Laboratory	**National Institute of Biologicals, Ministry of Health & Family Welfare, Government of India, A-32, Sector 62, Noida, Uttar Pradesh**
Accreditation Standard	**ISO/IEC 17025: 2005**
Certificate Number	**TC-7725** **Page 1 of 92**
Validity	**16.08.2018 to 15.08.2020** **Last Amended on --**

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection

BIOLOGICAL TESTING

I.	**BIOLOGICALS DERIVED PHARMACEUTICALS**			
A.	**Recombinant Proteins**			
1.	**rh-Erythropoietin**	Identification (In vivo Bioassay)	NIB/RPL/SOP/32/R0;dt. 07.06.17 Reference: IP 2014 Pg No. 3355-3359	Qualitative
2.	**Filgrastim**	Identification (Bioassay)	NIB/RPL/SOP/60/R3;dt. 05.03.18 Reference: IP 2014 Pg No. 3363-3365	Qualitative
3.	**Interferon Beta-1a**	Identification (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18 Reference: IP 2014 Pg No. 3373-3378	Qualitative
4.	**Interferon Alpha-2b**	Identification (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18 Reference: IP 2014 Pg No. 3371-3373	Qualitative
5.	**Peg-Filgrastim**	Identification (Bioassay)	NIB/RPL/SOP/92/R1;dt. 25.01.17 Reference:Manufacturer Protocol	Qualitative
6.	**Peg-Interferon Alpha 2b**	Identification (CPER Assay)	NIB/RPL/SOP/73/R1;dt. 05.04.17 Reference:Manufacturer Protocol	Qualitative
7.	**Peg Interferon Beta-1a**	Identification (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18 Reference: Reference:Manufacturer Protocol	Qualitative
8.	**rh-Erythropoietin**	Assay/Potency (In vitro Bioassay)	NIB/RPL/SOP/55/R3;dt. 21.10.16 Reference: IP 2014 Pg No. 3352-3359	80-125% of stated potency

Bhumi Rajyaguru
Convenor

Alok Jain
Program Manager

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
9.	**rh-Erythropoietin**	Assay/Potency (In vivo Bioassay)	NIB/RPL/SOP/32/R0;dt. 07.06.17 Reference: IP 2014 Pg No. 3352-3359	80-125% of stated potency
10.	**Filgrastim**	Assay/Potency (Proliferation Bioassay)	NIB/RPL/SOP/60/R3;dt:05. 03.18 Reference: IP 2014 Pg No. 3363-3365	NLT 80 and NMT 125% of the stated potency
11.	**Interferon Beta-1a**	Assay/Potency (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18 Reference: IP 2014 Pg No. 3373-3378	80-130% of stated potency
12.	**Interferon Alpha-2b**	Assay/Potency (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18 Reference: IP 2014 Pg No. 3371-3373	80-125% of stated potency
13.	**Peg-Filgrastim**	Assay/Potency (Bioassay)	NIB/RPL/SOP/92/R1;dt. 25.01.17 Reference: Manufacturer Protocol	80-125% of stated potency
14.	**Peg-Interferon Alpha 2b**	Assay/Potency (CPER Assay)	NIB/RPL/SOP/73/R1;dt. 05.04.17 Reference: Manufacturer Protocol	50-150% of stated potency
15.	**Teriparatide (rh-PTH)**	Assay/Potency (Bioassay)	NIB/RPL/SOP/104/R0;dt. 08.06.17 Reference: Manufacturer Protocol	60-160% Of Estimated potency
16.	**Peg Interferon Beta-1a**	Assay/Potency (CPER Assay)	NIB/RPL/SOP/78/R1;dt. 24.05.18, Reference:Manufacturer Protocol	12-40 IU/ml
17.	**Soluble Insulin, Isophane Insulin 1. Biphasic Isophane Insulin (25/75) 2. Biphasic Isophane Insulin (30/70) 3. Biphasic Isophane Insulin**	Bacterial Endotoxin (Gel Clot Method)	NIB/RPL/SOP/05/R3;dt. 26.04.18 Reference: IP 2014 (Appendix 2.2.3) 1963-1964, 1967-1968, 1977-1979, 3355-3359, 3363-3365, 3371-3373, 3373-3378, 3354	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	(50/50) 4. rh-Insulin Bulk 5. Insulin Glargine 6. Insulin Glulisine 7. Insulin Aspart 8. Insulin Aspart & Insulin Aspart Protamine Suspension (30/70) 9. Insulin Aspart & Insulin Aspart Protamine Suspension (50/50) 10. Exenatide 11. rh-Erythropoietin 12. Filgrastim 13. Interferon Beta-1a 14. Interferon Alpha-2b 15. Peg-Filgrastim 16. Peg-Interferon Alpha-2b 17. Peg Interferon Beta-1a			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
18.	**1. Soluble Insulin** **2. Isophane Insulin** **3. Biphasic Isophane Insulin (25/75)** **4. Biphasic Isophane Insulin (30/70)** **5. Biphasic Isophane Insulin (50/50)** **6. Insulin Glargine** **7. Insulin Glulisine** **8. Insulin Lispro** **9. Insulin Lispro & Insulin Lispro Protamine Suspension (25/75)** **10. Insulin Lispro & Insulin Lispro Protamine Suspension (50/50)** **11. Insulin Aspart** **12. Insulin Aspart & Insulin Aspart Protamine Suspension**	Sterility (Membrane Filtration)	NIB/STR/SOP/001/R4;dt. 26.02.18 NIB/RPL/SOP/07/R2;dt. 06.03.18 Reference: IP 2014 (Appendix 2.2.11)	Qualitative (Complies/not complies)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	(30/70) 13.Insulin Aspart & Insulin Aspart Protamine Suspension (50/50)Insulin Glargine 14. Insulin Detemir 15. Insulin Degludec 16. Insulin Degludec/ Insulin Aspart 17. Exenatide 18 Exenatide Once Weekly 18. Liraglutide 19. rh-Erythropoietin 20. Filgrastim 21. Interferon Beta-1a 22.Interferon Alpha-2b 23. Peg-Filgrastim 24. Peg-Interferon Alpha 2b 25.Teriparatide (rh-PTH) 26. Peg Interferon Beta-1a			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
B.	**Vaccines (Bacterial Vaccine)**			
1.	**Haemophilus influenzae type b TT conjugate vaccine Bacillus Calmette Guerin (BCG) vaccine**	Sterility (Membrane filtration)	NIB/STR/SOP/001/R4;dt. 26.02.18 NIB/BVL/SOP/06/R1;dt 09.10.17 NIB/BVL/SOP/18/R4;dt.31. 07.17 Reference:IP 2014 Pg No:59-66,	Qualitative
2.	**Bacillus Calmette Guerin (BCG) vaccine**	Test for Excessive dermal reactivity	NIB/BVL/SOP/17/R4;dt. 31.07.17 Reference IP 2014;Pg No. 3059	Qualitative
		Test for Virulent mycobacteria	NIB/BVL/SOP/16/R4;dt. 31.07.17 Reference IP 2014;Pg No. 3059	Qualitative
4.	**Haemophilus influenzae type b TT conjugate vaccine**	Test for Pyrogen (in-vivo)	NIB/AF/SOP/002/R4;dt 19.07.17 NIB/BVL/SOP/06/R1;dt 09.10.17 Reference:IP 2014;Pg No. 36-37	Qualitative Complies/Not complies
		Test for Abnormal toxicity	NIB/AF/SOP/001/R3;dt 05.10.17 NIB/BVL/SOP/06/R1;dt 09.10.17 References:IP 2014;Pg No. 27	Qualitative Complies/Not complies
5.	**Bacillus Calmette Guerin (BCG) vaccine**	Test for Assay/Colony Forming Units (CFU)	NIB/BVL/SOP/15/R4;dt. 31.07.17 Reference IP 2014;Pg No.34-35 & 3059	1-33 x 10^6 cfu/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Test for Temperature Stability	NIB/BVL/SOP/19/R4;dt. 31.07.17 Reference IP 2014;Pg No. 3059	NLT 20% of unheated vaccine
6.	**1. Cell Culture Rabies Vaccine 2. Live attenuated Measles Vaccine 3. Live attenuated Rubella Vaccine 4. Live attenuated MMR Vaccine 5. Live Attenuated Measles & Rubella Vaccine 6. Inactivated Polio vaccine 7. Rotavirus Vaccine Rotarix 8. Hepatitis A Inactivated Vaccine 9. Hepatitis B 10. (r-DNA) Vaccine**	Sterility (Membrane filtration)	NIB/STR/SOP/001/R4;dt. 26.02.18 Reference:IP 2014 Pg No:52-59	Qualitative (Complies/does not complies)
7.	**1. Cell Culture Rabies Vaccine 2. Inactivated**	Bacterial Endotoxin Test (Method A-Gel Clot method)	NIB/EHL/SOP/28/R3;dt.06. 07.17 Reference:IP 2014, Pg. no. 28	Qualitative (Complies/does not complies)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Polio vaccine 3. Hepatitis A Inactivated Vaccine			
8.	**Cell Culture Rabies Vaccine**	Virus inactivation test	NIB/VVL/SOP/008/R3dt 16.05.17 Reference:IP 2014,Pg. no 3135	Qualitative (Complies/does not complies)
		NIH Potency	NIB/VVL/SOP/007/R3dt. 01.5.18 Reference:IP 2014, Pg. no 3136 NIB/VVL/SOP/054/R0 dt. 07.07.17 Reference:BP 2017, Pg. no IV-662	Quantitative (NLT 2.5 IU/SHD) (Dilution 1:5 to 1:3125)
9.	**Live attenuated MMR Vaccine**	Identification & Potency-in vitro cell culture method using VERO & RK13 as indicator Cell Line	NIB/VVL/SOP/063/R0;dt.3 1.01.18 Reference:IP 2014, Pg no.3106	Mumps-NLT $5x10^3CCID_{50}$/single human dose;Measles-NLT $1x10^3CCID_{50}$/single human dose; Rubella-NLT $1x10^3CCID_{50}$/single human dose ($Log10^{1}$-$10^{5.5}$)
10.	**Live attenuated Measles Vaccine**	Identification &Potency-in vitro cell culture method using VERO as indicator cell line	NIB/VVL/SOP/062/R0;dt 31.01.18 Reference:IP 2014, Pg no. 3105	NLT $1x10^3CCID_{50}$ ($Log10^{1}$-$10^{5.5}$)
11.	**Live attenuated Rubella Vaccine**	Identification &Potency-in vitro cell culture method using RK 13 as indicator Cell line	NIB/VVL/SOP/061/R0;dt 31.01.18 Reference:IP 2014, Pg no. 3141	NLT $1x10^3CCID_{50}$ ($Log10^{1}$-$10^{5.5}$)
12.	**Live attenuated MMR Vaccine**	Thermal Stability using VERO & RK 13 as indicator Cell line	NIB/VVL/SOP/063/R0;dt. 31.01.18 Reference:IP 2014, Pg no.3106	NMT 1.0 log_{10} lower than that of unheated vaccine ($Log10^{1}$-$10^{5.5}$)
13.	**Live attenuated**	Thermal Stability using	NIB/VVL/SOP/062/R0;d	NMT 1.0 log_{10} lower

