a cardboard printed carton
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 5 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

31. HYDROCORTISONE POWDER FOR INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Hydrocortisone Sodium Succinate/Cortisol Sodium Succinate
Dosage Form	Sterile material of hydrocortisone hemi-succinate with the aid of a suitable alkali such as sodium hydroxide or sodium carbonate.
Strength	100 mg per vial
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	10 ml type I glass vial.
Primary Packaging	Hydrocortisone powder for injection is packed in type I flint glass vial provided with teflonised elastomer closure of type I butyl stopper and sealed with an aluminium over cap or type I flint glass vial with a butyl rubber plug and metal seal.
Secondary Packaging	Each vial along with water for injection/ diluents is co-packed in a printed duplex. 100 duplexes in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

32. IMIPENEM+CILASTATIN 500MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Imipenem + Cilastatin
Dosage Form	Sterile solution in water for injection with the aid of sodium hydroxide.
Strength	Each vial contains imipenem monohydrate equivalent to 500 mg imipenem anhydrate and cilastatin sodium equivalent to 500 mg cilastatin.
Route Of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	Imipenem cisplatin injection packed in an amber coloured type I glass ampoule.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

33. INSULIN INJECTION SOLUBLE

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Insulin
Dosage Form	Sterile solution of insulin.
Strength	1 vial contains 10 ml equivalent to 1,000 units.1 ml solution contains 100 units insulin aspart (equivalent to 3.5 mg).
Route Of Administration	Parental
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial
Primary Packaging	Type 1 glass vial closed with a disc (bromobutyl/polyisoprene rubber) and a protective tamper-proof plastic cap.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 30months from the time of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

34. INSULIN MIXED 30/70

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Insulin
Dosage Form	Sterile solution of insulin.
Strength	30 % soluble insulin / 70 % isophane insulin.
Route Of Administration	Parental
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass
Primary Packaging	Solution in vial (type 1 glass) closed with a disc (bromobutyl/polyisoprene rubber) and a protective tamper-proof plastic cap
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

35. KETOROLAC 30MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Ketorolac
Dosage Form	Sterile solution of Ketorolac in water for injection.
Strength	Each ampoule contains 30 mg of ketorolac Trometamol in 1 ml of solution.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I flint glass ampoule
Primary Packaging	Type 1 flint glass ampoule containing 4ml sterile, aqueous solution, packed in cardboard carton, together with a leaflet. 1 or 5 ampoules in each pack.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

36. LABETALOL 5MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Labetalol
Dosage Form	Sterile solution of Labetalol in water for injection.
Strength	5mg/ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule
Primary Packaging	Type 1 glass ampoule containing sterile, aqueous solution, packed in cardboard carton, together with a leaflet. 1 or 5 ampoules in each pack.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

37. LEVOFLOXACIN 100ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Levofloxacin
Dosage Form	Sterile solution of Levofloxacin in water for injection.
Strength	100 ml of solution for infusion contains 500 mg of levofloxacin as levofloxacin hemihydrate.
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Specific optical rotation	
Assay	
Sterility	
Water content	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule
Primary Packaging	Type I, glass with either chlorobutyl or bromobutyl rubber stopper and violet, polypropylene flip-off cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

38. LIGNOCAINE 2% W/W OINTMENT

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Lignocaine
Dosage Form	Ointment
Strength	Each tube contains 2% w/w of Lignocaine.
Route of administration	Topical
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related Substances	
Water	
Sulphated Ash	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2% collapsible tube.
Primary Packaging	Ointment packed in a collapsible tube and provided with a tamper evident HDPE screw cap.
Secondary Packaging	Tube packed in printed duplex NLT 350 gsm thick with complete labelling.
Tertiary Packaging	Duplex packed in cardboard carton NLT 3 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at normal room temperature.

39. LIGNOCAINE 1% INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Lignocaine
Dosage Form	Injection
Strength	1.0% w/v
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
2,6-dimethylaniline	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	30 ml in type I glass vial.
Primary Packaging	30 ml vial provided with 20 mm compatible elastomer type 1 stopper. A crimp on aluminium seal with plastic over cap to be fitted over the stopper. 5 vials are packed in a PVC blistered tray.
Secondary Packaging	4 PVC/paper blistered trays each containing 5 vials is packed in a cardboard carton NLT 350 gsm. 20 vials in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 5 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at normal room temperature.

40. LIGNOCAINE 2% INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Lignocaine
Dosage Form	Injection
Strength	2.0% w/v
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
2,6-dimethylaniline	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	30 ml in type I glass vial.
Primary Packaging	30 ml vial provided with 20 mm compatible elastomer type 1 stopper. A crimp on aluminium seal with plastic over cap to be fitted over the stopper. 5 vials are packed in a PVC blistered tray.
Secondary Packaging	4 PVC/paper blistered trays each containing 5 vials is packed in a cardboard carton NLT 350 gsm. 20 vials in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 5 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at normal room temperature.

41. MAGNESIUM SULPHATE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Magnesium Sulphate Heptahydrate Injection
Dosage Form	Parenteral
Strength	Each ml contains 500 mg of magnesium sulphate heptahydrate.
Route Of Administration	IV/IM
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Other Tests	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	10 ml type I glass ampoule or vial.
Primary Packaging	10 ml of magnesium sulphate heptahydrate injection packed in a type I glass ampoule or vial with compatible elastomer closure and crimp-on aluminium seal and PE plastic over-cap or Type I clear glass ampoule fusion sealed..
Secondary Packaging	25 ampoules or vials in a PVC tray are packed in a duplex NLT 350 gsm.
Tertiary Packaging	Must be packed in corrugated carton NLT 3 ply thick. The number of secondary packing units in one carton shall be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

42. MEROPENEM NJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Meropenem
Dosage Form	Sterile solution of Meropenem in water for injection.
Strength	Each vial of powder for solution for injection or infusion contains 1141.56 mg Meropenem trihydrate equivalent to 1 g anhydrous Meropenem.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial
Primary Packaging	Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminium seals having white colour polypropylene discs).
Tertiary Packaging	Bottles packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.

43. METHYLPREDNISOLONE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Methylprednisolone
Dosage Form	Sterile solution of Methylprednisolone injection.
Strength	Each vial of Methylprednisolone 40 mg contains 53.0 mg of methylprednisolone sodium succinate, equivalent to 40 mg of methylprednisolone.
Route of Administration	IM
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial
Primary Packaging	Type-I, tubular, clear glass vial with stopper (bromobutyl rubber with aluminium seals having white colour polypropylene discs).
Tertiary Packaging	Bottles packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.

44. METOPROLOL 1MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Metoprolol
Dosage Form	Sterile solution of Metoprolol in water for injection.
Strength	1mg/ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Specific optical rotation	
Assay	
Sterility	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule
Primary Packaging	Type I, glass with either chlorobutyl or bromobutyl rubber stopper and violet, polypropylene flip-off cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 4 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

45. METRONIDAZOLE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Metronidazole
Dosage Form	Sterile solution of metronidazole in water for injection.
Strength	5 mg/ml Each 100 ml contains 500 mg of metronidazole.
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
Pyrogen	
PACKAGING SPECIFICATIONS	
Basic Unit	100 ml plastic bottle.
Primary Packaging	100 ml is packed in bottle made from single stage FFS/BFS technology from a virgin polyethylene polymer.
Tertiary Packaging	50 bottles packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

46. MIDAZOLAM 1MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Midazolam
Dosage Form	Sterile solution of Midazolam in water for injection.
Strength	1mg/ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Glass type I, Ph. Eur.
Primary Packaging	Clear glass ampoules, glass type I, Ph. Eur. sealed with bromo-butyl rubber plugs with aluminium overseals or plastic 'flip-top' caps.
Tertiary Packaging	Bottles packed in corrugated cartons NLT 350 gsm .The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

47. MORPHINE 10MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Morphine Sulphate
Dosage Form	Sterile solution of Morphine Sulphate in water for injection.
Strength	Morphine Sulphate 10mg/ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
Sterility	
PACKAGING SPECIFICATIONS	
Basic Unit	Type glass vial.
Primary Packaging	Type I clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

48. NALOXONE 0.4MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Naloxone
Dosage Form	Sterile solution of Naloxone in water for injection.
Strength	Each 1ml of solution contains 400 micrograms (0.4mg) Naloxone Hydrochloride.
Route Of Administration	IM/SC/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoules.
Primary Packaging	Glass type 1 Ph. Eur. borosilicate glass, packed in cardboard cartons to contain 10 x 1ml ampoules; 3 x 1ml ampoules and 5 x 1ml ampoules..
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 4 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

49. NORADRENALINE 1MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Noradrenaline
Dosage Form	Sterile solution of Noradrenaline in water for injection.
Strength	1mg/ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Particulate Matter	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial.
Primary Packaging	Type I clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

50. ONDANDTERON 2ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Ondansetron
Dosage Form	Sterile solution of Ondansetron in water for injection.
Strength	Each ampoule with 2 ml contains 4 mg Ondansetron.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass vial
Primary Packaging	Type I clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

51. PANTOPRAZOLE 40MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Pantoprazole
Dosage Form	Sterile solution of Pantoprazole in water for injection.
Strength	Each vial contains 40 mg of pantoprazole
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Sterility	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I colourless glass vial.
Primary Packaging	Type I, colourless glass vial, sealed with a grey chlorobutyl stopper and an aluminium flip-off cap, containing 40 mg pantoprazole powder for solution for injection.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

52. PARACETAMOL INJECTION 150 MG/ML, 2 ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Paracetamol/Acetaminophen
Dosage Form	A clear solution of paracetamol in water for injection.
Strength	Each ml contains 150 mg of paracetamol.
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Light Absorption	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type I amber coloured OPC glass ampoule; fusion sealed.
Primary Packaging	2 ml of paracetamol injection packed in type I amber coloured OPC ampoule.
Secondary Packaging	10 PVC blistered trays each containing 5ampoules are packed together in a duplex with complete labelling and NLT 350 gsm. 100 ampoules in supply unit.
Tertiary Packaging	Packed in corrugated cartons at least 3 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

53. PHENIRAMINE 22.75 MG/ML, 2 ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Pheniramine
Dosage Form	Sterile solution of pheniramine maleate in water for injection.
Strength	22.75 mg/ml Each ml contains 22.75 mg of pheniramine maleate.
Route Of Administration	IM/IV (As infusion)
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related substances	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type 1 OPC glass ampoule; fusion sealed.
Primary Packaging	10 ampoules are packed in a PVC blister packed tray.
Secondary Packaging	10 PVC blistered trays each containing 10ampoules is packed together in a duplex. 100 ampoules in supply unit.
Tertiary Packaging	Must be packed in corrugated cartons NLT 350 gsm. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

54. PHENTYOIN SODIUM 30MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Phenytoin Sodium
Dosage Form	Sterile solution of Phenytoin Sodium in water for injection.
Strength	30mg/5ml
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Ph.Eur.
Primary Packaging	Clear glass ampoules, glass type I, Ph. Eur. packed in cardboard cartons to contain 10 x 5ml ampoules.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

55. PIPERACILLIN + TAZOBACTAM INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Piperacillin + Tazobactam
Dosage Form	Sterile solution of Piperacillin + Tazobactam in water for injection.
Strength	Each vial contains 4 g piperacillin and 0.5 g tazobactam ..
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type II glass vial
Primary Packaging	Packs of one two, five and ten Type II glass vial with butyl rubber stopper and aluminium/plastic seal
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

