

ANNEXURE – 2.2 (Pages 1-6) [Biological Tests]

S no	Group of products, materials or items tested	Specific tests or types of tests performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	MU (±)
1.	<u>Enzymes & Hormones</u> 1. Streptokinase bulk 2. Streptokinase inj.	Clot Lysis	Clot formation and lysis within 30 min with human plasma and no lysis with bovine plasma. Ref: IP2007	4000 IU/ml – 10000 IU/ml	Not applicable
2.	<u>Blood Products</u> 1. Human Albumin – 5%, 20%, 25%	Stability	The content of the final container remain unchanged, as determined by visual inspection, after heating at 57°C for 50 hrs when compared to its control consisting of a sample from the same lot which has not undergone this heating. Ref: IP2007	----	Not applicable
3.	<u>Blood Products</u> 1. Human Albumin – 5%, 20%, 25%	Immunodiffusion Double, Ouchterlony	Precipitation tests with suitable range of species –specific antisera which give positive results for the presence of proteins of human origin and negative results with antisera specific to plasma proteins of other test. Immunodiffusion Double, Ouchterlony Ref: IP2007	0.3%-0.078% protein	Not applicable
4.	<u>Enzymes & Hormones</u> 1. Streptokinase bulk 2. Streptokinase inj. 3. Heparin inj.	Sterility	Direct inoculation method, Membrane and Closed Methods Ref: IP2007	----	Not applicable
	<u>Recombinant Product</u> 1. rh-Insulin inj. 2. rh-Insulin Glargine inj.	-DO-	Closed Methods Ref: USP	----	
5.	<u>Enzymes & Hormones</u> 1. Streptokinase bulk 2. Streptokinase inj.	Abnormal Toxicity	Animal test on mice should comply with the monograph. Ref: IP2007	----	Not applicable
6.	<u>Blood Products</u> Human Albumin – 5%, 20%, 25%	Pyrogen Test	Animal Tests on Rabbits Ref: IP2007	----	

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7.	<u>Enzymes & Hormones</u> 1. Streptokinase bulk 2. Streptokinase inj. 3. Heparin inj.	Bacterial Endotoxin – Lal Test – Gel clot	Gel Clot Method Should not more than 23.33EU/ml of Streptokinase 10000IU/ml and should not be more than 0.03EU/ml for Heparin Ref: IP2007	0.5 EU/ml to 0.125 EU/ml	Not applicable
	<u>Recombinant Product</u> 1. rh-Insulin inj. 2. rh-Insulin Glargine inj.	-DO-	Less than 80 IU / 100 IU Ref: EP / BP/ USP	0.03 EU/ml – 0.06 EU/ml Lysate sensitivity as per maximum valid dilution.	Not applicable
8.	<u>Blood Products</u> Albumin-5%, 20%, 25%	HAEM	Not more than 0.15 at 403 nm In-house control/ Human albumin-Sigma Ref: IP2007	0.0017 – 2.3 OD at 403 nm (1.75 mg to 0.85 µg of haem)	In process
9.	<u>Immuno diagnostic kits</u> 1. Diagnostic kits for HIV 1 & 2 Antibody & Antigen	Rapid test	1. Immuno-chromatography Method 2. Immuno-filtration method 3. Immuno-dot assay Ref. : WHO Reports 1. HIV Assays: Operational characteristic ; Report 11 (1999) and Report 14 (2004). 2. HBsAg Assays: Operational characteristics; Report 2 (2004). 3. HCV Assays: Operational characteristics; January 2001. Drugs Controller General of India's Letter No.26-1/Misc/2003-DC, dated12.06.03, Directorate General of Health Services (Drug Control Section)	Sensitivity HIV ≥ 99.5% HCV ≥ 99% HBsAg ≥ 99% Specificity HIV ≥ 98% HCV ≥ 98% HBsAg ≥ 98%	In process
	2. Diagnostic Kits for HCV Antibody				
	3. Diagnostic Kits for HBs Antigen				
10.	-DO-	ELISA	1. Enzyme Immuno-assay Ref. : as above	-DO-	In process
11.	-DO-	Confirmatory assays	1. Immuno – Blot --- HIV & HCV 2. Neutralization assay --- HBsAg Ref. : as above	-DO-	In process
12.	Diagnostic Kits for Syphilis	Rapid test	1. RPR test	----	In process