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Measles Vaccine	VERO as indicator Cell line	t31.01.18 Reference:IP 2014, Pg no. 3105	than that of unheated vaccine ($Log10^{1}$-$10^{5.5}$)
14.	**Live attenuated Rubella Vaccine**	Thermal Stability using RK-13 as indicator Cell line	NIB/VVL/SOP/061/R0;dt. 31.01.18 Reference:IP 2014, Pg no. 3141	Not 1.0log_{10} lower than that of unheated vaccine ($Log10^{1}$-$10^{5.5}$)
15.	**Live attenuated Measles & Rubella Vaccine**	Identification, Potency & Thermal stability-in vitro cell culture method using VERO & RK-13 as indicator cell line	NIB/VVL/SOP/050/R0;dt. 10.01.17 Reference:IP 2014, Pg no. 3103-3105	Potency-Measles-NLT $1x10^{3}CCID_{50}$/single human dose;Rubella-NLT $1x10^{3}CCID_{50}$/single human dose Stability-NMT 1.0 log_{10} lower than that of unheated vaccine ($Log10^{1}$-$10^{5.5}$)
16.	**Inactivated Polio vaccine**	Identification, potency invitro	NIB/VVL/SOP/053/R0 dt:02.08.17 Reference:IP 2014 Pg. no. 3126-3127	D-antigen content should be NLT Type I 40DU/0.5mL Type II 8DU/0.5mL Type III 32DU/0.5mL Type I:5.66-0.044219 Type II:1-0.0078125 Type III:3.49-0.027266
17.	**Inactivated Polio vaccine**	Potency assayinvivo	NIB/VVL/SOP/057/R0 dt:02.08.17 Reference:IP 2014 Pg. no. 3126-3127	Efficacy from PLA Lower limit ≥0.25 for each type
18.	**Rotavirus Vaccine Rotarix**	Identification, potency & Thermal stability using immunofluorescence method, using MA 104 as indicator cell line	NIB/VVL/SOP/048/R0 dt:06.01.17 Reference:EP 8.0 Pg. no. 899-900	Potency: NLT 6.0 log_{10} $CCID_{50}$ Stability:Not 0.5 log_{10} lower than that of unheated vaccine ($Log10^{1}$-$10^{6.4}$)
19.	**Hepatitis A Inactivated Vaccine**	Identification and assay by ELISA	NIB/VVL/SOP/58/R0; dt:07.09.2017 Reference:BP-2017	NLT 500 IU/ml (250-15.625IU/ml)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Hepatitis B (r-DNA) Vaccine		NIB/VVL/SOP/59/R0; dt:07.09.17 NIB/VVL/SOP/060/R0 dt:05.01.18 Reference:IP-2014, BP-2017	NLT 20 µg/ml (80-125 %)
20.	**1. Live attenuated Measles Vaccine 2. Live attenuated Measles Mumps Rubella Vaccine 3. Cell culture Rabies Vaccine 4. Live attenuated Rubella Vaccine 5. Live attenuated Measles & Rubella Vaccine**	Abnormal toxicity (Mice and Guinea pig)	NIB/AF/SOP/001/R3;dt. 05.10.17 References:IP 2014, Pg No:27.	Qualitative (Complies/not complies)
21.	**1. Cell Culture Rabies Vaccine 6. Hepatitis B (r-DNA) Vaccine**	Pyrogen Test (Rabbit Injection)	NIB/AF/SOP/002/R4;dt. 19.07.17 Reference:IP 2014, Pg No:36 NIB/AF/SOP/002/R4;dt. 19.07.17 Reference:BP 2017, Pg No:662 EP 8.0 Pg No:183	Qualitative
22.	**1. Cell Culture Rabies Vaccine 2. Live Attenuated Measles Vaccine**	Bovine Serum Albumin content by ELISA	NIB/VVL/SOP/043/R0 dt. 22.11.16 Reference:IP 2014 Pg. No. 3136	NMT 50ng/single human dose (0.5ng/ml-32ng/ml)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	3. Live Attenuated Rubella Vaccine **4. Live Attenuated MMR Vaccine** **5. Live attenuated Measles & Rubella Vaccine** **6. Inactivated Polio vaccine**			
C.	**Enzymes**			
1.	**1. Streptokinase Bulk/Inj** **2. Recombinant Streptokinase Inj.** **3. Urokinase Bulk/Inj**	Identification (Clot Lysis Method A)	NIB/EHL/SOP/04/R3;dt 20.02.18 NIB/EHL/SOP/18/R3;dt. 20.02.18 References:IP 2014, Pg No:2793, 2795, 3380 NIB/EHL/SOP/30/R2;dt. 20.02.18 References:IP 2014, Pg No:2941	Qualitative
2.	**1. Streptokinase Bulk/Inj.**	Streptolysin activity (UV Vis spectrophotometry)	NIB/EHL/SOP/08/R3;dt 20.02.18 NIB/EHL/SOP/22/R3;dt 20.02.18 References:IP-2014 Pg No:2794,2796	The Absorbance of the supernatant liquid at about 550 nm is NMT 1.5 times the absorbance obtained by repeating the procedure using 0.5ml of the mixture of saline solution and citro-phosphate buffer pH 7.2 in place of the solution containing the substance under examination.

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
3.	**1. Streptokinase Bulk/Inj.** **2. Recombinant Streptokinase Inj.** **3. Urokinase Bulk/inj.**	Bacterial Endotoxin (Gel Clot method)	NIB/EHL/SOP/11/R3;dt. 20.02.18 Ref:IP 2014 Pg No:2795, 2796, 2942	Qualitative
4.	**1. Streptokinase Inj.** **2. Recombinant Streptokinase Inj.** **3. Urokinase inj.**	Sterility (Direct inoculation method)	NIB/STR/SOP/001/R4;dt. 26.02.18 References: IP-2014:Pg No. 2795, 3380, IP 2014:Pg No:2942	Qualitative
5.	**1Streptokinase Bulk/Inj.** **2. Recombinant Streptokinase Inj.** **3. Urokinase Bulk/Inj.**	Abnormal toxicity (Mice)	NIB/AF/SOP/001/R3;dt. 05.10.17 References:IP 2014, Pg No:2795, 3380, 2941	Qualitative Complies/Not complies
6.	**Urokinase inj./Bulk**	HIV 1&2 antibody (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17 References:IP 2014, Pg No:3380, 2941	Non-Reactive
		HCV antibody (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17 References:IP 2014, Pg No:3380, 2941	Non-Reactive
		HBs Ag Marker (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17 References:IP 2014, Pg No:3380, 2941	Non-Reactive