56. PLASMA-LYTE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Plasma-lyte
Dosage Form	Sterile solution of Plasma-lyte in water for injection.
Strength	Sodium Chloride(5.26 g/l) Potassium Chloride(0.37 g/)l Magnesium Chloride hexahydrate(0.30 g/l) Sodium Acetate trihydrate(3.68 g/l) Sodium Gluconate(5.02 g/l)
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Primary Packaging	The bags composed of polyolefin/polyamide co-extruded plastic (PL 2442), overwrapped with a protective plastic pouch composed of polyamide/polypropylene.
Tertiary Packaging	Bags packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

57. POTASSIUM CHLORIDE 10ML INJECTION

58. PROPOFOL 10MG/ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Potassium Chloride
Dosage Form	Sterile solution of KCL in water for injection
Strength	15% of Potassium Chloride in 10ml
Route Of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	Glass ampoules, hermetically sealed under flame at the gauging point. The ampoules are packed in cartons .
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.
ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Propofol
Dosage Form	Sterile solution of Propofol in water for injection.
Strength	10mg/mL
Route Of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type II glass vial
Primary Packaging	Colourless glass vial (type II) with a grey bromobutyl rubber closure.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

59. RANITIDINE INJECTION 25 MG/ML, 2 ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Ranitidine Hydrochloride
Dosage Form	Sterile solution of ranitidine hydrochloride in water for injection.
Strength	25 mg/ml Each ml contains 25 mg of ranitidine hydrochloride.
Route Of Administration	IM/IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass ampoule.
Primary Packaging	2 ml of ranitidine hydrochloride injection packed in an amber-coloured Type I glass ampoule
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons of 350 gsm and at least 5 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

60. RINGER LACTATE 500ML INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Ringer lactate
Dosage Form	Sterile solution of Ringer Lactate.
Strength	500ml
Route Of Administration	IV/IM
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Plastic bags
Primary Packaging	The bags composed of polyolefin/polyamide co-extruded plastic (PL 2442). overwrapped with a protective plastic pouch composed of polyamide/polypropylene.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

61. ROCURONIUM 50MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Rocuronium
Dosage Form	Sterile solution of Rocuronium in water for injection.
Strength	Each vial with 5 ml contains 50 mg .
Route Of Administration	IV infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Related Substances	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I glass vial
Primary Packaging	Colourless glass vials (type I) with chlorobutyl rubber stopper and aluminium cap.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 ampoules is packed in a cardboard carton. 100 ampoules in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 3 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

62. SALBUTAMOL / IPRATROPIUM INHALER

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Salbutamol/Ipratropium
Dosage Form	Inhalation aerosol Salbutamol and Ipratropium in a suitable liquid in a suitable pressurised container.
Strength	Each puff inhaler contain 100mg Salbutamol and 20mcg Ipratropium.
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related Substances	
Salbutamol Ketone	
Assay	
Basic Unit	A pressurized canister containing medication for 200 metered doses that fits into a boot-shaped plastic mouthpiece with a metering valve mechanism.
Primary Packaging	Salbutamol Inhalation packed in an aluminium alloy aerosol canister fitted with metering valve, actuator and a dust cap. *(It should not contain CFC based aerosol.)*
Secondary Packaging	The canister containing a set of actuations with a beige plastic actuator and a dust cap is packed in a mono-carton NLT 350 gsm.
Tertiary Packaging	Must be packed in at least 3 ply thick corrugated cartons. The number of secondary packing units in one carton shall not be more than 20 packets
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at normal room temperature.

63. SODIUM BICARBONATE INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Sodium Bicarbonate
Dosage Form	Injection ampoule
Strength	7.5% W/V
Route Of Administration	IV
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Uniformity of content	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass ampoules
Primary Packaging	Type I colourless glass ampoules, fusion sealed type I colourless glass ampoules.
Secondary Packaging	10 PVC/paper blistered trays each containing 10 vials is packed in a cardboard carton NLT 350 gsm. 100 vials in a supply unit.
Tertiary Packaging	Must be packed in corrugated cartons at least 5 ply thick.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

64. THIOPENTAL 500MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Thiopental
Dosage Form	Sterile solution of Thiopental in water for injection.
Strength	Each vial contains 500 mg thiopental sodium and sodium carbonate (equivalent to 470 mg thiopental sodium).
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type III Glass vial
Primary Packaging	Vials made from colorless type III glass with a rubber stopper, aluminum seal and a polypropylene flip-off cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

65. SUXAMETHONIUM CHLORIDE 50MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Suxamethonium Chloride
Dosage Form	Sterile solution of Suxamethonium Chloride in water for injection.
Strength	Each 1ml of solution contains 50mg of Suxamethonium Chloride.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
Ph	
Sterility	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Ph Eur Glass vial
Primary Packaging	Clear glass ampoules, glass type I Ph.Eur. borosilicate glass.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 18months from the time of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

66. TECIOPLANIN 400MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Teicoplanin
Dosage Form	Sterile solution of teicoplanin in water for injection.
Strength	Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
Route of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass vial
Primary Packaging	Type I, colourless glass vial of bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

67. THIAMINE INJECTION 100 MG/ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Thiamine Hydrochloride
Dosage Form	Injection
Strength	Each ml contains 100 mg of Thiamine hydrochloride.
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type I amber coloured OPC glass ampoule; fusion sealed.
Primary Packaging	2 ml of thiamine hydrochloride injection packed in type I amber coloured OPC ampoule.
Secondary Packaging	10 PVC blistered trays each containing 5 ampoules packed together in a duplex with complete labelling and NLT 350 gsm. 50 ampoules in supply unit.
Tertiary Packaging	Packed in corrugated cartons at least 5 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

68. VANCOMYCIN 500MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Vancomycin
Dosage Form	Sterile solution of Vancomycin in water for injection.
Strength	Each vial contains Vancomycin 500 mg equivalent to 500,000 IU vancomycin
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass vial
Primary Packaging	Type I clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

69. TECIOPLANIN 400MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Teicoplanin
Dosage Form	Sterile solution of teicoplanin in water for injection.
Strength	Each vial contains 400 mg teicoplanin equivalent to not less than 400,000 IU.
Route Of Administration	IM/IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass vial
Primary Packaging	Type I, colourless glass vial of bromobutyl rubber stopper and plastic flip-off top aluminium green overseal.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

70. THIAMINE INJECTION 100 MG/ML

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Thiamine Hydrochloride
Dosage Form	Injection
Strength	Each ml contains 100 mg of Thiamine hydrochloride.
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
pH	
Bacterial Endotoxins	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	2 ml type I amber coloured OPC glass ampoule; fusion sealed.
Primary Packaging	2 ml of thiamine hydrochloride injection packed in type I amber coloured OPC ampoule.
Secondary Packaging	10 PVC blistered trays each containing 5 ampoules packed together in a duplex with complete labelling and NLT 350 gsm. 50 ampoules in supply unit.
Tertiary Packaging	Packed in corrugated cartons at least 5 ply thick. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box must contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	Must be NLT 2 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Must be stable at temperature stated for the product.

71. VANCOMYCIN 500MG INJECTION

ITEM IDENTITY	
PARAMETER	**STANDARD**
INN/Generic Name	Vancomycin
Dosage Form	Sterile solution of Vancomycin in water for injection.
Strength	Each vial contains Vancomycin 500 mg equivalent to 500,000 IU vancomycin
Route Of Administration	IV Infusion
QUALITY SPECIFICATIONS (IN ADDITION TO GENERAL SPECIFICATION)	
Identification	Tests must be conducted in accordance with and strict adherence to the stated pharmacopoeia method and standard. All tests must comply with the stated pharmacopoeia methods.
Related substances	
pH	
Bacterial Endotoxin	
Assay	
PACKAGING SPECIFICATIONS	
Basic Unit	Type I Glass vial
Primary Packaging	Type I clear glass vials, closed with a Type I rubber stopper uncoated/coated in Omniflex and sealed with an aluminium/plastic cap.
Tertiary Packaging	Glass vials packed in corrugated cartons NLT 350 gsm suitably segregated through honeycomb partitioning. The number of secondary packing units in one carton must be as specified in the bid document.
Packaging Insert	Every box shall contain patient information leaflet as per Drug Standard Regulation 2043.
Shelf Life	NLT 3 years from the month of manufacture and at least 3/4th of the shelf life must be available at the time of delivery to the designated supply points.
Storage Stability	Stable at normal room temperature.

Annex IV: Detailed specifications of ICU/ventilator consumables

1. **Ventilator circuit**
   Corrugated plastic with universal connectors that connect the ventilator to the endotracheal tube (ETT), tracheostomy tube, or non-invasive interface.

2. **HME Filter**
   Non-toxic PVC, transparent soft and smooth. With cuff, suitable for short and long term ventilation and routine surgical procedures.

3. **Catheter mount**
   Light weight, Double swivel to rotate 360° on both axes, with low dead. To be compatible with all types of breathing and ventilator circuits. Provided with standard female connector on both the ends. Collapsible corrugated tubing being inert to all anaesthetic gases and reagents.

4. **Suction catheter FG10**
   With added plasticizers for gentle feel to tissues. Suitable for removal of secretions from mouth, trachea and bronchial tubes. Should be made up of non-irritant kink-resistant medical grade PVC. Provided with vacuum control facility as "thumb control system". Provided with two lateral eyes at the distal end for unobstructed suctioning. The distal end opening and side eyes be free of sharp edges. Should be sterile, peelable soft blister pack.

5. **ET Tube 7 and 7.5**
   Non-toxic, latex free, sterilized, Made from Thermo-sensitive, kink resistant and plastic flexible tube. Made from non-toxic silicon and PVC blend, with DEHP free radio opaque line and markings to facilitate identification of tube position.

6. **The Yankauer Suction Tube**
   They have shatter-resistant, one-piece construction or with vent for better suction control, rigid, shatter resistant, and transparent to be used in the mouth. A Rigid, shatter resistant, and transparent to be used in the mouth, with vent to improve suction control, Bulb or open tip with vent made of vinyl, with rigid Yankauer.

7. **Ambu bag**
   Bag made of plastic materials that re-expand after being manually collapsed, with oxygen inlet nipple air intake valve, oxygen reservoir with two one way valves, the inlet valve should allow air to enter if fresh gas flow is inadequate and an outlet valve allow oxygen to flow out if pressure is excessive non-rebreathing valve that directs fresh flow of oxygen to the patient and prevents exhaled gas re-entering the bag. Standard adapter for attaching to masks or tubes able to attach PEEP valve to exhalation port (either “built in” or detachable).

8. **Gudals airways 3.0 and 4.0**
   Should be made of Polyethylene/ethylene vinyl acetate (EVA) Polyvinyl chloride (PVC), siliconized. The oropharyngeal airway should be a curved, flattened part with an oval aperture Semi-rigid, transparent, colourless, autoclavable. The distal end (i.e. the pharyngeal extremity) should be curved with soft rounded edge. The proximal end (i.e. the buccal extremity) should be straight and reinforced.

