PRODUCT SPECIFICATIONS FOR CONSUMABLES

Liquid Acid Concentrate for Bicarbonate Dialysis

Description of the product: A clear colourless solution with the odour of acetic acid, used to prepare dialysate fluid for bicarbonate hemodialysis with a dialysate mixing ratio of 1+34.

The chemical composition details of various acid concentrate solution using in NKF 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++)	0.50	
Chloride (Cl^-)	110.5	
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	0.9/1 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-liter volume 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 hemodialysis concentrates.
- Sample of the approved label for the different formulations are to be provided at the point of tender submission.

Quality control:

- Suppliers must ensure the quality of concentrate 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
e) Country of manufacture: _____

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

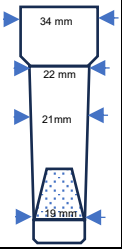
f) Product licence with Health Science Authority
g) Manufacturing licence with Health Science Authority
h) Quality Certificate of Product
i) Certificate of Analysis / Conformity with parameters as in General Specification point 2.
j) Material Safety Data Sheet
k) Any other relevant certification necessary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

Authorised Signature: _____ Vendor's stamp: _____

Annex B2

REQUIREMENT SPECIFICATIONS

SPECIFICATIONS OF BLOOD TUBING SET - HD			
Description of the Product: 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.			
1. General Specification			
SN.	**Parameter**	**Specification**	**Comply Yes/No/ Specify**
1.1	Universal HD Blood Tubing set	Blood tubing set should be appropriate for B Braun, Fresenius, Gambro and Nipro models in all series of haemodialysis machines.	
1.2	Tube material	Biocompatible / Medical Grade PVC Tube.	
1.3	Clamp	Provide clamps on all insert ports to secure blocking performance.	
1.4	Sterilization	Steam / Radiation (Gamma or E-beam) - Please Specify the method	
1.5	Priming Volume	Please specify the priming volume	
1.6	Universal Blood tubing set shall comprise	(1) An arterial bloodline set. (2) A venous bloodline set. (Both lines shall be packed in a sterile pouch.)	
2. Operating specification			
2.1	Fatigue Resistance	Max. Pressure – 500 to 600 mmHg (Please specify)	
		Max. Allowable Flow Rate – 400ml/min (Please specify)	
		Max. Continuous treatment time – 8 Hours (Please specify)	
2.2	Luer Lock	1. Colour code a. Arterial - RED b. Venous – BLUE 2. Arterial line must have a recirculation tube attached to the needle end. 3. Both Arterial and Venous line must have Luer lock connection to attach AVF needle and Dialyser.	
3. Arterial bloodline specification			
3.1	Arterial bloodline dimensions	Length of Arterial Line from Needling port to Blood Pump Segment: 1700mm to 1800 mm	
		Total Length of Arterial Line (From Needling port to Dialyzer): 3700mm to 3900mm	
		Inner Diameter: ~4.6mm	
3.2	Blood Pump Segment (Universal design)	Length of the Blood pump segment: 40mm	
		Diameter of Blood pump segment Inner: 8.0 mm Outer: 12.0 mm	