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
D.	**Hormones**			
1.	**1. Human Chorionic Gonadotropin Inj. 2. Menotropin (Human Menopausal Gonadotropin) Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Inj. 4. Recombinant Human Follicle Stimulating Hormone Inj. 5. Somatropin Inj. (Recombinant Human Growth Hormone)**	Sterility (Direct inoculation/Membrane Filtration)	NIB/STR/SOP/001/R4;dt. 26.2.18 References: IP-2014:Pg No. 1387 USP 37:Pg No. 3800 BP 2016:Pg No. 3377 EP 8.0:Pg No. 2958	Qualitative
2.	**1.Human Chorionic Gonadotropin Bulk/Inj.**	Abnormal toxicity (mice)	NIB/AF/SOP/001/R3;dt. 05.10.17 References:IP 2014, Pg No:1387	Qualitative Complies/Not complies
3.	**1. Human Chorionic Gonadotropin Bulk/Inj. 2. Menotropin (Human Menopausal Gonadotropin)**	Bacterial Endotoxin test by Gel clot method	NIB/EHL/SOP/39/R3;dt. 20.02.18 Ref:IP 2014, Page 1387,1388 Ref:IP Addendum 2016.Pg.no. 4216, Ref:EP 8.0, Page No. 3510 IP Addendum 2016. Pg.no.	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Bulk/Inj. **3. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj.** **4. Recombinant Human Follicle Stimulating Hormone Inj.** **5. Somatropin Inj. (Recombinant Human Growth Hormone)**		4321	
4.	**1.Human Chorionic Gonadotropin Bulk/Inj.**	Identification (Weight gain method)	NIB/EHL/SOP/40/R3;dt. 26.10.17	Qualitative
		Assay (Weight gain method)	Ref:IP 2014 Pg No:1386, 1387, 1388	80-125% of the stated potency
5.	**1. Menotropin (Human Menopausal Gonadotropin) Bulk/Inj.**	Identification (Weight gain method)	NIB/EHL/SOP/44/R3;dt. 10.05.18	Qualitative
		Assay (FSH activity) (Weight gain method)	NIB/EHL/SOP/45/R2;dt. 20.02.18	80-125%of the stated potency
		Assay (LH activity) (Weight gain method)	IP Addendum 2016, Pg no. 4216-4217	80-125%of the stated potency
6.	**1. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj.** **2. Recombinant Human Follicle Stimulating Hormone Inj.**	Identification (Weight gain method)	NIB/EHL/SOP/46/R2;dt. 20.02.18, Ref:BP 2014 Pg. No 2250 EP 8.0, 2289 & 3510	Qualitative
		Assay (Weight gain method)		80-125%of the stated potency
7.	**1. Human Chorionic**	HIV 1&2 antibody (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Gonadotropin Bulk/Inj. 2. Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj.		References:IP 2014, Pg No:3380, 2941 IP Addendum 2016. Pg.no. 4214,4216	
8.	**1. Human Chorionic Gonadotropin Bulk/Inj. 2. Menotropin (Human Menopausal Gonadotropin) Bulk/Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj.**	HIV 1&2 antibody (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17 References:IP 2014, Pg No:3380, 2941 IP Addendum 2016. Pg.no. 4214,4216	Qualitative
9.	**1. Human Chorionic Gonadotropin Bulk/Inj. 2. Menotropin (Human Menopausal Gonadotropin) Bulk/Inj.**	HBs Ag Marker (ELISA)	NIB/IDKL/SOP/33/R0;dt. 07.04.17 References:IP 2014, Pg No:3380, 2941 IP Addendum 2016. Pg.no. 4214,4216	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	3. Urofollitropin (Human follicle stimulating Hormone) Bulk/Inj.			
E.	**Miscellaneous**			
1.	**Heparin Sodium injection**	Identification by Clot delaying method	NIB/EHL/SOP/47/R1;dt. 16.1.17 Ref:IP 2014, Page 1888.	Qualitative
		Bacterial Endotoxin by Gel clot method	NIB/EHL/SOP/11/R3;dt. 20.02.18 Ref:IP 2014 Pg No:1888	Qualitative
		Sterility (Direct Inoculation)	NIB/STR/SOP/001/R4;dt. 26.02.18 References:IP-2014:Pg No. 1888	Qualitative
2.	**1. Human albumin** **2. Human Plasma Protein Fraction** **3. Human Normal Immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin IV**	Sterility (Membrane filtration/Direct Inoculation)	NIB/STR/SOP/01/R3;dt. 26.02. 2016 NIB/STR/SOP/02/R3;dt.26. 02.2016 Reference:IP 2014;2.2.11;Pg No:59-66;(3294, 3298, 3303, 3306, 3309, 3310, 3312, 3322)	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	6. Anti-D Immunoglobulin IM 7. Human Tetanus immunoglobulin IM 8. Human coagulation Factor VIII plasma derived 9. Human coagulation Factor VIII recombinant 10. Human Coagulation Factor IX 11. Anti-Inhibitor Coagulant complex 12. Fibrin sealant Kit 13. Anti-Thrombin III Concentrate 14. Human Fibrinogen 15. Hepatitis Immunoglobulin IV 16. Hepatitis Immunoglobulin IM			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	17. Rabies Immunoglobulin IM **18. Human Prothrombin Complex**			
3.	**1. Human Albumin** **2. Plasma Protein Fraction** **3. Dried Human Anti hemophilic fraction (factor VIII)** **4. Anti-D Immunoglobulin IM** **5. Tetanus immunoglobulin IM** **6. Human normal immunoglobulin IM** **7. Hepatitis B Immunoglobulin IM** **8. Rabies Immunoglobulin IM**	Abnormal toxicity (Mice and guinea pig)	NIB/AF/SOP/001/R3;dt. 05.10.2017 References: IP 2014;2.2.1;, Pg No:27 (3298, 3306, 3312, 3322).	Qualitative Complies/Not complies
4.	**1. Human Albumin** **2. Plasma Protein**	Pyrogen Test (Rabbit Injection)	NIB/AF/SOP/002/R4;dt. 19.07.2017 Reference:IP 2014;2.2.8;Pg No:36-	Qualitative Complies/Not complies

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Fraction **3. Human Normal Immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti D Immunoglobulin IM** **6. Anti D Immunoglobulin IV** **7. Tetanus Immunoglobulin** **8. Dried Human Anti-hemophilic fraction (factor VIII)** **9. Human Coagulation Factor IX** **10. Anti-Thrombin III Concentrate** **11. Human Fibrinogen** **12. Hepatitis B Immunoglobulin**		37;(3294, 3298, 3305, 3310, 3312, 3322)	

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	IM **13. Hepatitis B Immunoglobulin IV** **14. Rabies Immunoglobulin IM**			
5.	**1. Human Normal Immunoglobulin IV** **2. Dried Human Anti-hemophilic fraction (factor VIII)**	Anti-A, Anti-B Haemagglutinin test (Haemagglutination method)	NIB/BRL/SOP/29/R1;dt. 18.01.2017 Reference:IP 2014, Pg No. 3298, 3313	1:1 to 1:256
6.	**1. Human Coagulation Factor VIII Recombinant**	Bacterial Endotoxin Test (BET)	NIB/EHL/SOP/28/R3;dt. 06.07.2017 Reference:IP 2014, Pg No. 3309	Qualitative
7.	**1. Anti D Immunoglobulin IM**	Potency (Agglutination method)	NIB/BPL/SOP/60/R1;dt.28. 03.2017 Reference:IP 2014, Pg No. 318, 319, 3290, 3291	1.14ug/ml (1:256)
F.	**Monoclonal Antibodies (Therapeutics)**			
1.	**Rituximab**	Identification (CDC Assay)	NIB/TMA/SOP/10/R1;dt. 16.8.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.0098ug/ml-2.5ug/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			MethodVerification Doc.ID: NIB/TMA/MV001/Rituximab-CDC	
2.	**Adalimumab**	Identification (L929 Cytotoxicity inhibition bioassay)	NIB/TMA/SOP/35/R1;dt. 18.08.17 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.19ng/ml-100ng/ml
3.	**Trastuzumab**	Identification (Anti-Id Ab ELISA)	NIB/TMA/SOP/37/R0;dt. 22.11.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.1µg/ml-10µg/ml
4.	**Bevacizumab**	Identification (Binding Activity of VEGF by ELISA)	NIB/TMA/SOP/45/R0;dt. 24.02.17 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	1.56ng/ml-200ng/ml
5.	**Rituximab**	Assay/Potency (CDC Assay)	NIB/TMA/SOP/10/R1;dt. 16.8.16 References: Manufacturer'sdrugproduct releasespecifications	0.0098ug/ml-2.5ug/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			(Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	
6.	**Adalimumab**	Assay/Potency (L929 Cytotoxicity inhibition bioassay)	NIB/TMA/SOP/35/R1;dt. 18.08.17 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.19ng/ml-100ng/ml
7.	**Trastuzumab**	Assay/Potency (Inhibition of cell Proliferation assay)	NIB/TMA/SOP/40/R0;dt. 19.12.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.002µg/ml-0.25µg/ml
		Assay/Potency (HER2 Binding assay by flow cytometry)	NIB/TMA/SOP/39/R0;dt. 19.12.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	0.04µg/ml-20µg/ml
8.	**Bevacizumab**	Assay/Potency (Bioassay)	NIB/TMA/SOP/47/R0;dt. 21.04.17 References:	40ng/ml-1000ng/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysis protocol	
9.	**1. Rituximab 2. Adalimumab 3. Trastuzumab 4. Bevacizumab**	Bacterial Endotoxin (Gel Clot Method)	NIB/EHL/SOP/28/R3;dt. 06.07.2017 Reference: IP 2014, Page 28-31 Appendix:2.2.3	Positive/Negative
10.	**1. Rituximab 2. Adalimumab 3. Trastuzumab 4. Bevacizumab**	Sterility (Membrane Filtration/Direct Inoculation)	NIB/STR/SOP/001/R4; dt. 26.2.18 Reference: IP 2014, 2.2.11	Pass/Fail
G.	**Test Kits/Rapid tests:Immunodiagnostic Kits**			
1.	**HIV 1 &/2 Antibody**	Rapid test	NIB/IDKL/SOP/12/R6, Effective date:21.05.18 NIB/IDKL/SOP/24/R6, Effective date:21.05.18 References As per CDSCO letter No.29/Misc./4/2016-DC(65),Dt:12.07.2017	Positive/Negative
2.	**Hepatitis B**	Rapid test	NIB/IDKL/SOP/17/R6, Effective date:17.05.18	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			NIB/IDKL/SOP/24/R6, Effective date:21.05.18 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	
3.	**Hepatitis C Antibody**	Rapid test	NIB/IDKL/SOP/15/R6, Effective date:21.05.18 NIB/IDKL/SOP/24/R5, Effective date:19/5/2014 References As per CDSCO letter No.29/Misc./4/2016-DC(65),Dt:12.07.2017	Positive/Negative
4.	**Syphilis**	Rapid test	NIB/IDKL/SOP/27/R1, Effective date:15.05.18 References As per CDSCO letter No.29/Misc./4/2013-DC(52), Dt:14.02.2014	Positive/Negative
5.	**Hepatitis C**	CLIA	NIB/IDKL/SOP/35/R0 dt:17.05.17 NIB/IDKL/SOP/34/R0 dt:19.05.17 References As per CDSCO letter No.29/Misc./4/2016-DC(65),Dt:12.07.2017	Positive/Negative
6.	**HIV 1 &/2 Antibody**	CLIA	NIB/IDKL/SOP/36/R0 dt:19.05.17 NIB/IDKL/SOP/34/R0 dt:19.05.17	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	
7.	**Syphilis**	CLIA	NIB/IDKL/SOP/37/R0 dt:17.05.17 NIB/IDKL/SOP/34/R0 dt:19.05.17 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
8.	**Hepatitis B**	CLIA	NIB/IDKL/SOP/38/R0 dt:17.05.17 NIB/IDKL/SOP/34/R0 dt:19.05.17 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
9.	**Hepatitis C**	ELFA	NIB/IDKL/SOP/40/R0 dt:05.08.16 NIB/IDKL/SOP/39/R0 dt:05.08.16 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
10.	**Hepatitis B**	ELFA	NIB/IDKL/SOP/42/R0 dt:08.08.16 NIB/IDKL/SOP/39/R0 dt:05.08.16 References As per CDSCO letter No.29/Misc./4/2016-	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			DC(65), Dt:12.07.2017	
11.	**HIV 1 &/2 Antibody**	ELFA	NIB/IDKL/SOP/41/R0 dtr:05.08.16 NIB/IDKL/SOP/39/R0 dt:05.08.16 References As per CDSCO letter No.29/Misc./4/2016-DC(65),Dt:12.07.2017	Positive/Negative
H.	**ELISA:Immunodiagnostic Kits**			
1.	**HIV 1 &/2 Antibody**	ELISA	NIB/IDKL/SOP/13/R6, Effective date:14.05.18 NIB/IDKL/SOP/22/R6, Effective date:21.05.18 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
2.	**HIV 1 &/2 Antibody Western Blot**	Confirmatory assays	NIB/IDKL/SOP/14/R6, Effective date:14.05.18 NIB/IDKL/SOP/23/R5, Effective date:26/5/2014 References As per manufacturer specifications	Positive/Negative
3.	**Hepatitis B**	ELISA	NIB/IDKL/SOP/18/R6, Effective date:17.05.18 NIB/IDKL/SOP/22/R6, Effective date:21.05.18 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
4.	**Hepatitis B Neutralization**	Confirmatory assays	NIB/IDKL/SOP/25/R6, Effective date:21.05.18	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			References As per manufacturer specifications	
5.	**Hepatitis C Antibody**	ELISA	NIB/IDKL/SOP/16/R6, Effective date:17.05.18 NIB/IDKL/SOP/22/R6, Effective date:21.05.18 References As per CDSCO letter No.29/Misc./4/2016-DC(65), Dt:12.07.2017	Positive/Negative
6.	**Hepatitis C Antibody**	Confirmatory assays	NIB/IDKL/SOP/23/R6, Effective date:21.05.18 References As per manufacturer specifications	Positive/Negative
7.	**Syphilis**	ELISA	NIB/IDKL/SOP/32/R0, Effective date:15.03.17 References As per CDSCO letter No.29/Misc./4/2013-DC(52), Dt:14.02.2014	Positive/Negative
7.	**Anti-HBc Total**	ELISA	NIB/IDKL/SOP/28/R1, Effective date:22.09.17 References As per manufacturer specifications	Positive/Negative
8.	**Anti-HBc IgM**	ELISA	NIB/IDKL/SOP/29/R1, Effective date:22.09.17 References As per manufacturer specifications	Positive/Negative
9.	**HBe Ag/HBe Ag-Ab/Anti-HBe**	ELISA	NIB/IDKL/SOP/30/R1, Effective date:22.09.17	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			References As per manufacturer specifications	
10.	**Anti-HBs**	ELISA	NIB/IDKL/SOP/31/R1, Effective date:22.09.17 References As per manufacturer specifications	Positive/Negative
I.	**Qualitative PCR:Molecular Diagnostic Kit**			
1.	**Blood donor screening multiplex (HBV, HCV & HIV) molecular diagnostic test (Qualitative)**	Sensitivity Specificity	NIB/MDL/SOP/15/R1;dt. 30.08.2016 References:Manufacturer's Specifications	Positive/Negative
2.	**Infection Diagnostic test for HIV-1 (Qualitative)**	Sensitivity Specificity	NIB/MDL/SOP/12/R1;dt. 07.09.2016 References:Manufacturer's Specifications	Positive/Negative
3.	**Infection Diagnostic test for HCV (Qualitative)**	Sensitivity Sensitivity	NIB/MDL/SOP/14/R1;dt. 07.09.2016 References:Manufacturer's Specifications	Positive/Negative
I.	**Immunological Products:Blood Grouping Reagents**			
1.	**Anti-A (Monoclonal)**	Potency (Titer) (Haemagglutination method)	NIB/BRL/SOP/18/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	1:64 to 1:4096
2.	**Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	1:128 to 1:4096
3.	**Anti-A,B**		NIB/BRL/SOP/20/R2;dt.	1:128 to 1:4096