Annex V: Detail specification of equipment

1. Autoclave Electrical Table Top Pre-vacuum (40- 60 Lit.)

S.N.	Purchaser's Specifications
	Autoclave Electrical Table Top Pre-vacuum (40- 60 Lit.)
	Manufacturer
	Brand
	Type / Model
	Country of Origin
1	**Description of Function**
1.1	It is used for sterilizing of wrapped and un-wrapped instruments, pouches, porous load with pre-vacuum cycle.
2	**Operational Requirements**
2.1	Electrically heated, fully automated table-top autoclave.
3	**System Configuration**
3.1	Autoclave Electrical Table Top Pre-vacuum (40- 60 Lit.), with complete accessories.
4	**Technical Specifications**
4.1	Fully automatic processing via micro-processor controller with pre-programmed cycles with sterilization temperature of 121 degree C and 134 degree C.
4.2	Autoclave shall be horizontal, cylindrical single ended construction with internal sterilising chamber volume: (40- 60 Lit.).
4.3	Chamber shall be made of stainless steel. Autoclave shall be provided with a built-in electric steam generator.
4.4	The autoclave shall be provided with a vacuum pump capable of achieving a high vacuum.
4.5	The process shall include a pre-vacuum phase for effective air removal from the chamber to ensure 100% steam penetration.
4.6	The pre-vacuum process shall be a pulsating vacuum with simultaneous steam injection repeated several times.
4.7	The process shall preferably also include a post vacuum phase during the drying stage.
4.8	At the end of the post vacuum drying phase filtered air shall enter and equalize the chamber pressure to atmospheric through a 0.3-micron sterile filter.
4.9	Digital display of temperature, time, pressure, sterilising progress, pre-set sterilising time, pre-set drying time or selected pre-programmed cycle.
4.10	Alarm indicators (audible and visual) for overheating, completion of cycle & any relevant system failure.
4.11	Shall come with steam trapping / condensation collection bottle, 2 litter or capacity to match the autoclave offered.
4.12	Shall have integrated water reservoir for steam supply without requirement of external water piping and drainage installation.
4.13	Bidder shall indicate here detail and number of all available pre-programmed cycles and minimum cycle time (in minutes).
5	**Accessories, spares and consumables**
5.1	**Accessories:** • Spare heating element- 2 set • Air filter-5 set • Bowie-Dick test paper-1 box • Come with one tray rack with 3 instrument trays approx. 420L x 150W x 20H mm, suitable to fit into the autoclave and tray handle. The trays are to be moulded without welding.
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220-240V/ 50 Hz AC Single phase 50Hz. fitted with appropriate plug to meet purchaser's country requirements. The power cable must be minimum 3 metres long.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	European CE (93/42 EEC Directives) or USFDA approved product certificate.

S.N.	Purchaser's Specifications
7.3	Shall meet IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials.
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service during Warranty Period**
10.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**
12.1	User (Operating) manual in English,
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

2. Technical Specification of Automated Nucleic Acid Extraction Machine

Parameter	Description
Description of Function	Automated system capable of extraction of nucleic acids (RNA, DNA).
Operational Requirements	Automated Nucleic Acid extraction machine with complete accessories.
System Configuration	Automated Nucleic Acid extraction machine with complete accessories including PC and all the required software along with the instrument.
Technical Specifications	Chemistry: It shall work with proven magnetic bead technology or other chemistries for all the applications.
	The system should be compatible with a wide variety of sample types: blood, body fluids, serum, plasma, swabs to use with different downstream molecular biology applications.
	Throughput: The system must be able to do RNA/DNA extraction of minimum 96 or more samples in one run.
	Shall be able to process sample volume of less than or equal to 400µl
	Elute volume shall be more than or equal to 30µl.
	The system should have sensors for liquid level, reagent volume, waste level and consumable detection.
	Inbuilt UV lamp for decontamination or officially validated equivalent technology for safety.
	Run time not more than 60 minutes for RNA/DNA extraction of 96 samples per run.
	System shall be standardized with LIS/LIMS capability or any communication interface like USB for data transfer.
Accessories, spares and consumables	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
Operating Environment	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
	Power supply: 220 - 240 VAC, 50Hz fitted with appropriate plug. The power cable must be approx. 3 metres in length.
	Online UPS with minimum 2 hours back-up shall be supplied with the system.
Standards and Safety Requirements	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
	European CE or USFDA approved product certificate.
User Training	Must provide user on-site training (including how to use and maintain the equipment).
Warranty	Comprehensive warranty for 2 years.

Maintenance Service During Warranty Period	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required. And shall provide all PM kits.
Installation and Commissioning	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail. The bidder must demonstrate the required performance of the equipment.
	All the necessary documents (Instrumental Qualification/Operational Qualification/ Performance Qualification) and certification should be provided at the time of installation.
Documentation	User (Operating) manual in English.
	Service (Technical / Maintenance) manual in English.
	List of important spare parts and accessories with their part numbers and costing.
	Certificate of calibration and inspection from factory.

3. Automated External Defibrillator (AED)

S.N.	Purchaser's Specifications
	Automated External Defibrillator (AED)
	Manufacturer
	Brand
	Type/Model
	Country of Origin
1	**Description of Functions**
1.1	Defibrillator to be used to give electrical shocks to the patient's chest assisting the heart to resume its co-ordinated atria-ventricular pump function, in the context of advanced cardiac life support.
2	**Operational Requirements**
2.1	It shall operate on internal replaceable batteries.
3	**System Configurations**
3.1	Automated External Defibrillator (AED) with complete accessories, for adult paediatric and infant use.
4	**Technical Specifications**
4.1	It shall be portable Automated External Defibrillator (AED) for immediate operation, self-explanatory and based on intuitively understood design features.
4.2	Shock and splash resistant housing to allow functioning in demanding environment.
4.3	Shall perform self-test when device is switched on and shall indicate ready for use. Self-test to be performed upon each switched on ready-for-use is indicated
4.4	It shall have capability of automated assessment and analysis, adequately sensitive and specific for children and adults.
4.5	The device shall have facility of step-by-step guidance from the large pictograms when it is on
4.6	It shall analyse, shock with self-adhesive external pads, colour coded, each with pictogram.
4.7	It shall have automated direct defibrillation with biphasic waveform, maximum energy approximately 150J.
4.8	It shall have built-in load compensation algorithm to adjust energy delivery according to patient's impedance.
4.9	Shall come with standard pads fit for children (> 8 year or > 25kg) and adults.
4.10	For infants (> 1 year or > 6kg) shall come with attenuation pads, reduction to maximum approximately 50J.
4.11	It shall have pads with plug and power cord, length approximately 100cm
4.12	It shall have built-in audible metronome assists Cardiac Pulmonary Resuscitation (CPR) reports, with audio-visual alerts of operational status, malfunctions (electrodes) and low battery status.
4.13	Facility of internal safety discharge of accumulated energy upon 20sec non-delivery, switch-off or malfunction
4.14	Battery capacity approximately 100 shocks of 250J.
5	**Accessories, Spare Parts and Consumables**
5.1	**Accessories:** • 1 x Set of children, adult self-adhesive external pads, colour coded, • with pictogram • 1 x Set of infant attenuated adhesive external pads, colour coded, with • pictogram • 1 x CD-ROM or other electronic devices with training material • 2 x Set of spare batteries to use with machine (separately packed).1 x Carry case with storage pocket for leads and other accessories
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.

S.N.	Purchaser's Specifications
6.2	Power supply: It shall operate on internal replaceable batteries, type 9V PP3 / 6LR61 or M5070A type lithium long life battery.
7	**Standards & Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Comply to AHA & ACLS requirements or shall meet AAMI DF80 guidelines and AHA recommendations for adult defibrillation (Circulation 1997; 95:1677-1682).
8	**User Training**
8.1	The Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**
12.1	User (Operating) manual in English
12.2	Service (Technical / Maintenance) manual in English
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

4. BIPAP (Bi-level Positive Airway Pressure)

1	**Description of Function**	
1.1	BIPAP stands for Bi-level Positive Airway Pressure. It is a breathing apparatus that helps people get more air into their lungs.	
2	**Operational Requirements**	
2.1	Integrated display screen shall display easy-to-read real time graphics in waveform or bar scale format the measured and calculated parameters.	
3	**System Configuration**	
3.1	BIPAP (Bi-level Positive Airway Pressure), complete unit with all standard accessories.	
4	**Technical Specifications**	
4.1	Product class according to 93/42/EEC	II a
4.2	Dimensions W x H x D in cm approx.	17 x 13.5 x 18
4.3	Light Weight approx..	1.5 kg
4.4	Temperature range - operation - storage	 +5 °C to +40 °C -25 °C to +70 °C
4.5	Permissible humidity during operation and storage	Rel. humidity 15 % to 95 %, non- condensing
4.6	Air pressure range	700 hPa to 1060 hPa, corresponds to a height of 3000 m above sea level
4.7	Connection diameter for respiration hose in mm	19.5(to fit standard cone)
4.8	Electrical power	Max. 40 VA
4.9	System interface	12 V DC , Max. 10 VA
4.10	Current consumption during operation(Therapy) 230 V 115 V during standby mode (Standby) 230 V 115 V	 0.11 A 0.22 A 0.036 A 0.019 A
4.11	Classification acc. to DIN EN 60601-1-11: Protection class against elec. Shock. Degree of protection against elec. Shock Protection against harmful ingress of water and foreign bodies	Protection class II Type BF IP21
4.12	Classification as per DIN EN 60601-1: Operating mode	Continuous operation
4.13	Applied part	Respiratory mask
4.14	Electromagnetic compatibility (EMC) as per DIN EN 60601-1-2 Radio interference suppression Radio interference immunity	Test parameters and limit values can be requested from the manufacturer if required. EN55011 B IEC61000-4 Parts 2 to 6, Part 11, Part 8 IEC61000-3 Parts 2 and 3
4.15	Average sound pressure level in operation as per ISO 80601-2-70	Approx. 26.5 dB(A) at 10 hPa (corresponds to a sound power level of 34.5 dB(A))
4.16	Average sound pressure level in operation as per ISO 80601-2-70 with respiratory air Humidifier	Approx. 27.5 dB(A) at 10 hPa (corresponds to a sound power level of 35.5 dB(A))
4.17	Sound pressure level of alarm message	At least 58 db(A)
4.18	Alarms (optional)	**All device types** Disconnection, severe leakage (optional) **prisma30ST, prisma30ST-C, prismaLAB** Apnea, low minute volume, low tidal volume
4.19	Alarm output	Optical and acoustic
4.20	CPAP operating pressure range	4 hPa to 20 hPa
4.21	AcSV pressure range	4 hPa to 30 hPa
4.22	BiLevel pressure range	4 hPa to 30 hPa
4.23	Pressure accuracy	< 20 hPa: ± 0.6 hPa

		≥ 20 hPa: ± 0.8 hPa
4.24	P Limmax (maximum pressure in case of error)	< 40 hPa
4.25	Target volume in AcSV mode	It is not possible to set a target volume for the AcSV mode. The pressure control always stabilizes the volume at the respective current level.
4.26	Automatic backup frequency in AcSV and autoS/T mode	The automatic backup frequency is continuously adapted between 10 bpm and 20 bpm, depending on the filtered spontaneous rate and the relative respiratory minute volume of the patient.
5	**Accessories, spares and consumables**	
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
6	**Operating Environment**	
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**	
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.	
7.3	Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirement for Electrical safety of Medical Equipment.	
8	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	Supplier must accomplish proper commissioning of equipment onsite.	
12	**Documentation**	
12.1	User (Operating) manual in English.	
12.2	Service (Technical / Maintenance) manual in English.	
12.3	List of important spare parts and accessories with their part numbers and costing.	
12.4	Certificate of calibration and inspection from factory.	