SN.	Parameter	Specification	Comply Yes/No/ Specify
3.3	Arterial Chamber Size	Length: ~125mm	
		Diameter near blood entry port (IN) Outer: ~20 mm	
		Diameter near blood exit port (OUT) Outer: ~20 mm	
3.4	Arterial Pressure Monitoring Line	Pre pump arterial pressure monitoring line with clamp and transducer protector (hydrophobic filter) moulded to the monitoring line.	
		Length: ~500mm Diameter (Outer): ~3.00mm	
3.5	Medication Ports (All port provides with clamp)	Medication port attached to Arterial Chamber with Leuer lock connector	
		Medication port (Needling) with bungs (safety guard), Colour code – RED	
		Medication/ T junction Saline infusion line to pre-pump with clamp and recirculation tube attached at the end.	
4. Venous bloodline specification			
4.1	Venous bloodline dimensions	Length of Venous Bloodline from Venous Chamber out to Venous Needling port: 1700mm to 1800mm	
		Toal Length of Venous Bloodline: 2500mm to 2900mm	
		Inner Diameter: ~4.6mm Outer diameter: ~ 5.0mm	
4.2	Venous Chamber Size (Cone type Design, soft material) 	Length: ~ 112 mm	
		Diameter near blood entry port (IN) Outer: 34.00mm	
		Diameter middle (outer): 21.00mm	
		Diameter near blood exit port (OUT) Outer: 19.00mm	
4.3	Medication Ports- Venous (All port provides with clamp)	Medication port attached to Venous Chamber with Leuer lock connector	
		Medication port (Needling) size: 26 mm width with bungs (safety guard), colour code – BLUE	
4.4	Particulate Filter	Venous chamber must have one particulate filter	
4.5	Venous pressure monitoring	Venous pressure monitoring line 350mm in length with clamp and transducer protector (hydrophobic filter) moulded to the monitoring line.	
		Length: ~350mm Diameter (Outer): ~3.00mm	

SN.	Parameter	Specification	Comply Yes/No/ Specify
5.	**Packaging Requirements**		
5.1	Packaging must have Information (Language used – English)	Model number & Brief user Instruction	
		Batch number or lot number	
		Manufacturing & Expiry Date	
		Sterilization method	
		Priming Volume	
		Size of Blood pump Segment	
		Country of manufacture	
6.	**Documentation**		
6.1	Certification	Vendor shall provide HSA Registration number and classification/ attach screenshot from Singapore Medical Device Information Communication system (MEDICS) for registration and exemption products	
		Product license & Manufacturing licence with Health Science Authority	
		Vendors to indicate and attach the quality standards and certificates	
		a) Biocompatibility certificates b) Pressure testing and fatigue resistance data c) DEHP (Di-2 Ethylhexyl phthalate) free declaration	
		Any other relevant certification necessary for the product	
6.2	Brochures/ Catalogues/MSDS	Vendor shall complete and provide all necessary information including product literature, brochures, catalogue or MSDS related to the products	
7.	**Samples Upon Request**		
7.1	Samples	Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. Samples are FOC and non-returnable.	

Authorised Signature: _____ Vendor's stamp: _____

Annex B3

REQUIREMENT SPECIFICATIONS

SPECIFICATIONS OF BLOOD TUBING SET - HDF			
Description of the Product: 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.			
8. General Specification			
SN.	**Parameter**	**Specification**	**Comply Yes/No/ Specify**
1.1	Machine Specific HDF Blood Tubing set	Blood tubing set should be appropriate and compatible for intended HDF machine Brand/model. 1. B Braun – HDF (Dialog IQ) 2. Fresenius – HDF (5008S) 3. Nipro – HDF (Surdial X HDF)	Choose an item.
1.2	Tube material	Biocompatible / Medical Grade PVC Tube.	
1.3	Clamp	Provide clamps on all insert ports to secure blocking performance.	
1.4	Sterilization	Steam / Radiation (Gamma only) - Please Specify the method	
1.5	Priming Volume	Please specify the priming volume	
1.6	Machine Specific HDF Blood Tubing set shall comprise	(1) An arterial bloodline set. (2) A venous bloodline set. (3) A Substitution Line (4) Drain port safe connector (5) Recirculation connector (All items shall be packed in a sterile pouch.)	
9. Operating specification			
2.1	Fatigue Resistance	Max. Pressure – 500 to 600 mmHg (Please specify)	
		Max. Allowable Flow Rate – 400ml/min (Please specify)	
		Max. Continuous treatment time – 8 Hours (Please specify)	
2.2	Luer Lock	**1.** Colour code c. Arterial - RED d. Venous – BLUE **2.** Both Arterial and Venous line must have Luer lock connection to attach AVF needle and Dialyser.	
3. Arterial bloodline specification			
3.1	Arterial Pressure Monitoring	Pre pump arterial pressure monitoring - line with clamp and transducer protector (hydrophobic filter) moulded to the monitoring / Safe Transducer measurement technology	
3.2	Medication Ports – Arterial (All port provides with clamp)	Medication port (Needling) with bungs (safety guard), Colour code – RED	
		Medication/ T junction Saline infusion line to pre-pump with clamp and recirculation tube attached at the end.	
		Substitution port – Pre dilution	