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	(Monoclonal)		22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	
4.	**Anti-D(IgM) (Monoclonal)**		NIB/BRL/SOP/22/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	1:64 to 1:256
5.	**Anti-D(IgM+IgG) (Monoclonal)**		NIB/BRL/SOP/23/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	1:32 to 1:512
6.	**Anti-D(IgG) (Monoclonal)**		NIB/BRL/SOP/21/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	1:32 to 1:256
7.	**Anti-A_1 (Lectin)**		NIB/BRL/SOP/24/R2;dt. 22.09.17 References:Based on NIB data and recommendations	1:8 to 1:128

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			of experts	
8.	**Anti-H (Lectin)**	Potency (Titer) (Haemagglutination method)	NIB/BRL/SOP/25/R2;dt. 22.09.17 References:Based on NIB data and recommendations of experts	1:8 to 1:128
9.	**Anti-Fy^a reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:8 to 1:512
10.	**Anti-Jk^a reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:8 to 1:512
11.	**Anti-K reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:8 to 1:512
12.	**Anti-k reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:8 to 1:512
13.	**Anti-Le^a reagent**	Potency (Titer) (Haemagglutination method)	NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia	Neat to 1:512

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	
14.	**Anti-Le^b reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Neat to 1:512
15.	**Anti-Pi reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:4 to 1:512
16.	**Anti-M reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:4 to 1:512
17.	**Anti-N reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Neat to 1:512
18.	**Anti-S reagent**	Potency (Titer) (Haemagglutination method)	NIB/BRL/SOP/066/00;-. 22.09.17Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	1:4 to 1:512
19.	**Anti-A (Monoclonal)**	Avidity (Haemagglutination	NIB/BRL/SOP/18/R2;dt. 22.09.17	1-6 sec

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		method)	References:Indian Pharmacopoeia 2014	
20.	**Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	1-6 sec
21.	**Anti-A,B (Monoclonal)**		NIB/BRL/SOP/20/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	1-6 sec
22.	**Anti-D(IgM) (Monoclonal)**		NIB/BRL/SOP/22/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	5-10 sec
23.	**Anti-D(IgM+IgG) (Monoclonal)**		NIB/BRL/SOP/23/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	10-20 Sec
24.	**Anti-A (Monoclonal)**	Intensity (Haemagglutination	NIB/BRL/SOP/18/R2;dt. 22.09.17	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		method)	References:Indian Pharmacopoeia 2014	
25.	**Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	Positive/Negative
26.	**Anti-A,B (Monoclonal)**		NIB/BRL/SOP/20/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
27.	**Anti-D(IgM) (Monoclonal)**		NIB/BRL/SOP/22/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
28.	**Anti-D(IgM+IgG) (Monoclonal)**		NIB/BRL/SOP/23/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
29.	**Anti-A_1(Lectin)**		NIB/BRL/SOP/24/R2;dt. 22.09.17	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			References:Based on NIB data and recommendations of experts	
30.	**Anti-H(Lectin)**		NIB/BRL/SOP/25/R2;dt. 22.09.17 Reference:Based on NIB data and recommendations of experts	Positive/Negative
31.	**Anti-A (Monoclonal)**	Specificity (Haemagglutination method	NIB/BRL/SOP/18/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	Positive/Negative
32.	**Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;dt. 22.09.17 References:Indian Pharmacopoeia 201	Positive/Negative
33.	**Anti-A,B (Monoclonal)**		NIB/BRL/SOP/20/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
34.	**Anti-D(IgM) (Monoclonal)**	Specificity (Haemagglutination method	NIB/BRL/SOP/22/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
35.	**Anti-D(IgM+IgG) (Monoclonal)**		NIB/BRL/SOP/23/R2;dt. 22.09.17	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	
36.	**Anti-D(IgG) (Monoclonal)**		NIB/BRL/SOP/21/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Positive/Negative
37.	**Anti-A_1 (Lectin)**	Specificity (Haemagglutination method	NIB/BRL/SOP/24/R2; dt. 22.09.17 References:Based on NIB data and recommendations of experts	Positive/Negative
38.	**Anti-H (Lectin)**		NIB/BRL/SOP/25/R2;dt.22. 09.17 References:Based on NIB data and recommendations of experts	Positive/Negative
39.	**Gel card for Forward grouping**		NIB/BRL/SOP/055/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual 2003 and as per manufacturer's specifications	Positive/Negative
40.	**Anti-Fy^a reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			(21 CFR-660.25	
41.	**Anti-Jk^{a} reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
42.	**Anti-K reagent**	Specificity (Haemagglutination method)	NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
43.	**Anti-k reagent**	Specificity (Haemagglutination method)	NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
44.	**Anti-Le^{a} reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
45.	**Anti-Le^{b} reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and	Positive/Negative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Centre for Biologics Evaluation and Research (21 CFR-660.25)	
46.	**Anti-Pi reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
47.	**Anti-M reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
48.	**Anti-N reagent**	Specificity (Haemagglutination method)	NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
49.	**Anti-S reagent**		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Positive/Negative
50.	**Anti-A (Monoclonal)**	Reactivity Rouleaux/Haemolysis/Prozone* (Haemagglutination method)	NIB/BRL/SOP/18/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	Present/Absent

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
51.	**Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014	Present/Absent
52.	**Anti-AB (Monoclonal)**		NIB/BRL/SOP/20/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Present/Absent
53.	**Anti-D(IgM) (Monoclonal)**		NIB/BRL/SOP/22/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Present/Absent
54.	**Anti-D(IgM + IgG) (Monoclonal)**	Reactivity Rouleaux/Haemolysis/Pro zone* (Haemagglutination method)	NIB/BRL/SOP/23/R2;dt. 22.09.17 References:Transfusion Medicine Technical Manual-2003, Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Present/Absent
55.	**Anti-D (IgG)* (Monoclonal)**		NIB/BRL/SOP/21/R2;dt. 22.09.17 References:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Present/Absent
56.	**Anti-A_1 (Lectin)**		NIB/BRL/SOP/24/R2;dt.22.	Present/Absent