5. CPAP (Continuous Positive Airway Pressure)

S.N.	Purchaser's Specifications		
1	**Description of Function**		
1.1	CPAP stands for Continuous Positive Airway Pressure. It is an important treatment for obstructive sleep apnea		
2	**Operational Requirements**		
2.1	Integrated display screen shall display easy-to-read real time graphics in waveform or bar scale format the measured and calculated parameters.		
3	**System Configuration**		
3.1	CPAP, complete unit with all standard accessories.		
4	**Technical Specifications**		
4.1	**-CPAP pressure**	4 hPa to 20 hPa 1,2,3 Off to 45min	
4.2	**prisma30ST-C** - Inspiratory positive airway pressure (IPAP) - Expiratory positive airway pressure (EPAP) - Relative inspiration duration Ti/Tset - Ti - Trigger inspiration - Trigger expiration - Pressure rise rate - Backup frequency - Available modes	 4 hPa to 30 hPa 4 hPa to 25 hPa 20% to 67% 500 ms to 4000 ms Auto, can be set to 3 levels Auto, can be set to 3 levels Can be set to 4 levels 0 bpm to 35 bpm CPAP, S, S/T, T, aPCV	
4.3	Peak flow as per ISO 80601-2-70 CPAP and APAP mode Test pressures: 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa AcSV mode, BiLevel Test pressures: 4 hPa 10.5 hPa 17 hPa 23.5 hPa 25 hPa 30.0 hPa	Pressure measured at the patient connection opening with a flow of 40 l/min 4.0 hPa 8.0 hPa 11.9 hPa 15.9 hPa 19.9 hPa 4.0 hPa 10.4 hPa 17.0 hPa 23.5 hPa 25 hPa 30.0 hPa	Average flow at the patient connection opening 235 l/min 230 l/min 220 l/min 215 l/min 210 l/min 235 l/min 225 l/min 215 l/min 200 l/min 195 l/min 190 l/min
4.4	Warming of respiratory air	Max. +3°C	
4.5	Stability of the dynamic pressure (short-term accuracy) for 10 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose. 7 hPa 10 hPa 13.5 hPa 20 hPa Stability of the dynamic pressure (short-term accuracy) for 15 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose. 7 hPa 10 hPa 13.5 hPa 20 hPa	 Δp < 0.24 hPa Δp < 0.28 hPa Δp < 0.3 hPa Δp < 0.4 hPa Δp < 0.24 hPa Δp < 0.32 hPa Δp < 0.4 hPa Δp < 0.48 hPa	

S.N.	Purchaser's Specifications	
	Stability of the dynamic pressure (short-term accuracy) for 20 breaths/min as per ISO 17510-1:2007 when using the 19 mm hose. 7 hPa 10 hPa 13.5 hPa 20 hPa	 Δp < 0.4 hPa Δp < 0.32 hPa Δp < 0.46 hPa Δp < 0.56 hPa
4.6	Stability of the dynamic pressure (short-term accuracy) as per ISO 80601-2-70 in CPAP and APAP mode - when using the 19 mm hose 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa - when using the 15 mm hose, bacteria filter, and oxygen safety valve 4 hPa 8 hPa 12 hPa 16 hPa 20 hPa	 Δp < 0.68 hPa Δp < 0.58 hPa Δp < 0.52 hPa Δp < 0.44 hPa Δp < 0.64 hPa Δp < 1.06 hPa Δp < 1 hPa Δp < 1.08 hPa Δp < 1.02 hPa Δp < 0.96 hPa
4.7	Stability of the dynamic pressure (short-term accuracy) as per ISO 80601-2-70 in modes with 2 pressure levels At 10 bpm inspiratory At 15 bpm inspiratory At 20 bpm inspiratory At 10 bpm expiratory At 15 bpm expiratory At 20 bpm expiratory	 Δp = 0.8 hPa Δp = 1.4 hPa Δp = 2.4 hPa Δp = 0.6 hPa Δp = 0.6 hPa Δp = 0.6 hPa
4.8	Stability of the static pressure (long-term accuracy) as per ISO 80601-2-70 - when using the 19 mm hose - when using the 15 mm hose, bacteria filter, and oxygen safety valve	 Δp = 0.15 hPa Δp = 0.19 hPa
4.9	Pressure drop via the oxygen valve at 90 l/min at 60 l/min at 30 l/min	 0.5 hPa 0.25 hPa 0 hPa
4.10	Recommended maximum additional oxygen Flow	15 l/min
4.11	Accuracy of volume measurement at 20°C	±20%
4.12	Filter and smoothing techniques	Target volume that can be set: In the "slow" level, the device checks after every 8 breaths if the target volume has been reached and changes the pressure by 0.5 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation. In the "medium" level, the device checks after every 5 breaths if the target volume has been reached and changes the pressure by 1.0 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation. In the "fast" level, the device checks after every breath if the target volume has been reached and changes the pressure by 1.5 hPa. If the pressure reaches a corridor around the target volume, the device switches to exact regulation.

S.N.	Purchaser's Specifications	
		• Alarms: The "low minute volume" and "low tidal volume" alarms are triggered if at least three of the last five breaths were below the alarm limit. The alarms are reset automatically as soon as the corresponding alarm limit is exceeded again with at least three of the five breaths. If a target volume is activated, the "low tidal volume" alarm is only triggered once IPAPmax or PDIFFmax has also been attained. The "Apnea" alarm is triggered if apnea is identified which is longer than the set alarm limit. The alarm is reset automatically as soon as the end of the apnea is identified.
4.13	Pollen filter up to 1 µm up to 0.3 µm	Filter class E10 ≥ 99.5% ≥ 85 %
4.14	Service life of pollen filter	Approx. 250 hours
4.15	SD card	Memory sizes of 256 MB to 8 GB can be used, interface compatible with SD physical layer version 2.0
4.16	**Tolerances for measurements** Pressure: ± 0.75% of measurement or ± 0.1 hPa Flow: ± 4 l/min Temperature: ± 1.5°C Sound pressure level and sound power level ± 2dB(A) The right to make design modifications is reserved. All flow and volume values are determined under STPD conditions All the parts of the therapy device are free from latex. The WM 100 TD therapy devices use the following open source software: FreeRTOS.org This device's software contains code which is subject to the GPL. You will receive the source code and the GPL upon request	
5	**Accessories, spares and consumables**	
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
6	**Operating Environment**	
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**	
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.	
7.3	Electrical safety conforms to standards for electrical safety IEC 60601-1 General requirement for Electrical safety of Medical Equipment.	
8	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	
10	**Maintenance Service During Warranty Period**	
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.	
11	**Installation and Commissioning**	
11.1	Supplier must accomplish proper commissioning of equipment onsite.	
12	**Documentation**	
12.1	User (Operating) manual in English.	
12.2	Service (Technical / Maintenance) manual in English.	
12.3	List of important spare parts and accessories with their part numbers and costing.	
12.4	Certificate of calibration and inspection from factory.	

6. ECG Machine, Portable (12 Channel)

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	ECG Machine is primary equipment to record ECG Signal in various configurations.
2	**Operational Requirements**
2.1	Portable digital ECG machine must be able to acquire all 12 Leads simultaneously.
3	**System Configuration**
3.1	Portable digital ECG machine with complete accessories
4	**Technical Specifications**
4.1	Simultaneous recording of 12 standard leads: aVR, aVL, aVF, I, II, III and V1-6 pre-cordials.
4.2	Internal memory for data storage.
4.3	Splash-resistant alphanumeric keyboard with function keys.
4.4	With zeroing reset, auto-base-line correction (0.5Hz) and 1mV test/calibration signal.
4.5	Filter setting for line-frequency (50 or 60Hz) and tremor.
4.6	Continuous check on the quality of electrodes connection, audio visual alert on loss of signal
4.7	Appropriately protected for operation during defibrillation.
4.8	Alphanumeric LCD display, approximately: 10x14cm. Display shows ECG-curves, heart rate, patient name and ID, time, speed and filter setting.
4.9	Front panel provides indication of system and battery status, electrode connection and paper.
4.10	Built-in high-resolution 300 dpi thermal printer, width 210mm, automatic and manual print-out mode.
4.11	Print-out on folded thermo-reactive paper, format A4.
4.12	Number of channels printed is user selectable: 3, 6 or 12.
4.13	Combination of channels printed is standard and user selectable and with copy function.
4.14	Paper speed, user adjustable: 5, 25 and 50mm/sec.
4.15	Sensitivity, automatic or user selectable: 5, 10 and 20mm/mV.
4.16	Data interface: RS232 or equivalent Self-test is performed each time the device is switched on.
4.17	Transformer, charger and rechargeable battery integrated in device.
4.18	Autonomy, approximately 50 readings.
4.19	With internal re-chargeable battery Power consumption, approximately: 200W
5	**Accessories, spares and consumables**
5.1	**Accessories:** • Patient cable-1 no. • Reusable chest electrodes, suction ball-type- 6 nos. • Extremity clamp electrodes, reusable- 4 nos. • Box of A4 recording paper, 1000 sheets- 1 no. • Bottles of electrode gel, approximately 350ml- 2 nos. • Spare rechargeable battery pack- 1 no. • Set of spare fuses- 1 set • Plastic protective dustcover- 1 no.
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220–240V AC, 50Hz fitted with appropriate plug type D round 3 pins. The power cable must be at least 3 metre in length.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Shall meet IEC-60601-1-2:2001 General Requirements of Safety for Electromagnetic Compatibility.
7.4	Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms.
8	**User Training**

8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	Supplier must accomplish proper installation and commissioning of the equipment on site.
12	**Documentation**
12.1	User (Operating) manual in English
12.2	Service (Technical / Maintenance) manual in English
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

7. ICU Bed, (Fowler's Bed)

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	Fowler bed is a bed specially designed for hospitalized patients in need of patient ease. These beds have special features both for the comfort and wellbeing of the patient and for the convenience of hospital staff.
2	**Operational Requirements**
2.1	It shall have anti-corrosive and antirust treated baked hard epoxy powder coating, four sections fowler bed.
3	**System Configuration**
3.1	Fowler bed, four sections with mattress.
4	**Technical Specifications**
4.1	Dimensions approx.: 2080Lx920Wx600H mm (without mattress) **(±10%)**.
4.2	The main frame shall be made from 60mmx30mmx16G ERW (Electric Resistance Welded) rectangular tubes.
4.3	Four sections top shall be made from 18G CRCA sheets uniformly perforated and shall be suitably fitted to the main frame.
4.4	All adjustments for fowler position must be obtained from crankshaft, manually operated with stainless steel foldable handle on both the shaft.
4.5	Bed frame must be sturdy and stable to support weight of at least 150 kg.
4.6	The finished bed must be rust proof, pre-treated and treated with washable epoxy polyester antimicrobial powder coated to increase the bacteriostatic property.
4.7	The bed shall have a pair of swing down type full length side rails, mild steel (MS), washable epoxy powder coated with self-locking.
4.8	It shall have easily removable head and foot panels made up of stainless steel (SS) or ABS moulded with four corner buffers.
4.9	There must be suitable buffer mechanism to avoid hitting of the bed to the wall.
4.1	Bed frame fitted with non-rusting, noiseless, non-marking 360 deg. swivel heavy-duty castor wheels of 125mm dia, 2 with brakes and 2 without brakes.
4.11	It must have provision of fixing suitable rod for hanging intravenous / irrigation fluid bottle on both sides at head end and foot end.
4.12	It must have hooks on bed frame on both sides for holding urine / drainage bag (at least 4 nos.).
4.13	Shall provide with one dual hook 304-grade stainless steel telescopic IV rod.
4.14	**Mattress:**
	Shall provide with one no. four section mattress of dimensions at least (2000mm L x 900mm W) with washable cover of good quality. The mattress must be made of high-density PU foam of 100mm thickness.
4.15	The colour of the paint or coating shall be white.
5	**System Configuration Accessories, spares and consumables**
5.1	All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer, which have not been specified in this Technical Specifications Form.
6	**Operating Environment**
6.1	The system offered shall be designed to store and to operate normally under the conditions of the purchaser's country. The conditions include Climate, Temperature, Humidity, etc.
7	**Standards and Safety Requirements**
7.1	Must submit ISO 9001 or ISO 13485:2003/AC:2007 **AND**
7.2	CE or USFDA approved product certificate.
8	**User Training**
8.1	Not applicable.
9	**Warranty**
9.1	Warranty for 1 year after acceptance.