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13.	Blood grouping reagents	Potency (Titre)	Tube Method		1:2 to 1:4096 or above	In process
			Cells	Titre		
	1. Anti-A	-DO-	A ₁	1:256		
			A ₂	1:128		
			A ₂ B	1:64		
	2. Anti-B	-DO-	B	1:256		
			A ₁ B	1:128		
	3. Anti-A,B	-DO-	A ₁	1:256		
			B	1:256		
			A ₂	1:128		
	4. Anti-D(IgM)	-DO-		IS 37 ⁰ C		
			R ₁ r or R ₁ R ₂	1:64 - 1:128 1:128 - 1:256		
	5. Anti-D(IgM+IgG)	-DO-	R ₁ r or R ₁ R ₂	1:32 - 1:64 1:128 - 1:256		
6. Anti-D(IgG)	-DO-	R ₁ r or R ₀ r	≥ in-house / Working standard			
7. Anti-A ₁ (Lectin)	-DO-	A ₁ (2)	1:8 (1+)			
		A ₁ B (2)	1:4 (+)			
8. Anti-H(Lectin)	-DO-	O (2)	1:8 (1+)			
		A ₂ (2)	1:4 (+)			
		A ₁ (2)	1:1 – 1:2 (1+)			
14.	1. Anti-A	Potency (Avidity)	Slide Method		-----	In process
			Cells	Avidity (Seconds)		
	1. Anti-A	-DO-	A ₁	3 - 4		
			A ₂	5 - 6		
			A ₂ B	5 - 6		
	2. Anti-B	-DO-	B	3 - 4		
			A ₁ B	5 - 6		
	3. Anti-A,B	-DO-	A ₁	3 - 4		
			B	3 - 4		
			A ₂	5 - 6		
	4. Anti-D(IgM)	-DO-	R ₁ r or R ₁ R ₂	5 - 10		
	5. Anti-D(IgM+IgG)	-DO-	R ₁ r or R ₁ R ₂	10 - 20		

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15	1. Anti-A	Potency (Intensity)	Slide Method		Not Applicable	Not Applicable
			Cells	Intensity		
			A ₁	3+		
			A ₂	2+ to 3+		
	2. Anti-B	-DO-	B	4+		
			A ₁ B	2+ to 3+		
	3. Anti-A,B	-DO-	A ₁	4+		
			B	4+		
			A ₂	3+		
	4. Anti-D(IgM)	-DO-	R ₁ r or R ₁ R ₂	3+		
	5. Anti-D(IgM+IgG)	-DO-	R ₁ r or R ₁ R ₂	3+		
	6. Anti-A ₁ (Lectin)	-DO-	A ₁ (2)	2+ to 3+		
	7. Anti-H(Lectin)	-DO-	O (2)	3+ to 4+		
			A ₂ (2)	2+		
A ₁ (2)			< 2+			

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16.	1. Anti-A	Specificity	Tube Method		Not Applicable	Not Applicable
			Cells	Specificity		
			A ₁	Positive		
			A ₂	Positive		
			A ₂ B	Positive		
			B	Negative		
	O	Negative				
	2. Anti-B	-DO-	B	Positive		
			A ₁ B	Positive		
			A ₁	Negative		
			O	Negative		
	3. Anti-A,B	-DO-	A ₁	Positive		
			B	Positive		
			A ₂	Positive		
			A _x	Positive		
			O	Negative		
	4. Anti-D(IgM)	-DO-	R ₁ r or R ₁ R ₂	Positive		
			IAT - Negative	Negative		
	5. Anti-D(IgM+IgG)	-DO-	R ₁ r or R ₁ R ₂	Positive		
			IAT - Negative	Negative		
	6. Anti-D(IgG)	-DO-	R ₁ r or R ₀ r (Sensitized)	Positive		
			R ₁ r or R ₀ r (Unsensitized)	Negative		
	7. Anti-A ₁ (Lectin)	-DO-	A ₁ (2)	Positive		
			A ₁ B (2)	Positive		
			A ₂ (2)	Negative		
			A ₂ B(2)	Negative		
			B(2)	Negative		
			O(2)	Negative		
8. Anti-H (Lectin)	-DO-	O (2)	Positive			
		A ₂ (2)	Positive			
		A ₁ (2)	Weak Positive			
		Oh (2)	Negative			

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17.	1. Anti-A	Reactivity Rouleaux/ Haemolysis/Prozone	Microscopic and Tube Method		Not Applicable	Not Applicable
			Cells	Reactivity (Rouleaux/Haemolysis/Prozone)		
			A ₁	Absent		
			A ₂	Absent		
			A ₂ B	Absent		
			B	Absent		
	2. Anti-B	-DO-	O	Absent		
			B	Absent		
			A ₁ B	Absent		
			A ₁	Absent		
	3. Anti-A,B	-DO-	O	Absent		
			A ₁	Absent		
			B	Absent		
			A ₂	Absent		
			A _x	Absent		
	4. Anti-D(IgM)	-DO-	O	Absent		
			R _{1r} or R ₁ R ₂	Absent		
	5. Anti-D(IgM+IgG)	-DO-	IAT - Negative	Absent		
			R _{1r} or R ₁ R ₂	Absent		
	6. Anti-D(IgG)	-DO-	IAT - Negative	Absent		
			R _{1r} or R _{0r} (Sensitized)	Absent		
	7. Anti-A ₁ (Lectin)	-DO-	R _{1r} or R _{0r} (Unsensitized)	Absent		
			A ₁ (2)	Absent		
			A ₁ B (2)	Absent		
			A ₂ (2)	Absent		
			A ₂ B(2)	Absent		
			B(2)	Absent		
	8. Anti-H (Lectin)	-DO-	O(2)	Absent		
A ₂ (2)			Absent			
A ₁ (2)			Absent			
Oh (2)			Absent			