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			09.17 References:Based on NIB data and recommendations of experts	
57.	**Anti-H (Lectin)**		NIB/BRL/SOP/25/R2;dt.22. 09.17 References:Based on NIB data and recommendations of experts	Present/Absent
58.	**Anti-Fy^{a} reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
59.	**Anti-Jk^{a} reagent***	Reactivity Rouleaux/Haemolysis/Pro zone* (Haemagglutination method)	NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
60.	**Anti-K reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
61.	**Anti-k reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and	Present/Absent

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Centre for Biologics Evaluation and Research (21 CFR-660.25)	
62.	**Anti-Le^a reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
63.	**Anti-Le^b reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
64.	**Anti-Pi reagent***	Reactivity Rouleaux/Haemolysis/Prozone* (Haemagglutination method)	NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
65.	**Anti-M reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
66.	**Anti-N reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and	Present/Absent

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Centre for Biologics Evaluation and Research (21 CFR-660.25)	
67.	**Anti-S reagent***		NIB/BRL/SOP/066/00;-. Dt 22.09.17 References:Indian Pharmacopoeia 2014 and Centre for Biologics Evaluation and Research (21 CFR-660.25)	Present/Absent
J.	**Other Specified Tests:Biochemical Kits**			
1.	**Automated analyzer based Glucose Reagent Kit**	Linearity and Range evaluation of Glucose estimation based on Colorimetry	NIB/BKL/SOP/08/R2;dt. 06.07.17 Reference:CLSI EP6-A, Vol 23 No.16 Evaluation of Linearity of Quantitative Measurement Procedures:A Statistical Approach Guideline	40-400 mg/dl
2.	**Automated analyzer based Glucose Reagent Kit**	TEa (Allowable Total Error limits) evaluation of Glucose estimation based on Colorimetry	NIB/BKL/SOP/09/R2;dt. 06.07.17 NIB/BKL/SOP/10/R2;dt. 06.07.17 Reference:CLSI EP5-A2, Vol24 No.25 Evaluation of Precision performance of Quantitative Measurement Methods;Approved Guideline CLSI EP9-A2, Vol22 No.19 Method Comparison and Bias Estimation Using Patient Samples;Approved Guideline	+/-10 % deviation from the 'Reference Method' values

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			CLSI EP21-A, Vol23 No.20 Estimation of Total Analytical Error for Clinical Laboratory Methods;Approved Guideline [Limits prescribed by Clinical Laboratory Improvement Amendments (CLIA) and American Association of Bioanalysts (AAB)]	
3.	**Blood Glucose Test Strips for Glucometers**	Intermediate Precision evaluation of blood glucose results from glucometers	NIB/BKL/SOP/14/R2;dt. 06.07.17 Reference:ISO15197 In-vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	≤ 7.1
4.	**Blood Glucose Test Strips for Glucometers**	Repeatability Precision evaluation of blood glucose results from glucometers	NIB/BKL/SOP/15/R2;dt. 06.07.17 Reference:ISO15197 In-vitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	≤ 7.1
5.	**Blood Glucose Test Strips for**	Accuracy/Bias evaluation of blood glucose results	NIB/BKL/SOP/13/R2;dt. 20.02.18	95% of glucometer results fall within +/-

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Glucometers	from glucometers by Method comparison	Reference:ISO15197 Invitro diagnostic test systems-Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus CLSI EP9-A2, Vol22 No.19 Method Comparison and Bias Estimation Using Patient Samples;Approved Guideline WHO:Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002	15mg/dL of those from 'Reference Method' at glucose levels <75mg/dL and within+/-20 % at glucose levels >75mg/dL Maximum deviation is within +/-15%

CHEMICAL TESTING

I.	**DRUGS AND PHARMACEUTICALS**			
A.	**Parenteral Preparations:Recombinant Products**			
1.	**1. Soluble Insulin 2. Isophane Insulin 3. Biphasic Isophane Insulin (25/75) 4. Biphasic Isophane Insulin (30/70) 5. Biphasic**	Identification (RP-HPLC)	NIB/RPL/SOP/54/R2 28.10.16 References: IP 2014	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Isophane Insulin (50/50) **6. rh-Insulin Bulk**			
2.	**Insulin Glargine**	Identification (RP-HPLC)	NIB/RPL/SOP/40/ R5;24.05.18 Reference: IP Addendum 2016	Qualitative
		Identification (RP-HPLC)	NIB/RPL/SOP/102/R0;28.03.17 Reference: Manufacturer's specifications	Qualitative
3.	**1. Insulin Lispro** **2. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **3. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Identification (RP-HPLC)	NIB/RPL/SOP/49/ R2;-30.09.16 NIB/RPL/SOP/54/ R2;28.10.16 References:IP 2014	Qualitative
4.	**1. Insulin Aspart** **2. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** **3. Insulin Aspart& Insulin Aspart Protamine**	Identification (RP-HPLC)	NIB/RPL/SOP/51/ R2;-30.09.16 NIB/RPL/SOP/54/ R2;-28.10.16 References:IP 2014	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Suspension (50/50)			
5.	**Insulin Detemir**	Identification (RP-HPLC)	NIB/RPL/SOP/50/ R2;, 30.9.16 Reference: Manufacturer's specifications	Qualitative
6.	**Insulin Degludec**	Identification (RP-HPLC)	NIB/RPL/SOP/80/ R0;25.01.18 Reference: Manufacturer's specifications	Qualitative
7.	**Insulin Degludec/Insulin Aspart**	Identification Degludec (RP-HPLC)	NIB/RPL/SOP/80/ R0;25.01.18 Reference: Manufacturer's specifications	Qualitative
		Identification Aspart (RP-HPLC)	NIB/RPL/SOP/97/ R0;28.03.17 Reference: Manufacturer's specifications	Qualitative
8.	**Exenatide**	Identification (SEC-HPLC)	NIB/RPL/SOP/67/ R2;30.9.16, Reference: Manufacturer's specifications	Qualitative
9.	**Exenatide Once Weekly**	Identification (Strong Cation Exchange-HPLC)	NIB/RPL/SOP/100/ R0;-28.03.17, Reference: Manufacturer's specifications	Qualitative
10.	**Liraglutide**	Identification (RP-HPLC)	NIB/RPL/SOP/84/ R0;-. 24.01.18, Reference:Manufacturer'sspecifications	Qualitative
11.	**rh-Erythropoietin**	Identification	NIB/RPL/SOP/47/	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		(SDS-PAGE followed by Immunoblotting)	R3;-. 05.03.18, References:IP 2014	
12.	**Filgrastim**	Identification (SDS-PAGE)	NIB/RPL/SOP/47/ R3;-. 05.03.18, References:IP 2014 (Appendix 2.4.12),	Qualitative
		Identification (SEC-HPLC)	NIB/RPL/SOP/70/ R3;-. 06.03.18, References: IP 2014 (Appendix 2.4.12),	Qualitative
13.	**Interferon Beta-1a**	Identification (SDS-PAGE)	NIB/RPL/SOP/79/R1;-. 22.05.18;Manufacturer's specifications	Qualitative
		Identification (RP-HPLC)	NIB/RPL/SOP/74/R0;-. 21.10.16;Manufacturer's specifications	Qualitative
14.	**Interferon Alpha-2b**	Identification (SDS-PAGE)	NIB/RPL/SOP/79/R1;-. 22.05.18;References:IP 2014	Qualitative
		Identification (RP-HPLC)	NIB/RPL/SOP/89/R0;-. 30.06.16;References:IP 2014	Qualitative
15.	**Peg-Filgrastim**	Identification (SDS-PAGE, Non Reducing)	NIB/RPL/SOP/96/R0;-. 27.03.17;Manufacturer's specifications	Qualitative
		Identification (RP-HPLC)	NIB/RPL/SOP/95/R0;-. 27.03.17;Manufacturer's specifications	Qualitative
		Identification (SEC-HPLC)	NIB/RPL/SOP/94/R0;-. 28.03.17;Manufacturer's specifications	Qualitative
16.	**Peg-Interferon Alpha-2b**	Identification (SDS-PAGE)	NIB/RPL/SOP/96/R0;-. 27.03.17;Manufacturer's specifications	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
17.	**Teriparatide (rh-PTH)**	Identification (SDS-PAGE)	NIB/RPL/SOP/47/R3;-. 05.03.18;Manufacturer's specifications	Qualitative
		Identification (RP-HPLC)	NIB/RPL/SOP/90/R0;-. 30.06.16;Manufacturer's specifications	Qualitative
18.	**Peg-Interferon beta-1a**	Identification (Peptide mapping)	NIB/RPL/SOP/28/R1 dt.. 24.05.18;Manufacturer's specifications	Qualitative
19.	**1. Soluble Insulin** **2. Isophane Insulin** **3. Biphasic Isophane Insulin (25/75)** **4. Biphasic Isophane Insulin (30/70)** **5. Biphasic Isophane Insulin (50/50)** **6. rh-Insulin Bulk**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/54/R2 28.10.16 NIB/RPL/SOP/13/R5 dt:30.09.16 References:IP-2014	90-110%
20.	**Isophane Insulin**	Insulin in the supernatant (RP-HPLC)	NIB/RPL/SOP/13/R5 dt:30.09.16 Reference IP 2014	NMT 2.5% of total insulin content
21.	**1. Biphasic Isophane Insulin (25/75)** **2. Biphasic Isophane Insulin (30/70)** **3. Biphasic**	Soluble human insulin content (RP-HPLC)	NIB/RPL/SOP/72/R1;-. 30.09.16 References:IP 2014	a) 25/75 (20-30%) b) 30/70 (25-35%) c) 50/50 (45-55%)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Isophane Insulin (50/50)			
22.	**Insulin Glargine**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/40/ R5;-. 24.05.18 Reference: IP Addendum 2016	95-105%
		Assay/Potency (RP-HPLC)	NIB/RPL/SOP/102/R0;-. 28.03.17 Reference: Manufacturer's specifications	NLT 95% and NMT 105%
23.	**1. Insulin Lispro 2. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75) 3. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/49/ R2;-. 30.9.16 Reference:IP 2014	95-105%
24.	1. **Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** 2. **Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Soluble Insulin lispro content (RP-HPLC)	NIB/RPL/SOP/49/R2;-. 30.9.16 References: IP 2014&IP Addendum 2015	1. For 25/75 formulation:15-30 U/ml 2. L-10 to L+5 i.e. For 50/50 formulation 40-55 U/ml
25.	1. **Insulin Aspart**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/51/R2;-. 30.9.16	90-110%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	2. **Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** 3. **Insulin Aspart& Insulin Aspart Protamine Suspension (50/50)**		References:IP 2014	
26.	**1. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** **2. Insulin Aspart& Insulin Aspart Protamine Suspension (50/50)**	Insulin aspart in solution (SEC-HPLC)	NIB/RPL/SOP/51/R2;-. 30.9.16 References:IP 2014 &IP Addendum 2015	For 30/70:24-36% For 50/50:42-58%
27.	**Insulin Detemir**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/50/R2;-. 30.09.16 Reference: Manufacturer's specifications	95-105%
28.	**Insulin Degludec**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/80/R0;-. 25.01.18 Reference: Manufacturer's specifications	95.0-105.0%
29.	**Insulin Degludec/Insulin Aspart**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/80/R0;-. 25.01.18 Reference: Manufacturer's specifications	Degludec:95.0-105.0% Aspart:95.0-105.0%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
30.	**Exenatide**	Assay/Potency (SEC-HPLC)	NIB/RPL/SOP/67/R2;-. 30.9.16 Reference: Manufacturer's specifications	NLT 95% and NMT 105%
31.	**Exenatide Once Weekly**	Assay/Potency (SEC-HPLC)	NIB/RPL/SOP/101/R0;-. 28.03.17 Reference: Manufacturer's specifications	NLT 90% and NMT 110%
		In vitro Initial Release (SEC-HPLC)	NIB/RPL/SOP/98/R0;-. 28.03.17 Reference: Manufacturer's specifications	NMT 1.5%
		In vitro Complete Release (SEC-HPLC)	NIB/RPL/SOP/99/R0;-. 28.03.17 Reference: Manufacturer's specifications	Day 31:NLT 30% & NMT 50%
32.	**Liraglutide**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/84/R0;-. 24.01.18, Reference: Manufacturer's specifications	NLT 88.4% and NMT 105.0%
33.	**Teriparatide**	Assay/Potency (RP-HPLC)	NIB/RPL/SOP/90/R0;-. 30.06.16, Reference: Manufacturer's specifications	NLT 95.0% and NMT 105.0%
34.	**1. Soluble Insulin 2. Isophane Insulin 3. Biphasic**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/13/R5 dt:30.09.16 NIB/RPL/SOP/45/R2;-. 30.9.16, References:	A21 Desamido HI:NMT 5% of total areas of peaks Sum of areas of any other peaks apart from