S.N.	Purchaser's Specifications
10	**Maintenance Service During Warranty Period**
10.1	Standard warranty conditions are applicable.
11	**Installation and Commissioning**
11.1	Must supply preassembled unit, ready to use.
12	**Documentation**
12.1	Users/Instructions manual shall be provided in English.

8. Infusion pump

S.N.	Purchaser's Technical Specifications
1.	**Description of Function**
1.1	The infusion pump provides uniform flow of fluid by precisely driving the plunger of a liquid (NS, Glucose, etc.). It provides accurate and continuous flow rate for precise deliver of I.V. medication in critical medical care
2.	**Operational Requirements**
2.1	The infusion pump must be user friendly, safe to use and must have battery backup and comprehensive alarm system
3.	**System Configuration**
3.1	Infusion pump with battery backup alarm and with complete accessories
4	**Technical Specifications**
4.1	Should come factory calibrated with at least 2 types of commonly used infusion set.
	Should have option of onsite calibration of at least 5 types of different infusion set.
4.2	Shall be compatible with most of the IV set (macro/ micro drip sets)
4.3	Shall have a LED/LCD display with backlight and graphical display of infusion
4.4	Should have three Occlusion Level Settings.
4.5	It shall have facility of audible and visual alarm for occlusion pressure, air alarm, door open, empty, low battery.
4.6	Should be able to show real time pressure inside infusion set
4.7	Should have Ultrasonic Buddle Detector.
4.8	Should Have Option of On/Off and adjustable KVO from 1-5ml/Hr.
4.9	Should have Built in Lithium Iron Phosphate battery with a backup of at least 5 hours.
4.10	Should have RS 232 for Bidirectional communication.
4.11	Infusion Rate 1ml/hr to 1220ml/Hr.
4.12	Should be able to set two infusion programmes at a time.
4.13	Shall have a flow rate accuracy of ±5% and drip rate accuracy of ± 3%
4.14	Shall have rechargeable battery having at least 2 hours backup at highest delivery rate
5.	**Accessories, spares and consumables**
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above)
6.	**Operating Environment**
6.1	The system offered must be designed to store and be operated normally under the condition of the purchaser's country. The conditions include climate, temperature and relative humidity.
6.2	Power supply: 220-240 V AC/ 50 Hz, fitted with appropriate plug type D round 3 pins. The power cable must be minimum 2.5 meters long
7	**Standards and Safety Requirements**
7.1	Must submit ISO 13485:2003/ AC:2007 for Medical Devices AND
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate
8.	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment)
9.	**Warranty**
9.1	Comprehensive warranty for 2 year after installation
10.	**Maintenance Service During Warranty Period**
10.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11.	**Installation and Commissioning**
11.1	Supplier must accomplish proper installation and commissioning of the equipment onsite.
12	**Documentation**

S.N.	Purchaser's Technical Specifications
13.1	User (Operating) manual in English.
13.2	Service (Technical / Maintenance) manual in English.

9. Oxygen Concentrator (10 L)

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	Oxygen concentrator produces oxygen from ambient air.
2	**Operational Requirements**
2.1	Integrated Oxygen sensing device (OSD) measures concentration at flow meter entrance.
3	**System Configuration**
3.1	Oxygen Concentrator set complete.
4	**Technical Specifications**
I	**Oxygen Concentrator**
4.1	Output flow: max 10 l/min.
4.2	Flow meter range: 1 to 10 l/min.
4.3	Output pressure: 60kPa.
4.4	Oxygen concentration: 95% +/- 3% at 1-3l/min, 92% +/- 3% at 4l/min, 90% +/- 3% at 5l/min., 95% +/- 3% at 10 l/min
4.5	Time to reach 95% the specified performance: 5 minutes.
4.6	Four-step filtering (coarse, pre, inlet and bacterial) of air-intake.
4.7	All filters replaceable, coarse filter washable/reusable.
4.8	Continuous monitoring, with visual and audible alert on: • Low and high output pressure • Low oxygen concentration • Oxygen monitor: amber light on the front illuminates when oxygen concentrator is below 85%. If concentration remains below 85% for more than 15 minutes, an audible alarm sounds. • Power failure • Battery test.
4.9	Temperature operating range: 20 to 60^{O}C.
4.10	Sound level produced: max 50 dB(A).
4.11	Shall have 4 antistatic swivel casters, 2 with brakes and with integrated handle allows for easy moving and positioning.
5	**Accessories, spares and consumables**
5.1	**Accessories:** • 2 x Adult cannula, with 2m tubing. • 4 x Infant/Paediatric cannula, with 2m tubing. • 4 x New-born cannula, with 2m tubing. • 3 x Connector for above. • 4 x Humidifiers. • 4 x 50' tubing. • 4 x tubing adapter kit. • 6 x Spare coarse filters. • 3 x Spare pre-filters. • 3 x Spare inlet-filters. • 3 x Spare bacterial-filters.
5.2	All standard accessories/consumables/parts required for the proper operation of the above item shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Form.
6	**Operating Environment**
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Climate, Temperature, Humidity, etc.
6.2	Power supply: 220-240VAC, 50Hz fitted with appropriate plug. The power cable must be minimum 3 metres long. Power consumption, approx.: 500 W.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
8	**User Training**
8.1	Must provide user training.
9	**Warranty**

S.N.	Purchaser's Specifications
9.1	Comprehensive warranty for 3 year after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The supplier must accomplish proper installation and commissioning of equipment onsite.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part number and costing.
12.4	Certificate of calibration and inspection from factory.

10. Patient Monitor, Portable

S N.	Purchaser's Specifications
1	**Description of Functions**
	For monitoring vital signs of all patient categories, at bedside, OT or during transportation.
2	**Operational Requirements**
2.1	It shall operate on AC power supply as well as built-in battery.
3	**System Configurations**
3.1	Patient Monitor, portable with complete accessories.
4	**Technical Specifications**
4.1	Portable vital sign monitor, suitable for all patient categories neonatal, infant and adult.
4.2	Monitor can be mounted on standard bed/wall rail, and mobile pole/stand.
4.3	It shall have robust design allows for use in demanding environments.
4.4	It shall have soft-touch keys, durable and easy to clean.
4.5	Parameters monitored: ECG, Heart Rate (HR), Respiration Rate (RR), SpO2, NIBP and Temperature measurements with ECG leads I, II, III.
4.6	Measurements range: • HR approximately 30 to 250bpm <3bpm> • NIBP approximately 20 to 290mmHg (systolic) <1mmHg> • SpO2 approximately 40 to 100% <1%> • RR (ECG derived) approximately 6 to 180bpm <1bpm > • Temperature approximately 10 to 45C <0.1C>
4.7	NIBP oscillometric step deflation, manual/automatic, initial inflation pressure user selectable
4.8	Bright 4-channel TFT colour display, approximately 18cm (across), equals to 7 inch.
4.9	It shall have sweep, adjustable 12.5, 25 or 50mm/second.
4.10	Sensitivity (amplitude) of all signals user adjustable.
4.11	Standardising marker, 1mV.
4.12	Shall have user pre-set of high/low alarms on all monitored parameters.
4.13	Audio visual alarm in case measurements are outside pre-set range.
4.14	Shall have silencing feature for audio alarms.
4.15	Trend display from 2 to 24 hours.
4.16	Data interface (for ECG) through RS232, BNC, USB or equivalent.
4.17	Shall have defibrillator sync and protection during defibrillation.
4.18	Shall have pacemaker detection/rejection.
4.19	Display shall have facility to report system errors, leads and sensors failure and built-in battery status.
4.20	Autonomy of built-in rechargeable battery approximately 3 hours, automatic recharge when connected to mains.
4.21	Automatic switch to batteries in case of power failure.
5	**Accessories, Spare Parts and Consumables**
5.1	**Accessories:** 1 x Mounting bracket for fixation to standard bed/wall rail and mobile pole/stand 1 x Spare rechargeable battery pack 1 x Set of spare fuses NIBP accessories: • 3 x NIBP hose (1 x neonate, 1 x infant, 1 x adult) • 3 x Blood pressure cuff (1 x infant, 1 x child, 1 x adult) ECG accessories • 2 x Patient cable extremities (1x neonate/paediatric, 1 x adult) • 2 x Set of electrodes (1x neonate/paediatric, 1 x adult) • 1 x Electrode gel, bottle 350ml Temperature accessories • 2 x Skin temperature probes (incl. connection cable) Pulse oximetry (SpO2) sensors with cable and plug • 2 x Adult size, reusable clip-on type • 2 x Infant size, reusable clip-on type

S N.	Purchaser's Specifications
	• 3 x New-born size, reusable clip-on type • 10 x New-born size, single-use wrap-around type
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.
7	**Standards & Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	European CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Shall meet IEC-60601-1-2:2001 General Requirements of Safety for Electromagnetic Compatibility.
7.4	Shall meet the safety requirements as per IEC 60601-2-27:1994—Medical electrical equipment—Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment.
8	**User Training**
8.1	The Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.
9	**Warranty**
9.1	Comprehensive warranty for 2 years, after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**
12.1	User (Operating) manual in English
12.2	Service (Technical / Maintenance) manual in English
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

11. Portable X-ray Machine (Mobile, 10KW)

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	Mobile X-Ray Unit is required to perform X-Ray studies in Emergency and trauma departments and at bedside in wards and ICU.
2	**Operational requirements**
2.1	Compact, lightweight, easily transportable mobile radiographic unit suitable for bedside X-ray for trauma units (accidental cases), intensive care units, operation theatres and also in the Radiology department for conventional radiography.
3	**System Configuration**
3.1	X-ray Machine Mobile, 10KW complete unit and with complete accessories.
4	**Technical Specifications**
4.1	**The Generator:** • Microprocessor-controlled high frequency generator of not less than 6KHz. • Max output: not less than 10kW at 100kv, 100ms • Voltage range: 40 - 125kV in more than 25 steps. • Max tube current: 250mA • mAs range: 0.5 - 200mAs in more than 30 steps • Minimum Exposure time: not more than 5ms • Soft touch key or membrane keypad or screen touch panel for operations • Anatomical Programmable Radiographic mode shall be available.
4.2	**X-Ray Tube:** • Rotating anode type • Anode rotation: 2800rpm • Anode heat capacity: not less than 100 kHU • Dual focal spot: not more than 0.8mm
4.3	**Collimator:** • Manually adjustable multi-leaf collimator, rotatable ±90° • Collimator light halogen lamp: 180 lux at 1m SID
4.4	**Tube positioning:** • Max tube height: not less than 1800mm, • Min tube height: not more than 450 mm • Max horizontal extension: not less than 800mm
4.5	The unit shall have counter balanced arm system
4.6	Shall have remote control of exposure to protect operator.
4.7	The unit must have an effective braking system for parking, transport and emergency braking.
4.8	The unit shall come with overload protection device.
5	**Accessories, spares and consumables**
4.1	**Accessories:** • Lead apron lightweight- 2 nos. • Grid (Ratio 6:1) of 12"x15" and 10"x12": 01 each. • Remote control kit: 01 no.
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with 5m automatic retractable power cable for easy connection to any wall outlet with protective ground conductor.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Shall meet: • IEC 60601-1-3 - Part 1: General Requirements for safety - Collateral Standard: General Requirements for Radiation Protection in Diagnostic X-Ray Equipment.