4. Venous bloodline specification			
4.1	Venous pressure monitoring	Venous pressure with clamp and transducer protector (hydrophobic filter) moulded to the monitoring line.	
4.2	Medication Ports- Venous (All port provides with clamp)	Medication port attached to Venous Chamber with Leuer lock connector	
		Medication port (Needling) with bungs (safety guard), colour code – BLUE	
		Substitution port – Post dilution	
4.3	Particulate Filter	Venous chamber must have one particulate filter	
5. Packaging Requirements			
5.1	Packaging must have Information (Language used – English)	Model number & Brief user Instruction	
		Batch number or lot number	
		Manufacturing & Expiry Date	
		Sterilization method	
		Priming Volume	
		Size of Blood pump Segment	
		Country of manufacture	
6. Documentation			
6.1	Certification	Vendor shall provide HSA Registration number and classification/ attach screenshot from Singapore Medical Device Information Communication system (MEDICS) for registration and exemption products	
		Product license & Manufacturing licence with Health Science Authority	
		Vendors to indicate and attach the quality standards and certificates	
		d) Biocompatibility certificates e) Pressure testing and fatigue resistance data f) DEHP (Di-2 Ethylhexyl phthalate) free declaration	
		Any other relevant certification necessary for the product	
6.2	Brochures/ Catalogues/MSDS	Vendor shall complete and provide all necessary information including product literature, brochures, catalogue or MSDS related to the products	
7. Samples			
7.1	Samples	Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. Samples are FOC and non-returnable.	

Authorised Signature: _____ Vendor's stamp: _____

Annex B4

ARTERIAL VENOUS FISTULA NEEDLES

SPECIFICATION OF ARTERIAL VENOUS FISTULA NEEDLES			
Description of the Product: 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/Specify**
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	Steam / Gamma	
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 e) Country of manufacture: _____ <u>Vendor shall provide the following documents to support the certification of the product</u>: f) Product licence with Health Science Authority g) Manufacturing licence with Health Science Authority h) Quality Certificate of Product i) Any other relevant certification necessary for the product		
11	Samples a) Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. b) Samples are FOC and non-returnable.		

Authorised Signature: _____ Vendor's stamp: _____

REQUIREMENT SPECIFICATION OF HIGH FLUX DIALYZER

Specification for High Flux Dialyzer						
Description of the Product: The dialyzers are equipped with a semi permeable membrane, and it is used for performing hemodialysis. During dialysis therapy Dialyzer acts as an artificial Kidney.						
1. General Specification						
SN.	**Parameter**		**Specification**		**Remarks**	**Comply (Yes / No/ Specify)**
1.1	Housing material		Polypropylene			
1.2	Potting Compound		Polyurethane			
1.2	Membrane material		Synthetic Membrane - Poly sulfone (PS) / Polyether sulfone (PES) / Poly nephron / Helixone			
1.3	Sterilization Method		Inline Steam / Radiation (Gamma only)			
1.4	Treatment Mode		Haemodialysis/ HDF treatment			
2. Operating specifications						
2.1	Effective Surface Area (m²) Range		1.3 - 2.5		Range for high flux dialyzers	
2.2	Effective Length (mm)		165 - 305			
2.3	Maximum Pressure (mmHg)		500 - 600			
2.4	Blood Priming Volume (ml)		40 - 165			
	Dialysate Flow Resistance		Minimal resistance at 500-800 mL/min			
2.5	UF-coefficient (ml/hr/ mmHg)		50 – 93			
3. Performance Data specifications						
	In vitro performance data with Qd 500 ml/min,T=37°C & Qb: (ISO8637)		**Qb: 200 ml/min**	**Qb: 300 ml/min**	**Qb: 400 ml/min**	Typical Clinical Data	
3.1	Clearance (ml/min)	Urea	165 -200	202-294	222 - 365		
		Creatinine	140 - 200	215 -285	242 - 342		
		Phosphate	138 - 196	208 – 288	234 - 322		
		Vitamin B12	80 - 178	134 – 224	156 - 247		
3.5	Sieving Coefficient		Inulin	0.90 - 1.10			
			β2 micro globulin	>0.63			
			albumin	<0.01			