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Isophane Insulin (25/75) **4. Biphasic Isophane Insulin (30/70)** **5. Biphasic Isophane Insulin (50/50)** **6. rh-Insulin Bulk**		IP-2014	HI & A21 desamido HI:NMT 6% of total areas of peaks
35.	**Insulin Glargine**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/40/R5;-. 24.05.18, Reference: IP Addendum 2016	O-A Arg insulin Glargine:NMT 5% Sum of areas of any other peaks apart from Insulin Glargine & O-A Arg insulin Glargine:NMT 6% of total areas of peaks
		Related Proteins (RP-HPLC)	NIB/RPL/SOP/102/R0;-. 28.03.17 Reference: Manufacturer's specifications	21^{A}-desamido insulin glulisine≤ 1.0% Any other single related impurity ≤ 0.5% Total impurities:≤ 3%
36.	**1. Insulin Lispro** **2. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **3. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/49/R2;-. 30.9.16 References:IP 2014	A21 Desamido Insulin lispro:NMT 1.5% Total impurities excluding A21 desamido insulin lispro NMT 4%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
37.	1. **Insulin Aspart** 2. **Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** 3. **Insulin Aspart& Insulin Aspart Protamine Suspension (50/50)**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/51/R2;-. 30.9.16 References:IP 2014	B28isoAsp isulinaspart:NMT 2.5% Total area of peaks due to A21Asp insulin aspart, B3Asp insulin aspart& B3 isoAsp insulin aspart:NMT 5% Other peaks corresponding to impurities:NMT 3.5%
38.	**Insulin Detemir**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/50/R2;-. 30.9.16 Reference: Manufacturer's specifications	B3deasamido insulin detemir:≤ 2.3% Insulin detemir related impurities ≤ 2.2%
39.	**Insulin Degludec**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/85/R0; 03.01.18 Reference: Manufacturer's specifications	Hydrophilic impurities:≤1.2% Hydrophobic related substances:≤3.7% Hydrophobic impurities:≤1.5%
40.	**Insulin Degludec/Insulin Aspart**	Related Proteins Degludec (RP-HPLC)	NIB/RPL/SOP/85/R0;-. 03.01.18 Reference: Manufacturer's specifications	Hydrophilic impurities:≤1.3% Hydrophobic related substances:≤3.0% Hydrophobic impurities:≤1.6%
		Related Proteins Aspart (RP-HPLC)	NIB/RPL/SOP/97/R0;-. 28.03.17 Reference: Manufacturer's specifications	B28isoAsp insulin aspart:≤2.2% Desamido insulin aspart:≤4.5% Insulin aspart related

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
				impurities:≤1.6% Applicable range of Measurement:0.0-3.5 %
41.	**Exenatide**	Product Related Impurities (Strong cation exchange-HPLC)	NIB/RPL/SOP/69/R2;-. 30.9.16 Reference: Manufacturer's specifications	Total product related impurities NMT 10% Specified product related impurities: [3-39]AC2993:NMT 1.0% [Asu^{9}]AC2993:NMT 1.0% Largest unspecified product related impurities (excluding [double coupled Pro^{38}] AC2993 peak):NMT 3% Applicable range of Measurement:0.0-10.0 %
42.	**Exenatide Once Weekly**	Purity (Strong Cation Exchange-HPLC)	NIB/RPL/SOP/100/R0;-. 28.03.17 Reference: Manufacturer's specifications	Total Product Related Impurities:NMT 10.0% Specific Product Related Impurities: - RRT 0.35 to RRT 0.60:NMT 1.5% - RRT 0.80 to 1.00:NMT 3.0% - RRT 1.00 to 1.20:NMT 1.6% Largest Unspecific Impurity:NMT 0.5% Applicable range of Measurement:0.0-10.0 %
43.	**Liraglutide**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/84/R0;-. 24.01.18 Reference:	Sum of Liraglutide related impurities:≤11.7%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Manufacturer's specifications	Other hydrophilic Liraglutide related impurities:≤4.2% Liraglutide related impurities A:≤3.6% Liraglutide related impurities B:≤3.7% Liraglutide related impurities C:≤1.6% Other hydrophobic Liraglutide related impurities:≤2.3% Applicable range of Measurement:0.00-11.7 %
44.	**G-CSF**	Related Proteins (SDS-PAGE)	NIB/RPL/SOP/47/R3;-. 05.03.18 Reference: IP-2014	Qualitative
		Related Proteins (RP-HPLC)	NIB/RPL/SOP/71/R2;-. 05.02.18 Reference: IP-2014	Each impurity:NMT 2% Total impurity:NMT 3.5%
45.	**Interferon β 1a**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/74/R0;-. 21.10.16 Reference: Manufacturer's specifications	Minimum 95%
46.	**Interferon Alpha-2b**	Impurity (SDS-PAGE)	NIB/RPL/SOP/79/R1;-. 22.05.18;References: IP-2014	Qualitative
		Related Proteins	NIB/RPL/SOP/89/R0;-.	Individual impurity:NMT

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		(RP-HPLC)	30.06.16;References: IP-2014	3%, Total impurity:NMT 5% Applicable range of Measurement:0.0-3.0 %
47.	**Peg-Filgrastim**	Impurity (SDS-PAGE, Non Reducing)	NIB/RPL/SOP/96/R0;-. 27.03.17;Reference: Manufacturer's specifications	Qualitative
		Related Proteins (RP-HPLC)	NIB/RPL/SOP/95/R0;-. 27.03.17Reference: Manufacturer's specifications	Individual impurity:NMT 3%, Total impurity:NMT 5%
48.	**Peg-Interferon Alpha-2b**	Purity (SDS-PAGE)	NIB/RPL/SOP/96/R0;-. 27.03.17Reference: Manufacturer's specifications	Qualitative
49.	**Teriparatide (rh-PTH)**	Related Proteins (RP-HPLC)	NIB/RPL/SOP/91/R1;-. 02.1.17Reference: Manufacturer's specifications	Individual impurity:NMT 3% Total impurity:NMT5% Applicable range of Measurement:0.0-3.0 %
50.	**1. Soluble Insulin 2. Isophane Insulin 3. Biphasic Isophane Insulin (25/75) 4. Biphasic Isophane Insulin (30/70) 5. Biphasic Isophane Insulin**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/03/R5;-. 24.05.18 NIB/RPL/SOP/46/R2;-. 30.9.16 References: IP-2014	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP Non protamine insulin:NMT 2% Protamine containinginsulin:NMT 3%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	(50/50) **6. rh-Insulin Bulk**			
51.	**Insulin Glargine**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/43/R4;-. 24.05.18 Reference: IP Addendum 2016	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP <=0.3% & NMT 1.7%
		Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/103/R0;-. 28.03.17 Reference: Reference: Manufacturer's specifications	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP <=1.5%
52.	**1. Insulin Lispro** **2. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **3. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/03/R5;-. 28.03.17 References: IP 2014	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP NMT 1.5% (for regular) NMT 3.0% (for biphasic)
53.	**1. Insulin Aspart** **2. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** **3. Insulin Aspart& Insulin Aspart Protamine**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/03/R5;-. 28.03.17 References: IP 2014	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP NMT 2.0% (for regular) NMT 3.0% (for biphasic)

