Annex D1

CONSUMABLES PRODUCT SPECIFICATIONS

Item Description: Liquid Haemodialysis Concentrate for Bicarbonate Dialysis

(a) Description of the Goods
- A clear colourless solution with the odour of acetic acid

(b) The composition details of the Goods are as follows:

- **NKFS 06**

Electrolytes in the Final dilution (Part A + Part B + RO water)	Expected value. (mmol/l)	Comply – Yes/No
Sodium (Na+)	140.0	
Potassium (K+)	2	
Calcium (Ca++)	1.25	
Magnesium (Mg++)	0.37	
Chloride (Cl^-)	110.3	
Acetate (CH_3COO^-)	4	
Bicarbonate (HCO_3^-)	31	
Glucose	1 g/l	

- **NKFS 07**

Electrolytes in the Final dilution (Part A + Part B + RO water)	Expected value (mmol/l)	Comply – Yes/No
Sodium (Na+)	140	
Potassium (K+)	2	
Calcium (Ca++)	1.5	
Magnesium (Mg++)	0.5	
Chloride (Cl^-)	111	
Acetate (CH_3COO^-)	3	
Bicarbonate (HCO_3^-)	32	
Glucose	0.9 g/l	

Authorised Signature: _____ Vendor's stamp: _____

- **NKFS 09**

Electrolytes in the Final dilution (Part A + Part B + RO water)	Expected value (mmol/l)	Comply – Yes/No
Sodium (Na+)	138	
Potassium (K+)	3	
Calcium (Ca++)	1.25	
Magnesium (Mg++)	0.5	
Chloride (Cl^-)	109.5	
Acetate (CH_3COO^-)	3	
Bicarbonate (HCO_3^-)	32	
Glucose	1 g/l	

- **NKFS 10**

Electrolytes in the Final dilution (Part A + Part B + RO water)	Expected value (mmol/l)	Comply – Yes/No
Sodium (Na+)	138	
Potassium (K+)	3	
Calcium (Ca++)	1.5	
Magnesium (Mg++)	0.5	
Chloride (Cl^-)	110	
Acetate (CH_3COO^-)	3	
Bicarbonate (HCO_3^-)	32	
Glucose	1 g/l	

Packaging requirement:

- Each 5 litre in volume capacity of liquid concentrate should be contained in air-tight, tamper-proof plastic container or bag with appropriate label and volume marking.
- The label must be clear with indication on the composition of the solution and enable easy identification on the different types of liquid haemodialysis concentrates.
- Sample of the approved label for the different formulations are to be provided at the point of tender submission.

Quality control:

- Supplier must ensure the quality of concentrates and meet the NKF individual biochemistry parameters limits before releasing for use in NKF dialysis centers. The Certificate of analysis need to be submitted.

Certification:

a) Is HSA registration required? Yes / No
b) Has the product been registered? Yes / No / Pending
c) If yes, the registration no. is_____
d) The HSA classification is Class A / B / C / D

Vendor shall provide the following documents to support the certification of the product:

e) Product licence with Health Science Authority
f) Manufacturing licence with Health Science Authority
g) Quality Certificate of Product
h) Any other relevant certification necessary for the product

Authorised Signature: _____ Vendor's stamp: _____

Annex D2

BLOOD TUBING SET

SPECIFICATIONS OF BLOOD TUBING SET WITH DRAINAGE BAG			
Description of function			
Blood tubing set is required as integral part of dialysis therapy along with the Dialyzer. Blood tubing set is used for drawing blood and returning to body through Dialyzer during dialysis therapy.			
General Specification			
S.N.	**Parameter**	**Specification**	**Comply Yes/No**
1	Universal Tubing set	Set should be appropriate for Fresenius, Gambro, and B Braun models in all series of haemodialysis machines.	
2	Tube material	Biocompatible / Medical Grade PVC Tube.	
3	Clamp	Provide clamps on all insert ports to secure blocking performance.	
4	Sterilization	ETO Gas / Steam	
5	Universal tubing set shall comprise	(1) An arterial bloodline set. (2) A venous bloodline set. (3) One unit of drainage bag. (Both lines and the drainage bag shall be packed in a sterile pouch.)	
Operating specification:			
6	Size of Blood Pump Segment	Inner Diameter: 8mm and Outer diameter: 12mm	
7	Size of Arterial and Venous Blood Line	Inner Diameter: 4.6mm and Outer diameter: 6.8mm	
8	Length of Arterial and Venous Blood Line	Arterial line: 3680mm Venous line: 2400mm	
9	Length of Arterial and Venous Chamber	Arterial Chamber: 125mm Venous Chamber :112mm	
10	Size of Inner diameter of Arterial and Venous Chamber	Arterial Chamber one end:15.7mm, other end: 16.6mm Venous Chamber: 18.80mm	
11	Size of Outer diameter of Arterial and Venous Chamber	Arterial Chamber: 18mm Venous Chamber: 20mm	
12	Pre pump Arterial pressure monitoring blood line	Pre pump arterial pressure monitoring line 500mm in length with clamp and transducer moulded to the monitoring line.	
13	"T" junction saline infusion line.	It should have a clamp and a recirculation tube attached at the end.	