SN.	Parameter	Specification	Comply (Yes / No/ Specify)
4.	**Packaging Requirements**		
4.1	Packaging must have Information (Language used – English)	Model number & Brief user Instruction	
		Batch number or lot number	
		Manufacturing & Expiry Date	
		Sterilization method	
		Priming Volume	
		Country of manufacture	
5.	**Documentation**		
5.1	Certification	Vendor shall provide HSA Registration number and classification/ attach screenshot from Singapore Medical Device Information Communication system (MEDICS) for registration and exemption products	
		Product license & Manufacturing licence with Health Science Authority	
		Vendors to indicate and attach the quality standards and certificates	
		a) Biocompatibility certificates b) Clinical Study & Research papers g) The invitro performance data	
		Any other relevant certification necessary for the product	
5.2	Brochures/ Catalogues/MSDS	Vendor shall complete and provide all necessary information including product literature, brochures, catalogue or MSDS related to the products	
6.	**Samples**		
6.1	Samples	Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. Samples are FOC and non-returnable.	

Authorised Signature: _____ Vendor's stamp: _____

Annex B6

DRY CARTRIDGE BICARBONATE POWDER

Description of the Product: Dry cartridge bicarbonate powder is used for the on-line preparation of bicarbonate solution in hemodialysis machines. This solution is subsequently used to formulate the dialysate fluid with a mixing ratio of 1+34.

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) Volume 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
3	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 e) Country of manufacture: _____ Vendor shall provide the following documents to support the certification of the product: f) Product licence with Health Science Authority g) Manufacturing licence with Health Science Authority h) Quality Certificate of Product i) Certificate of Analysis / Conformity with parameters as in General Specification point 2. j) Material Safety Data Sheet k) Any other relevant certification necessary for the product	
4	Samples a) Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. b) Samples are FOC and non-returnable.	

Authorised Signature: _____ Vendor's stamp: _____

Annex B7

ENDOTOXIN FILTER – PROPRIETARY CONSUMABLE

SPECIFICATION OF ENDOTOXIN FILTERS			
Description of the Product: Endotoxin filter is an essential component in HD and HDF machines, ensuring that both the dialysate and substitution fluid remain free from harmful bacterial endotoxins. The endotoxin filters are proprietary to specific brands of HD/HDF machines.			
General Specification			
S.N.	**Parameter**	**Specification**	**Comply Yes/No**
1	Packaging	Each box of the packaging must have clear indication of the batch number or lot number, manufacturing date & expiry date. Product information (PI) insert is required.	
2	Membrane Material	Poly Sulphone (PS) / Polyether Sulphone (PES)	
3	Housing Material	Polycarbonate (PC) / Polypropylene (PP)	
4	Potting Material	Polyurethane (PU)	
5	Sealing / O ring Material	Silicone	
6	Sterilization Method	Inline Steam / Radiation / Gamma	
7	Purity of Dialysate Fluid	< 0.03 EU/ml and < 0.1 CFU/ml	
8	Certification a) Is HSA registration required? Yes / No b) Has the product been registered with HSA? Yes / No / Pending c) If yes, the registration no. is_____ d) The HSA classification is Class A / B / C / D e) Country of manufacture: _____ <u>Vendor shall provide the following documents to support the certification of the product</u>: f) Product licence with Health Science Authority g) Manufacturing licence with Health Science Authority h) Quality Certificate of Product i) Material Safety Data Sheet j) Product information; Catalogue or Brochure k) Any other relevant certification necessary for the product		
9	<u>Samples</u> a) Upon request, vendor shall submit samples for each item of the items in the full range of products set out in the requirement in respect of which vendor is quoting. b) Samples are FOC and non-returnable.		

Authorised Signature: _____ Vendor's stamp: _____