S.N.	Purchaser's Specifications
	• IEC 60601-2-7 - Part 2-7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-Ray Generators.
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part number and costing.
12.4	Certificate of calibration and inspection from factory.

12. Portable Blood Gas Analyser

S.N.	Purchaser's Specifications	
	Blood Gas Analyser	
	Manufacturer	
	Brand	
	Type / Model	
	Country of Origin	
1	**Description of Function**	
1.1	Portable Blood gas analysers are used to measure blood gases, electrolytes, pH values and biochemical parameters of the blood	
2	**Operational Requirements**	
2.1	Portable, Fully automatic, upgradeable, fast electrolyte combi analyser.	
3	**System Configuration**	
3.1	Fully automatic Portable Blood Gas Analyser with electrodes and built in printer.	
4	**Technical Specifications**	
4.1	Essential Measured parameters; pH, pCO2, pO2, tHb, Barometric Pressure, Na+, K+, Ca++, Cl-, Bl urea and Sr Creatinine & Blood sugar. All these parameters must be measured simultaneously.	
4.2	Calculated parameters must include BE, BE ecf, HCO3, Lactate, Anion Gap, SaO2.	
4.3	Sample volume-less than 100ul.	
4.4	Fast analysis time – less than 60 sec	
4.5	Maintenance free electrodes with individual electrodes ON/OFF facility	
4.6	Fully automatic liquid calibration of all parameters at user-defined intervals without the use of Gas calibrated reagents, external gases, tanks or regulators	
4.7	Continuous reagent level monitoring with graphic display.	
4.8	Data display on well-illuminated, adequate size LCD colour touch screen display.	
4.9	Data print out on built in graphic printer.	
4.10	Built in auto Quality control facility	
4.11	Automatic result processing, test ordering and transmission to the LIS/HIS system (laboratory Information System/Hospital Information System)	
4.12	Automatic data archiving and customizable layout. Data backup with read/write CD-ROM drive	
4.13	Must come with at least 2 USB ports	
5	**Accessories, spares and consumables**	
5.1	**Accessories:** • Reagents for one year@20 samples/day or as per requirement must be provided along with the machine. • Electrodes for all the parameters as specified -01 set • Quality control tools/reagents for one year @20 samples a day-01 set or as per requirement. • Cost of reagents must be quoted for comparative evaluation.	
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).	
6	**Operating Environment**	
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.	
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.	
6.3	UPS of suitable rating shall be supplied for minimum 30 min. backup for the entire system.	
7	**Standards and Safety Requirements**	
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**	
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.	
7.3	Shall meet IEC 61010-2-081: Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes	
8	**User Training**	
8.1	Must provide user training (including how to use and maintain the equipment).	
9	**Warranty**	
9.1	Comprehensive warranty for 2 years after acceptance.	

S.N.	Purchaser's Specifications
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**
12.1	User (Operating) manual in English
12.2	Service (Technical / Maintenance) manual in English
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

13. Pulse Oximeter with ECG Monitor

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	A combined pulse oximeter with ECG for monitoring ECG, heart rate and SpO2.
2	**Operational Requirements**
2.1	Suitable for all types of patient range, adult, paediatric and infant and shall operate on AC mains as well as from internal rechargeable battery.
3	**System Configuration**
3.1	Pulse Oximeter with ECG Monitor with all standard accessories.
4	**Technical Specifications**
4.1	Self-contained Pulse Oximeter unit for non-invasive, continuous measurement of arterial oxygen saturation level in human blood.
4.2	The unit shall be a portable and light weight model and easy to carry.
4.3	Control keys shall be touch screen, touch button or equivalent.
4.4	Minimum 5 inches multi-colours TFT / LCD display screen.
4.5	**SpO2 Function shall provide:** • O2 saturation % level. • Pulse rate/beats per minute. • Standard range for SPO2: 0% to 100%. • Accuracy: better than +/- 3% from 70-100% SpO2 range. • Pulse rate range: approximately 30 to 250 bpm with accuracy better than +/- 5%.
4.6	**ECG function shall have:** Monitor shall be able to display 3 channels of ECG waveforms simultaneously.
4.7	Facility to monitor and display ECG and SpO2.
4.8	Audible alarms for high/low oxygen saturation, high/low pulse rate.
4.9	Able to set alarm limits for heart rate and SpO2
4.10	Trend of at least 72 hours.
4.11	Automatic self-test on start-up and continuous memory tests during operation.
4.12	It must be suitable to operate in the presence of potentially flammable anaesthetic gases, and it shall not cause fire or explosion during operations.
4.13	The monitor must have electro cautery and defibrillator protection.
4.14	It shall operate from the AC mains supply as well as with inbuilt rechargeable battery having automatic charging function.
4.15	A fully charged battery must be able to power the unit for a minimum of 3-4 hours. It shall achieve functional operation recharged up to 80% or better in not more than 6 hours of recharging.
4.16	It shall have a low battery warning system, providing a warning at least 10 minutes normal unit working time before the battery is completely flat.
4.17	RS 232C or USB or equivalent interface for data communication.
4.18	Capability of storage of patient data and printing of patient reports.
4.19	Integrated thermal array printer for report output.
5	**Accessories, spares and consumables**
5.1	3 lead ECG cable with complete reusable ECG electrodes for adult & paediatric: 02 set each.
5.2	ECG cable and patient cable 3 leads for disposable electrodes: 01 set
5.3	Disposable ECG electrodes for adult, paediatric & infant: 50 each.
5.4	ECG jelly (approx.350ml): 2 bottles
5.5	SpO2 reusable sensor for adult and paediatric: 01 each
5.6	SpO2 reusable sensor for infant: 01 no.
5.7	SpO2 ear sensor, adult size:01 no.
5.8	Universal Y sensor: 01 no.
5.9	Thermal printer paper for 500 patients.
5.10	Plastic protective dustcover: 01 no.
5.11	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.

S.N.	Purchaser's Specifications
6.2	Power supply: 220 – 240V AC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms.
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	Supplier must accomplish proper installation & commissioning of equipment onsite.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

14. Resuscitation Set, Emergency

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	Emergency resuscitation set is use in the hospitals for all emergency situations where respiratory support is needed.
2	**Operational Requirements:**
2.1	Shall be portable unit.
3	**System Configuration**
3.1	Emergency Resuscitation Set with complete items and with complete accessories.
4	**Technical Specifications**
4.1	**Controlled Mechanical Ventilation:** • Short term Automatic Resuscitation or longer periods of continuous ventilation of Adult & Child • Mode: Pneumatically controlled Time Cycled • Tidal Volume: 200-1200cc (approx.) • Breathing frequency: 8-30 breaths per minute • I:E Ratio: 1:1 to 1:7 • Alarm: Audio-visual high pressure, low pressure & patient disconnection • Manual over riding button for hyperventilation. • Pneumatic suction of secretion, mucus, blood: 190mmHg (Approx.) • Tubing for suction, suction catheter • Oxygen delivery:1-10l/min • Oxygen concentration in CMV mode: 100% and 60% • Pressure Regulator: 60 PSI • Cylinder: Portable – Pin indexed type cylinder • Tubing for use of bigger Cylinder • Oxygen catheter, cylinder Key • Refilling attachment for filling the small cylinder from a bigger cylinder
4.2	**Manually Operated Suction (Foot Suction) Suitable for Infant, Children & Adult:** • Compact light weight, easy to handle & operate • Durable rubber bellow • Long lasting stainless spring to provide minimum friction pumping • Complete autoclavable polycarbonate vacuum jar with Lid (500ml capacity) • Scratch resistant powder coated frame
4.3	**Manual Resuscitator for Infant, Children & Adult:** • Silicon bellows - 250ml, 500ml & 1600ml one each. • Non-rebreathing valve for adult. • Non-rebreathing valve with 40cmH2O pressure release - 2 Nos. • Mask size: No. 5 & 3, 1& 0 (1 each) • 3600 swivelling patient connector - 2 Nos. • Standard 15mm inside/22mm outside diameter - 2 Nos. • Corrugated PVC oxygen reservoir - 2 Nos. • 1.5m PVC oxygen tubing - 2 Nos. • Carrying pouch
4.4	**Airways:** • Silicon, autoclavable & reusable size 00,0,1,2,3
4.5	**Intubation:** • Laryngoscope: Stainless steel straight & curved (for children & adult) • Laryngoscopes blades of three sizes (small, medium & large) suitable for infant, children & adult. • Spare laryngoscope bulbs 2 nos. each • Magill's Forceps for adult and paediatric • Reusable Endotracheal tube (Cuffed & Uncuffed) with corresponding connectors size 2.5, 3, 3.5, 4, 5, 6, 7, 8, 9 mm. • Carrying pouch
4.6	**Intravenous Access & Administration:** • I.V. rod in two (folded). • IV cannula with three way stop for adult & paediatric sizes 18G, 20G, 22G • IV. giving Set • Tourniquet

S.N.	Purchaser's Specifications
	• Adhesive plaster- 01 Roll • Rolled bandages • Disposable syringe (2ml & 5 ml) 05 No each • Disposable needles- 10 nos.
4.7	**Diagnostics, Dressings & Others:** • Stethoscope • Clinical Thermometer • Aneroid Sphygmomanometer • Percussion Hammer • Tongue spatula • Examination torch • Dissecting forceps • Tissue forceps • Haemostatic forceps • Dressing scissors • Sterilized gauge-01 No • Needle holder • Mouth bite • B.P. handles (Size No.03). • B.P. blades 02 (Size No.03); • Sterilized gloves 6.5 & 7.5 (One Pair each)
4.8	All the components must be conveniently assembled in a sturdy blow-moulded lockable carrying case with shaped compartments and extra space for drugs, medicines etc.
5	**Accessories, spares and consumables**
5.1	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Climate, Temperature, Humidity, etc.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for one year after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	Supplier must accomplish proper commissioning of the equipment onsite.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part number and costing.
12.4	Certificate of calibration and inspection from factory.