Authorised Signature: _____ Vendor's stamp: _____

S.N.	Parameter	Specification	Comply Yes/No
14	Colour coded ports and connectors	1. All Ports and Connectors of Arterial line must be in RED colour. 2. All Ports and Connectors of Venous line must be in BLUE colour.	
15	Injection Port	1. All injection port should have minimum width of 26mm. 2. All injection port must be colour coded in RED for Arterial line and BLUE for Venous line.	
16	Luer Lock	1. Arterial line must have a recirculation tube attached to the needle end. 2. Venous line does not need the recirculation tube. The needle end of venous line should be connected to the drainage bag. 3. Both Arterial and Venous line must have luer lock connection to attach AVF needle and Dialyser. 4. All injection ports must have bungs attached.	
17	Drainage Bag *Optional	1. The bag should have capacity of 2000mls.	
18	Particulate Filter	1. Venous chamber must have particulate filter, with one insertion line, with clamp attached and venous pressure monitoring line 350mm with clamp and transducer moulded to the monitoring line. 2. Arterial bubble chamber with insertion line with clamp attached.	
19	<u>Certification</u> a) Is HSA registration required? Yes / No b) Has the product been registered? Yes / No / Pending c) If yes, the registration no. is_____ d) The HSA classification is Class A / B / C / D <u>Vendor shall provide the following documents to support the certification of the product</u>: e) Product license with Health Science Authority f) Manufacturing licence with Health Science Authority g) Quality Certificate of Product h) Any other relevant certification necessary for the product		

Authorised Signature: _____ Vendor's stamp: _____

Annex D3

ARTERIAL VENOUS FISTULA NEEDLES

SPECIFICATION OF ARTERIAL VENOUS FISTULA NEEDLES			
Description of function			
Fistula needle set is required as integral part of dialysis therapy along with dialyser and blood tubing set			
(extra-corporeal circuit). It is used for drawing and returning blood to the body through extra-corporeal			
circuit during dialysis therapy.			
General Specification			
S.N.	**Parameter**	**Specification**	**Comply Yes/No**
1	Gauge	14G, 15G, 16G. 17G	
2	Needle Length	1 inch (25mm) with Back-Eye	
3	Cannula	Extra thin wall with clear kink resistant tube fitted with female luer lock connection and pinch clamp to secure blocking performance.	
4	Tube Material	Biocompatible / Medical Grade PVC Tube	
5	Tube length	300 mm	
6	Tube volume	2.8 ml	
7	Wing	Fixed wing	
8	Wing Colour	15G (Ivory), 16G (Light green), 14G (Purple) , 17G (Orange)	
9	Sterilization	ETO Gas / Steam	
10	Certification a) Is HSA registration required? Yes / No b) Has the product been registered? Yes / No / Pending c) If yes, the registration no. is_____ d) The HSA classification is Class A / B / C / D <u>Vendor shall provide the following documents to support the certification of the product</u>: e) Product licence with Health Science Authority f) Manufacturing licence with Health Science Authority g) Quality Certificate of Product h) Any other relevant certification necessary for the product		