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Suspension (50/50)			
54.	**Insulin Detemir**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/03/R5;-. 28.03.17 Reference: Reference: Manufacturer's specifications	Resolution for 4.0 mg/ml of Insulin containing more than 0.4% HMWP ≤ 1.1%
55.	**Insulin Degludec**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/83/R0;-. 25.01.18 Reference: Reference: Manufacturer's specifications	≤ 1.0% Applicable range of Measurement: 0.09-4.31 %
56.	**Insulin Degludec/Insulin Aspart**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/83/R0;-. 25.01.18 Reference: Reference: Manufacturer's specifications	≤ 1.0%
57.	**Exenatide**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/68/R2;-. 30.9.16 Reference: Reference: Manufacturer's specifications	0.248 mg/ml NMT 3%
58.	**Liraglutide**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/81/R0;-. 22.12.17 Reference: Reference: Manufacturer's specifications	≤ 2.7% Applicable range of Measurement: 0.0-0.27 %
59.	**rh-Erythropoietin**	Higher Molecular Weight Proteins (HMWP) (SEC-HPLC)	NIB/RPL/SOP/66/R0;-. 22.12.17 Reference:	NMT 2%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			IP 2014	
60.	**Filgrastim**	Higher Molecular Weight impurities (SEC-HPLC)	NIB/RPL/SOP/70/R3;-. 06.03.18 IP-2014	NMT 2%
61.	**Interferon Beta-1a**	Dimer and related substances of higher molecular mass (SEC-HPLC)	NIB/RPL/SOP/77/R0;-. 28.10.16 Reference: Manufacturer's specifications	≤ 2.0% aggregate Applicable range of Measurement: 0.0-2.5 %
62.	**Peg-Filgrastim**	Impurity (SEC-HPLC)	NIB/RPL/SOP/94/R0;-. 28.03.17Reference: Manufacturer's specifications	HMWP 1:NMT 2% HMWP 2:NMT 1%
63.	**Peg-Interferon Alpha-2b**	Purity (SEC-HPLC)	NIB/RPL/SOP/93/R0;-. 28.03.17Reference: Manufacturer's specifications	Di Peg IFN:≤10.0% Mono Peg IFN:≥ 85.0% IFN:≤ 5.0% Other:≤ 1.0%
64.	**1. Soluble Insulin 2. Isophane Insulin 3. Biphasic Isophane Insulin (25/75) 4. Biphasic Isophane Insulin (30/70) 5. Biphasic Isophane Insulin (50/50) 6. rh-Insulin Bulk 7. Insulin Glargine**	Zinc metal ion estimation (Atomic Absorption Spectrometry)	NIB/RPL/SOP/04/R3;-. 25.04.18 References:IP 2014 IP Addendum 2016-4204-4205	NMT 40 µg/100 IU NMT 1.0% w/w on dried basis 5.89-71.3 µg/ml 23.3-31.5 µg/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	8. Insulin Lispro **9. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **10. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)** **11. Insulin Aspart** **12. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** **13. Insulin Aspart& Insulin Aspart Protamine Suspension (50/50)** **14. Insulin Detemir** **15. Insulin Degludec** **16. Insulin Degludec/Insulin Aspart**			
65.	**Peg Interferon beta 1a**	Purity (SEC-HPLC)	NIB/RPL/SOP/77/R0 dt.28.10.16 Reference: Manufacturer's	NMT 4.5 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			specifications	
		Purity (Oxidized content)	NIB/RPL/SOP/28/R1dt.24.05.18 Reference: Manufacturer's specifications	NMT 5.5 %
66.	**1. Soluble Insulin** **2. Isophane Insulin** **3. Biphasic Isophane Insulin (25/75)** **4. Biphasic Isophane Insulin (30/70)** **5. Biphasic Isophane Insulin (50/50)** **6. Insulin Glargine** **7. Insulin Glulisine** **8. Insulin Lispro** **9. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **10. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)**	Color (Visual Observation)	NIB/RPL/SOP/06/R4;-.26.03.18 References: IP 2014 (Appendix 2.4.1), IP Addendum 2016-	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	11. Insulin Aspart 12. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70) 13. Insulin Aspart& Insulin AspartProtamine Suspension (50/50) 14. Insulin Detemir 15. Insulin Degludec 16. Insulin Degludec/Insulin Aspart 17. Exenatide 18. Exenatide Once Weekly 19. Liraglutide 20. rh-Erythropoietin 21. Filgrastim 22. Interferon Beta-1a 23. Interferon Alpha-2b 24. Peg-Filgrastim 25. Peg-Interferon Alpha-2b 26. Teriparatide (rh-PTH) 27. Peg Interferon			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	beta 1a **28. rh-Insulin bulk**			
67.	**1.Soluble Insulin** **2.Isophane Insulin** **3.Biphasic Isophane Insulin (25/75)** **4.Biphasic Isophane Insulin (30/70)** **5.Biphasic Isophane Insulin (50/50)** **6.Insulin Glargine** **7.Insulin Glulisine** **8.Insulin Lispro** **9.Insulin Lispro& Insulin Lispro Protamine Suspension (25/75)** **10 Insulin Lispro& Insulin Lispro Protamine Suspension (50/50)** **11. Insulin Aspart** **12. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70)** **13. Insulin Aspart& Insulin Aspart Protamine**	Clarity (Visual Observation)	NIB/RPL/SOP/06/R4;-. 26.03.18, References: IP-2014 (Appendix 2.4.1) IP Addendum 2016-	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Suspension (50/50) **14. Insulin Detemir** **15. Insulin Degludec** **16. Insulin Degludec/Insulin Aspart** **17. Exenatide** **18. Exenatide Once Weekly** **19. Liraglutide** **20. rh-Erythropoietin** **21. Filgrastim** **22. Interferon Beta-1a** **23. Interferon Alpha-2b** **24. Peg-Filgrastim** **25. Peg-Interferon Alpha-2b** **26. Teriparatide (rh-PTH)** **27. Peg Interferon beta 1a** **28. rh-Insulin bulk**			
68.	**1. Soluble Insulin** **2. Isophane Insulin** **3. Biphasic Isophane Insulin (25/75)**	Particulate Matter (Light Obscuration; Microscopy)	NIB/RPL/SOP/11/R3;-. 24.05.18 References: IP 2014 (Appendix 2.5.9) IP Addendum 2016-	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	4. Biphasic Isophane Insulin (30/70) 5. Biphasic Isophane Insulin (50/50) 6. Insulin Glargine 7. Insulin Glulisine 8. Insulin Lispro 9. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75) 10. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50) 11.Insulin Aspart 12.Insulin Aspart& Insulin Aspart Protamine Suspension (30/70) 13.Insulin Aspart& Insulin Aspart Protamine Suspension (50/50) 14.Insulin Detemir 15.Insulin			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Degludec 16.Insulin Degludec/Insulin Aspart 17. Liraglutide			
69.	**1. Soluble Insulin 2. Isophane Insulin 3. Biphasic Isophane Insulin (25/75) 4. Biphasic Isophane Insulin (30/70) 5. Biphasic Isophane Insulin (50/50) 6. Insulin Glargine 7. Insulin Glulisine 8. Insulin Lispro 9. Insulin Lispro& Insulin Lispro Protamine Suspension (25/75) 10. Insulin Lispro& Insulin Lispro Protamine Suspension (50/50) 11. Insulin**	pH Determination (Potentiometric)	NIB/RPL/SOP/06/R4;-. 26.03.18 References: IP 2014 (Appendix 2.4.24) IP Addendum 2016-	pH 4.0-9.0

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Aspart 12. Insulin Aspart& Insulin Aspart Protamine Suspension (30/70) 13. Insulin Aspart& Insulin Aspart Protamine Suspension (50/50) 14.Insulin Detemir 15.Insulin Degludec 16.Insulin Degludec/Insulin Aspart 17.Exenatide 18.Exenatide once weekly 19.Liraglutide 20.rh-Erythropoietin 21.Filgrastim 22.Interferon Beta-1a 23.Interferon Alpha-2b 24.Peg-Filgrastim 25.Peg-Interferon Alpha-2b 26.Teriparatide (rh-PTH) 27.Peg Interferon beta 1a			