15. Electric Suction Pump, (Surgical Aspirator)

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	To extract fluid from the body during surgery or emergency treatments.
2	**Operational Requirements**
2.1	An electric double jar suction pump for surgical use.
3	**System Configuration**
3.1	Suction machine with two bottles and accessories.
4	**Technical Specifications**
4.1	It shall be mounted on four robust, fully 360-degree swivelling, antistatic, non-marking grey tires castors, minimum size 75 mm with at least 2 diagonal brakes.
4.2	Come with suction controller and vacuum gauge / indicator.
4.3	The pump shall be oil free vacuum pump where the pumped liquid shall be sealed off from the pump.
4.4	Come with overflow control valves. Bidder shall provide technical design and details of the pump with this TSF
4.5	Vacuum rate shall be from 0 to not less than 640 mmHg (0.85 bars).
4.6	Air flow rate shall be at least 25 l/min.
4.7	The pump shall come fitted with twin unbreakable, transparent, autoclavable polycarbonate suction bottles minimum 2 litre each.
4.8	The bottles shall be incorporated with an automatic suction cut-off mechanism when they become full.
4.9	The suction bottles shall come with overflow lid.
4.10	Noise level: not more than 55 dBA.
4.11	Air discharge from pump shall be filtered by a 0.3-micron bacterial hydrophobic filter.
5	**Accessories, spares and consumables**
5.1	**Accessories:** • Electrical cable: 1 minimum 3 meter length • Clear suction tubing: 1 set of 5 meter length • Bacterial filter: 0.3 micron, 10 pcs • Spare unbreakable, transparent, autoclavable polycarbonate suction bottle 2L: 1pc • Complete connection tubing set: 1 set • Hand switch & foot switch with cables for operating easily.
6	**Operating Environment**
6.1	The product offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Must operate on 220-240V AC as well as rechargeable batteries.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Shall meet IEC-60601-1-2 General Requirements of Safety for equipment.
8	**User Training**
8.1	Not applicable.
9	**Warranty**
9.1	Warranty for 1year.
10	**Maintenance Service During Warranty Period**
10.1	During warranty period supplier must ensure corrective/breakdown maintenance whenever required.
11	**Installation, Inspections and Commissioning**
11.1	Must supply preassembled unit, ready to use.
11.2	Inspections to verify the compliance of the offered equipment as per specifications will be conducted by the technical team appointed by the purchaser.
12	**Documentation**
12.1	User (Operating) and Service (Technical/Maintenance) manuals to be supplied in English.
12.2	Certificate of calibration and inspection.
12.3	List of important spare parts and accessories with their part numbers and costing

16. Syringe Infusion Pump

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	The Syringe Infusion Pump provides uniform flow of fluid by precisely driving the plunger of a syringe down its barrel. It provides accurate and continuous flow rate for precise delivery of I.V. medication in critical medical care.
2	**Operational Requirements**
2.1	The syringe pump must be programmable, user friendly, safe to use and must have battery backup and comprehensive alarm system. This must be able to integrate in the HIS.
3	**System Configuration**
3.1	Syringe infusion pump with battery backup alarm and with complete accessories.
4	**Technical Specifications**
4.1	Flow rate programmable from 0.1 to 200 ml/hr. or more in steps of 0.1 ml/hr. with user selectable flow set rate option. SAVE last infusion rate even when the AC power is switched OFF.
4.2	Bolus rate must be programmable to 400 – 500 ml/hr. or more with infused volume display. Reminder audio after every 0.5 ml delivered bolus. SAVE last Bolus rate even when the AC power is switched OFF.
4.3	Display of Drug Name with a provision of memorizing 10~15 names by the operator.
4.4	Keep Vein Open (KVO) must be available 1.0 ml/hr. or set rate if lower than 1.0 ml. User must have choice to disable KVO whenever desired.
4.5	Selectable Occlusion pressure trigger levels.
4.6	Must Work on commonly available 20, 50/60 ml Syringes with accuracy of minimum of +/-2% or better.
4.7	Automatic detection of syringe size & proper fixing. Must provide alarm for wrong loading of syringe such as flanges out of slot; disengaged plunger, unsecured barrel etc.
4.8	Anti-bolus system to reduce pressure on sudden release of occlusion
4.9	Must have comprehensive alarm package including: Occlusion limit exceed alarm, near end of infusion pre-alarm & alarm, Volume limit pre-alarm & alarm, KVO rate flow, Low battery pre-alarm and alarm, AC power failure, Drive disengaged and preventive maintenance.
4.10	Rechargeable Battery having at least 1-hour backup for about 5ml/hr. flow rate with 50ml syringes. Larger battery life and indication of residual life will be preferred.
5	**Accessories, spares and consumables**
5.1	**Accessories:** • Docking Station for four pumps as per requirement so as to enable to power up to 4 pumps with one power cord when mounted on IV pole. -01 pc. The docking station and pump shall be of same manufacturers.
5.2	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Certified for meting IEC60601-2-24:Particular requirements for the safety of infusion pumps and controllers
7.4	Must meet IEC 529 Level 3 (IP3X) (spraying water) for enclosure protection, water ingress.
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment).
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail.
12	**Documentation**

S.N.	Purchaser's Specifications
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English
12.3	List of important spare parts and accessories with their part number and costing.
12.4	Certificate of calibration and inspection from factory.

17. USG Portable Colour Doppler with 3 Probes

S. N.	Purchaser's Specifications
1	**Description of Functions**
1.1	A general-purpose notebook-type colour Doppler ultrasound imaging system.
2	**Operational Requirements**
2.1	It shall operate on AC power supply as well as built in rechargeable battery. The machine is intended to be carried to the field or the patient ward with the inbuilt battery system to examine patients who could not come to USG room.
3	**System Configurations**
3.1	Portable colour Doppler ultrasound imaging system, 1unit.
3.2	1 unit of broad bandwidth of 2 - 5MHz, convex array probe for OB/GYN and abdominal application.
3.3	1 unit of broad bandwidth of 5 - 10 MHz, linear array probe for small part and superficial scanning application.
3.4	1 unit of broad bandwidth of 5 - 8 MHz, endo-vaginal probe for OB/GYN endo-vaginal scanning application.
3.5	1 unit of Black & White thermal printer.
4	**Technical Specifications**
4.1	The machine is intended to be carried to the field or the patient ward with the inbuilt battery system to examine patients who could not come to USG room. It shall comply with the following requirements for this purpose:
4.2	The unit shall be lightweight and easy to carry, the total weight including 1 probe and battery shall not be more than 5kg.
4.3	The unit must be sturdy, "drop safe", resistant to breakage & damage on minor fall or hit against the wall or hard surface.
4.4	Shall have long lasting built-in rechargeable battery which shall support up to 2 hours of routine ultrasound examinations.
4.5	This machine shall come with main unit, 3 units of probes, 2 built-in rechargeable Lithium ion battery packs and 1unit of black and white thermal printer.
4.6	It shall come with a custom-made trolley on castors to hold the main unit on top with provision of a probe holder and drawers for storage of 3 probes, printer and ultrasound gel.
4.7	Main applications: OB/GYN, abdominal, small parts, cardiac and vascular.
4.8	**Main unit:**
4.9	Display not less than 26cm (10") colour LCD display
4.10	Full alphanumeric keyboard.
4.11	Probe connector: at least 1 probe connector.
4.12	Shall come with 1 unit of broad bandwidth of 2 - 5MHz, not less than 30cm scan depth, convex array probe for OB/GYN and abdominal application.
4.13	Shall come with 1 unit of broad bandwidth of 5 - 10 MHz, not less than 9cm scan depth, linear array probe for small part and superficial scanning application.
4.14	Shall come with 1 unit of broad bandwidth of 5 - 8 MHz, not less than 10cm scan depth, endo-vaginal probe for OB/GYN endo-vaginal scanning application.
4.15	The system shall accept most of the common probe types of: convex array, linear array, phased array.
4.16	Scan modes: M-mode, B-mode and 2-D.
4.17	System shall be incorporated with English operation menu and reporting.
4.18	With digital broad bandwidth multi-frequency imaging capability.
4.19	With Doppler angle and angle correction.
4.20	Frame rate: not less than 50fps.
4.21	Display depth: minimum 30cm.
4.22	Matrix size: 512 x 512 x 8bit.

S. N.	Purchaser's Specifications
4.23	Grayscale levels: 256.
4.24	**The machine shall include the following functions:**
4.25	Programmable pre-set examination protocols store common setting related to image display/adjustment, annotation.
4.26	Obstetric analysis: BPD (biparietal diameter), CRL (crown-rump length), AC (abdominal circumference), HC (heart circumference), FL (foetal length), GS (gestation sac), GA (estimation of gestation age), foetal weight, heart rate and etc.
4.27	OB/GYN reporting.
4.28	Small part analysis.
4.29	Cardiac analysis with intima medial thickness measurement.
4.30	Velocity Colour to detect colour flow with PW & CW Doppler.
4.31	Body markers.
4.32	Time & slope for M-Mode.
4.33	Contrast with 8 - 10 steps adjustment.
4.34	Image pan, zoom, freeze, text annotation.
4.35	Focus: 4-point adjustment.
4.36	Automatic gain control.
4.37	Near and far Gain adjustment.
4.38	With pre- and post- processing.
4.39	With tissue harmonic imaging.
4.40	With tissue optimization function.
4.41	With function to reduce patch noise and other image artefacts without compromising quality of images.
4.42	With multi-beam imaging.
4.43	With clear visual of biopsy needle position.
4.44	With dual and duplex imaging.
4.45	Dynamic range, selectable up to approximately 165dB.
4.46	Image storage: Shall be able to store still and video images, shall be able to store about 1000 images on main unit.
4.47	Cine memory of 250 or more frames for cine loop playback.
5	**Accessories, Spare Parts and Consumables**
5.1	All standard accessories/consumables/parts (including 2 bottles of ultrasound gel) required for the proper operation of the above item shall be included in the offer. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Form.
5.2	All standard Maintenance tools and cleaning /lubrication materials where applicable shall be included. Bidders shall specify, in a separate Excel worksheet, the quantity and details of any items included in this offer which have not been specified in this Technical Specifications Form.
6	**Operating Environment**
6.1	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metres in length.
7	**Standards & Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	CE (93/42 EEC Directives) or USFDA approved product certificate.
7.3	Electrical safety conforms to standards for Electrical Safety IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.
8	**User Training**

S. N.	Purchaser's Specifications
8.1	The Supplier shall conduct user training for this equipment to enable operators to use the equipment properly. The training shall include the use of all operational functions of the equipment, as well as routine checks and maintenance expected by users.
9	**Warranty**
9.1	Comprehensive warranty for 2 years after acceptance.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	Supplier must accomplish proper installation & commissioning of equipment onsite.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part number and costing.
12.4	Certificate of calibration and inspection from factory.