Authorised Signature: _____ Vendor's stamp: _____

High FLUX DIALYZER

Annex D4

General Specification for High Flux Dialyzer						
Description of function						
Dialyzer equipped with a semi permeable membrane and used for performing dialysis. During dialysis therapy Dialyzer acts as an artificial Kidney.						
S.N	**General Specification:**					**Comply to Specification (Yes / No)**
	Parameter	**Specification**			**Remarks**	
1	Membrane material	Synthetic Membrane – Poly sulfone (PS) / Polyether sulfone (PES) / Poly nephron / Polyamide blend / Ethylene vinyl alcohol (EVAL) / Polyacrylonitrile (PAN) / Polyester polymer alloy (PEPA) / Polymethylmethacrylate (PMMA)				
2	Treatment Mode	Haemodialysis treatment				
3	Clearance (ml/ min): with Qd 500 & Qb:	200	300	400	Typical Clinical Data	
	Urea	165 -199	202-287	222 - 354		
	Creatinine	140 - 198	215 -277	242 - 329		
	Phosphate	138 - 191	208 - 260	234 - 294		
	Vitamin B12	80 - 164	134 - 215	156 - 215		
4	Sterilization	Steam / Gamma				
	Dimensional Specification:					
5	Effective Surface Area (m^2) Range	0.7 to 2.4			Range for high flux dialyzers	
6	Effective Length (mm)	165-280			Typical Clinical Data	
7	UF-coefficient (ml/h. mmHg)	20 to 77				
8	Blood Priming Volume (ml)	40 - 165				
9	Maximum Pressure (mmHg)	500 - 600				
10	Sieving Coefficient	Inulin	0.94 - 1.04			
		β2 micro globulin	>0.63			
		albumin	<0.01			
11	Packaging Packaging must be able to open easily with lot number and expiry date printed clearly.					
12	Certification a) Is HSA registration required? Yes / No b) Has the product been registered? Yes / No / Pending c) If yes, the registration no. is_____ d) The HSA classification is Class A / B / C / D Vendor shall provide the following documents to support the certification of the product: e) Product licence with Health Science Authority f) Manufacturing licence with Health Science Authority g) Quality Certificate of Product h) Any other relevant certification or clinical papers necessary for the product					

Authorised Signature: _____ Vendor's stamp: _____

DRY CARTRIDGE BICARBONATE POWDER

Annex D5

Product: Dry Cartridge Bicarbonate Powder for on-line bicarbonate preparation for use in Haemodialysis	
1	Quality: a) BP / EP / USP Grade (British Pharmacopoeia / European Pharmacopoeia / US Pharmacopoeia Grade) b) Product shall comply with General Specification as in point 2. c) Capacity per unit: 760gm
2	General Product Specification:

Formula	$NaHCO_3$
Molecular Weight	84.01
Chemical Analysis	**Maximum Level**
Iron (as Fe)	5 ppm
Organic (as COD)	100 ppm
Carbonate (as CO_3)	0.23%
Arsenic (as As)	2 ppm
Sulphur Compounds	150 ppm
Chloride (as Cl)	150 ppm
Aluminium (as Al)	2 ppm
Copper (as Cu)	1 ppm
Calcium (as Ca)	100 ppm
Magnesium (as Mg)	40 ppm
Heavy Metals	5 ppm
Additional Analyses	
Assay	99.0% - 100.5%
Loss on drying	0.25% max
Insoluble substances	Meet BP/ EP/ USP requirements
Ammonia	Meet BP/ EP/ USP requirements
Organic volatile impurities	Meet BP/ EP/ USP requirements
Particle Size Distribution	Free flow and dissolve easily.
General Properties	
Particle density, g/cm^3	2.22
pH of 1% solution @ 25^0 C (77^0 F)	8.3
Appearance	White crystalline powder
Thermal decomposition	Decomposes (without melting) into Na_2CO_3, H_2O and CO_2

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Certification Requirement:

a) Is HSA registration required? Yes / No
b) Has the product been registered? Yes / No / Pending
c) If yes, the registration no. is _____
d) The HSA classification is Class A / B / C / D

Vendor shall provide the following documents to support the certification of the product:

e) Product licence with Health Science Authority
f) Manufacturing licence with Health Science Authority
g) Quality Certificate of Product
h) Certificate of Analysis / Conformity with parameters as in General Specification point 2.
i) Copy of Material Safety Data Sheet and
j) Any other relevant certification necessary for the product

Authorised Signature: _____ Vendor's stamp: _____