18. Ventilator, Invasive

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	Invasive ICU ventilator provides artificial respiratory support to the critical patients in the intensive care units. Designed to provide temporary ventilator and respiratory assistance to adult and paediatric patients who cannot breathe on their own or who require assistance to maintain adequate ventilation.
2	**Operational Requirements**
2.1	Turbine based ventilator with integrated facility for ventilation monitoring suitable for paediatric to adult ventilation.
3	**System Configurations**
3.1	Invasive ICU Ventilator for Paediatrics to Adult, complete unit with all standard accessories.
4	**Technical Specifications**
4.1	Imported hinged arm holder for holding the circuit.
4.2	Alarms, related to gas delivered Adjustable, visual and audible for: • High/low FiO2; • High/low inspiratory pressure and PEEP; • High/low tidal volume (not achieved or exceeded); • Apnoea, adjustable from 10-30 sec; • High/low respiratory rate; • Continuously high pressure/occlusion; • Breathing circuit disconnect. Alarms, related to equipment operation Visual and audible for: • Gas supply failure; • Power failure; • Low battery
4.3	Colour TFT screen, 12" or more with facility to measure and display parameters: • Display easily readable in low ambient light and sunlight. • 3 scalar waveforms: pressure, volume and flow. • 3 loop (axis) displays: pressure-volume, flow-volume and pressure-flow, preferable. • Status indicators for ventilator mode, battery status, patient data, alarm settings. • FiO2. • Airway pressures (peak, plateau mean and PEEP). • Tidal volume (inspired and expired). • Minute volume (inspired and expired). • I:E ratio • RR (spontaneous and mechanical) • End-tidal CO2
4.4	Trending facility for 72 hours with minimum 5 minutes resolution for recent 24 hours.
4.5	Automatic compliance & leakage compensation for circuit and ET tube.
4.6	Must have following settings for all age groups (new-born to adult): • Tidal Volume up to 2000ml. • Pressure (insp.). • Pressure Ramp. • Flow Pattern. • Respiratory rate up to 80 breaths per minute. • SIMV Respiratory Rate up to 40 breaths per minute. • CPAP/PEEP: PEEP 50cmH2O. • Pressure Support. • FIO2. • Inspiratory Pause Time. • Pressure & Flow Trigger: Pressure Trigger 0-20 cmH2O below PEEP, Trigger Flow 0-100%. • Inspiratory rise time: 0-20% of breath cycle time. • I:E Ratio: 1:9 to 4:1
4.7	Monitoring of the following parameters: • FiO2: 21 to 100%;

S.N.	Purchaser's Specifications
	• Tidal Volume: 20 - 2,000 mL, ideally; • Inspiratory flow: 1 - 160 [L/min]; • Inspiratory pressure: 0 – 40 [cmH2O]; • I:E ratio; I:E inverse ratio; • RR: 10 to 60 [breaths/min], minimum; • Inspiratory pause manoeuvre capability to measure plateau pressure; • Peak pressure limitation/pressure-cycling mechanism adjustable range of 5 - 20 cmH2O above measured peak pressure. PEEP: 0 to 20 [cmH2O], minimum.
4.8	Modes of ventilation: • Pressure regulated volume control (PRVC), or similar. • Pressure control (PC) • Volume control (VC) • Synchronized intermittent mandatory ventilation (SIMV) • Pressure support ventilation (PSV) • Non-Invasive ventilation capability
4.9	Shall have apnoea /backup ventilation
4.10	Expiratory block must be autoclavable and no routine calibration is required.
4.11	Shall have the ability to calculate / procedure: • Intrinsic PEEP & Intrinsic PEEP Volume. • Occlusion Pressure. • Spontaneous breathing trial. • Facility to calculate lower and upper inflection point.
4.12	Autoclavable T-piece Nebulizer with capability to deliver particle size of < 3 micron & to be used in both Off and On line
4.13	Shall have automatic patient detection facility.
4.14	**Reusable Face Mask & Nasal Mask (Non-invasive) (Small and Medium size): 2 set each** • Reusable face & nasal mask with textured dual flap silicone cushion flap for easy fit. • Removable forehead support and pad to match the angle of patient's forehead. • Stability selector for easy fit and angle. • Ball & Socket headgear attachments. • Must be autoclavable.
4.17	Shall have battery backup for minimum 1 hour.
4.18	RS 232C interface or other suitable connectors for communications with networked devices.
5	**Accessories, spares and consumables**
5.1	Adult and Paediatric reusable, autoclavable silicon breathing circuits: 02 set each
5.2	Reusable Masks (Small, Medium, and Large): 02 set each.
5.3	Connecting hose with regulator/ flow meter or probe for connection to Pin index oxygen cylinder and BOC type oxygen wall outlet, 3-meter length: 01 set.
5.4	Humidifier: Servo controlled with digital monitoring of inspired gas temperature complete with heating wire: 01 no.
5.5	Filter paper for humidifier for 100 uses.
5.6	O2 cell with O-ring.
5.7	Silicone test lung adult and child size: 01 set each
5.8	Nipple connector 15-10 mm.
5.9	Flow sensors: 05 nos.
5.10	Inspiration bacterial filter, able to filter 99.97% of all 0.3 microns particles: 05 nos.
5.11	Expiration bacterial filter, able to filter 99.97% of all 0.3 microns particles: 05 nos.
5.12	Non corrosive imported trolley with wheels & brakes and hinged arm: 01 no.
5.13	T-piece autoclavable nebuliser set.
5.14	All standard accessories, consumables and parts required to operate the equipment, including all standard tools and cleaning and lubrication materials, to be included in the offer. Bidders must specify the quantity of every item included in their offer (including items not specified above).
6	**Operating Environment**
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220 – 240V AC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.

S.N.	Purchaser's Specifications
7	**Standards and Safety Requirements**
7.1	Must submit ISO13485:2003/AC:2007 for Medical Devices **AND**
7.2	European CE and USFDA approved product certificate. Certificate given by a third certified party for the specific medical devices proposed (no only declaration of conformity)
8	**User Training**
8.1	Must provide user training (including how to use and maintain the equipment) to all the staffs related with the particular setup until they are completely satisfied and confident for using the equipment.
9	**Warranty**
9.1	Comprehensive warranty for 3 years after acceptance. Availability of accessories, consumables and spare parts for at least 5 years.
10	**Maintenance Service During Warranty Period**
10.1	During the warranty period supplier must ensure preventive maintenance and corrective/breakdown maintenance whenever required.
11	**Installation and Commissioning**
11.1	The bidder must arrange for the equipment to be installed and commissioned by certified or qualified personnel; any prerequisites for installation to be communicated to the purchaser in advance, in detail. Further, for the first case from the equipment, trained personnel must attend the equipment prior to its use in real environment.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory.

19. Ventilator, Portable

S.N.	Purchaser's Specifications
1	**Description of Function**
1.1	The portable ventilator is used during transport of a patient with artificial respiration support or home care of a patient after discharge from a hospital.
2	**Operational Requirements**
2.1	The portable ventilator shall be light weight(< 10 kg) Shall be microprocessor controlled. Shall operate with mains electric supply as well as with battery. Shall be able to work both with cylinders and pipeline, connectors and high-pressure tubing of appropriate length to be supplied.
3	**System Configuration**
3.1	Portable ventilator for paediatric to adult and with battery backup.
4	**Technical Specifications**
4.1	Shall have turbine/venturi/jet mixing- technology for supplying air- oxygen mixture
4.2	Must have a built in Electronic Blender for Air and Oxygen.
4.3	Must be able to accept low pressure Oxygen source in addition to High Pressure Oxygen.
4.4	Facility to estimate the residual capacity of Oxygen Cylinder connected to the ventilator.
4.5	Must have at least 3 hours of built in battery back-up for the complete ventilator including compressed Air Source.
4.6	The ventilator shall be compatible with DC power cables for powering the ventilator from Ambulance Cigarette lighter power supply.
4.7	Shall have following settings a. TV 200– 900ml b. PEEP/CPAP 0-20cm H2O c. Pressure Support: 0-40cm H2O d. RR up to 40bpm e. I: E ratio 1:3 to 2:1 f. FiO2: 21 – 100% g. Respiratory rate: 0-60 breaths per minute
4.8	Shall have VCV, PCV with SIMV & PSV. Must be suitable for NPPV application.
4.9	It shall have ability to adjust variable flow and time termination criterion for PSV.
4.10	Shall have selectable Flow trigger or Pressure trigger or both.
4.11	Shall have provision for automatic leak compensation.
4.12	Shall have monitoring of PIP, Type of breath initiation, Exhaled VT, Total breath rate, I:E ratio, PEEP on display so that these can be read in outdoor conditions often associated with the field ambulances and during patient transfers.
4.13	Shall have measurement of static compliance & Auto-PEEP through inspiratory & expiratory hold respectively. Shall have apnoea back up ventilation also.
4.14	Audio-visual alarms for a. Low supply pressure b. High/low airway pressure c. Leakage/disconnection d. Power failure e. Apnea f. Low battery
4.15	The design of ventilator must be compact in order to store as well as transfer the ventilator in Ambulances (including air ambulances) and / or for inter or intra hospital transfer of patients.
4.16	Shall fix, on rails of transport trolley and on stand with wheels.
5	**Accessories, spares and consumables**
5.1	• Adult Reusable /Autoclavable Silicon Patient Circuit-02 • Paediatric Reusable/Autoclavable Silicone Patient Circuit-02 • Oxygen Hose-01 • Air Hose-01 • Rechargeable Batteries- 01 set • Disposable Patient Circuits (adult & paediatric) –50 nos. • HME Filters (adult & paediatric) – 100 nos.

S.N.	Purchaser's Specifications
	• Bacteria Filters (adult & paediatric)–100 nos.
5.2	All standard accessories/consumables/parts required for the proper operation of the above equipment shall be included in the offer.
6	**Operating Environment**
6.1	The system offered shall be designed to be stored and to operate normally under the conditions of the purchaser's country. The conditions include Power Supply, Climate, Temperature, Humidity, etc.
6.2	Power supply: 220 – 240 VAC, 50Hz fitted with appropriate plug. The power cable must be at least 3 metre in length.
7	**Standards and Safety Requirements**
7.1	The unit offered shall be certified to meeting the relevant quality and safety requirements of CE (93/42/EEC) or USFDA Certificates showing the compliance of this unit offered with any relevant quality and safety standards MUST be submitted with this TSF.
7.2	Must submit ISO 13485:2016 certificate or quality standards.
7.3	Equipment safety standard shall follow IEC 60601, document evidence shall be submitted for evaluation
8	**User Training**
8.1	On site operational training and technical training till the familiarity of the system and satisfaction of end user (clinical staff and technical staff) shall be provided.
9	**Warranty**
9.1	Comprehensive warranty for 2 years.
10	**Maintenance Service During Warranty Period**
10.1	**Preventive & Corrective Maintenance:** During the warranty period supplier must ensure planned preventive maintenance (PPM) at least 3 nos. in a year along with corrective/breakdown maintenance whenever required.
11	**Installation, Inspections and Commissioning**
11.1	Supplier must accomplish proper installation and commissioning of the equipment on site.
11.2	Inspections to verify the compliance of the offered equipment as per specifications will be conducted by the technical team appointed by the purchaser.
12	**Documentation**
12.1	User (Operating) manual in English.
12.2	Service (Technical / Maintenance) manual in English.
12.3	List of important spare parts and accessories with their part numbers and costing.
12.4	Certificate of calibration and inspection from factory