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
70.	**Interferon Beta-1a**	Protein Concentration (RP-HPLC)	NIB/RPL/SOP/74/R0;-. 21.10.16, References: Reference: Manufacturer's specifications	90-105%
71.	**1. Exenatide 2. Filgrastim 3. Interferon Beta-1a 4. Peg-Filgrastim 5. Peg Interferon beta 1a**	Osmolality (Osmometry)	NIB/RPL/SOP/36/R0;-. 26.02.18, References: IP 2014 (Appendix 2.4.23), Reference: Manufacturer's specifications	100-1500 mosmol/Kg
72.	**rh-Insulin Bulk**	Loss on Drying (Gravimetric)	NIB/RPL/SOP/42/R2;-. 30.9.16 References:IP 2014 (2.4.19),	NMT 10.0%
73.	**1. Exenatide Once Weekly 2. rh-Erythropoietin 3. Filgrastim 4. Peg-Interferon Alpha-2b**	Water Content (Karl Fischer)	NIB/RPL/SOP/63/R2;-. 30.9.16 References: IP 2014 (2.3.43), Reference: Manufacturer's specifications	NMT 1.5%
74.	**1. rh-Erythropoietin 2. Filgrastim**	Dissolution	NIB/RPL/SOP/25/R0;-. 31.07.17 Reference: Manufacturer's specifications	<300 seconds
75.	**1. Insulin Degludec 2. Liraglutide 3. rh-Erythropoietin**	Dose accuracy/Volume Tolerance (Gravimetric)	NIB/RPL/SOP/06/R4;-. 26.03.18 References: IP 2014 References:	5%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	4. Filgrastim 5. Interferon Alpha-2b 6. Peg-Filgrastim 7. Peg-Interferon Alpha-2b 8. Teriparatide (rh-PTH) 9. Interferon Beta-1a 10. Peg Interferon beta 1a		Reference: Manufacturer's specifications	
76.	**Parenteral Preparations:Blood Product**			
77.	**1. Human Albumin 2. Plasma Protein Fraction 3. Human Normal immunoglobulin IV 4. Human Normal Immunoglobulin IM 5. Anti-D Immunoglobulin IV 6. Anti-D Immunoglobulin IM 7. Tetanus immunoglobulin**	Molecular size distribution (HPLC)	NIB/BPL/SOP/11/R2;dt. 24.04.18 NIB/BPL/SOP/23/R3 dt:03.05.18 NIB/BPL/SOP/24/R3 dt:03.05.18 NIB/BPL/SOP/47/R1 Dt:28.04.17 Reference:IP 2014,	80-100%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	IM **8. Rabies Immunoglobulin IM** **9. Hepatitis Immunoglobulin IM** **10. Hepatitis Immunoglobulin IV** **11. Human Immunoglobulin I.V. (Bulk)** **12. Human Immunoglobulin I.M. (Bulk)**			
78.	**1. Human Albumin** **2. Plasma Protein Fraction** **3. Human Normal immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin IV** **6. Anti-D Immunoglobulin IM** **7. Tetanus immunoglobulin** **8. Rabies**	Assay for Protein (Kjeldahl method/Biuret method/Clottable protein)	NIB/BPL/SOP/08/R3;dt.23.04.18 NIB/BPL/SOP/22/R3 dt:23.04.18 NIB/BPL/SOP/21/R4 dt:23.04.18 NIB/BPL/SOP/51/R2 dt:18.04.18 NIB/BPL/SOP/07/R2;dt.02.04.18 NIB/BPL/SOP/48/R1 dt:28.04.17 Reference:IP 2014,	Kjeldahl:1-30 % Biuret:1-30 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Immunoglobulin **9. Hepatitis Immunoglobulin IV** **10. Hepatitis Immunoglobulin IM** **11. Fibrin sealant kit** **12. Human Fibrinogen** **13. Human Immunoglobulin I.V. (Bulk)** **14. Human Immunoglobulin I.M. (Bulk)**			
79.	**1. Human Albumin** **2. Plasma Protein fraction** **3. Human Normal Immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin**	Identification (Double Immunodiffusion)	NIB/BPL/SOP/06/R4;dt. 13.01.2017 NIB/BPL/SOP/20/R3;dt.12. 01.2017 NIB/BPL/SOP/34/R1;dt. 28.04.2017 Reference:IP 2014	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	IV **6. Anti-D Immunoglobulin IM** **7. Tetanus Immunoglobulin** **8. Rabies Immunoglobulin** **9. Hepatitis Immunoglobulin IM** **10. Hepatitis Immunoglobulin IV** **11. Human Immunoglobulin I.V. (Bulk)** **12. Human Immunoglobulin I.M. (Bulk)**			
80.	**1. Human Albumin** **2. Plasma Protein fraction**	Haem content (UV-Vis spectrophotometry)	NIB/BPL/SOP/05/R2;dt.27.04.18 NIB/BPL/SOP/46/R2;dt.23.10.2017 IP 2014,	0.030973-0.045727 OD at 403 nm
81.	**1. Human Albumin** **2. Plasma Protein Fraction** **3. Factor VIII**	Assay for sodium by Atomic Absorption Spectrophotometry (AAS)	NIB/BPL/SOP/09/R2;dt.28.03.18 NIB/BPL/SOP/14;dt.29.06.2016 References:IP 2014	30-200mmol/L
82.	**1. Human Albumin** **2. Plasma Protein Fraction**	Assay for Potassium by Atomic Absorption Spectrophotometry (AAS)	NIB/BPL/SOP/10/R2;dt.27.03.18 References:IP 2014	0.05-1.5 mmol/L
83.	**1. Human**	Protein Composition by	NIB/BPL/SOP/52/R2;dt.	79.8 %-100 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Albumin **2. Plasma Protein Fraction** **3. Human Normal Immunoglobulin IV** **4. Human Normal immunoglobulin IM** **5. Human Immunoglobulin I.V. (Bulk)** **6. Human Immunoglobulin I.M. (Bulk)** **7. Anti-D Immunoglobulin IV** **8. Anti-D Immunoglobulin IM** **9. Tetanus immunoglobulin IM** **10. Rabies Immunoglobulin IM** **11. Hepatitis Immunoglobulin IV** **12. Hepatitis Immunoglobulin IM**	Zone electrophoresis	04.08.2017 References:IP 2014	

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
84.	**1. Human Albumin** **2. Plasma Protein Fraction** **3. Human Normal immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin IV** **6. Anti-D Immunoglobulin IM** **7. Human Tetanus immunoglobulin** **8. Rabies Immunoglobulin** **9. Hepatitis Immunoglobulin** **10. Human Immunoglobulin I.V. (Bulk)** **11. Human Immunoglobulin I.M. (Bulk)**	Test for Purity (SDS-PAGE)	NIB/BPL/SOP/12/R5;dt.28.03.18 NIB/BPL/SOP/49/R2;dt.26.05.17 NIB/BPL/SOP/25/R6;dt.23.03.2017 Reference:IP 2014	Qualitative
85.	**1. Human Albumin** **2. Plasma Protein Fraction**	pH Determination (Potentiometry)	NIB/BPL/SOP/04/R2;dt.24.04.18 NIB/BPL/SOP/45/R2;dt 23.10.2017	pH 1.0-11.0

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	3. Human Normal immunoglobulin IV **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin IV** **6. Anti-D Immunoglobulin IM** **7. Tetanus immunoglobulin** **8. Rabies Immunoglobulin** **9. Hepatitis Immunoglobulin IV** **10. Hepatitis B Immunoglobulin IM** **11. Human Coagulation factor VIII (plasma derived)** **12. Human Coagulation Factor VIII rDNA** **13. Human Coagulation Factor IX** **14. Anti-Thrombin III concentrate**		NIB/BPL/SOP/19/R2;dt.20.04.18 NIB/BPL/SOP/31/R2;dt.20.04.18 NIB/BPL/SOP/35/R3;dt.27.03.2017 Reference: IP 2014.	

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	15. Anti-inhibitor coagulant complex **16. Fibrin sealant kit** **17. Human Fibrinogen** **18. Human Norma Immunoglobulin I.V. (Bulk)** **19. Human Normal Immunoglobulin I.M. (Bulk)** **20. Human Tetanus Immunoglobulin (Bulk)** **21. Human Prothrombin complex**			
86.	**1. Human Normal immunoglobulin IV** **2. Human Coagulation factor VIII (plasma derived)** **3. Human Coagulation Factor VIII rDNA** **4. Human Coagulation**	Osmolality	NIB/BPL/SOP/27/R5;dt.03.04.18 NIB/BPL/SOP/28/R3;dt.23.03.2017 References:IP 2014	100-1500mOsmol/kg

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Factor IX **5. Anti-Thrombin III concentrate** **6. Anti-inhibitor coagulant complex** **7. Human Fibrinogen** **8. Hepatitis Immunoglobulin IV** **9. Anti-D Immunoglobulin IV**			
87.	**1. Human Albumin** **2. Plasma Protein Fraction** **3. Human Normal immunoglobulin IV** **4. Human Normal Immunoglobulin IM** **5. Anti-D Immunoglobulin** **6. Tetanus immunoglobulin** **7. Rabies Immunoglobulin** **8. Hepatitis Immunoglobulin** **9. Human Coagulation factor VIII (plasma**	Physical Characteristics & solubility	NIB/BPL/SOP/01/R5 dt:17.04.18 NIB/BPL/SOP/30/R3;dt 04.04.18 NIB/BPL/SOP/36/R2;dt. 28.04.2017 Reference:IP 2014	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	derived) **10. Human Coagulation Factor VIII rDNA** **11. Human Coagulation Factor IX** **12. Anti-Thrombin III concentrate** **13. Anti-inhibitor coagulant complex** **14. Fibrin sealant kit** **15. Human Fibrinogen**			
88.	**1. Fibrin sealant kit**	Stability (Visual Observation)	NIB/BPL/SOP/36/R2;dt. 28.04.2017 Reference IP 2014:3303	Qualitative
89.	**1. Human albumin** **2. Human Normal Immunoglobulin IV** **3. Hepatitis Immunoglobulin IV** **4. Anti-D Immunoglobulin IV**	Prekallikrein Activator Assay	NIB/BPL/SOP/56/R2 dt. 22.08.2017 NIB/BPL/SOP/26/R2;dt. 27.02.2017 Reference IP 2014:	0.375IU/ml-6IU/ml (Albumin) 0.39IU/ml-6IU/ml (IVIg)
90.	**1. Human**	Potency by Clotting Assay	NIB/BPL/SOP/53/R1 dt.	80-120% of stated

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Coagulation factor VIII (plasma derived) **2. Human Coagulation Factor VIII Recombinant** **3. Human Coagulation Factor IX** **4. Human Coagulation Factor IX Complex (Human Prothrombin Complex)**		27.07.2017 NIB/BPL/SOP/54/R1;dt. 31.07.2017 Reference IP 2014; Pg. 3298, 3309, 3310.	Potency (Factor VIII plasma derived & Human Prothrombin Complex) 80-125% of stated Potency (Factor VIII Recombinant & Factor IX)(IP 2014)
91	**1. Human Coagulation factor VIII (plasma derived)** **2. Human Coagulation Factor VIII Recombinant**	Potency by Chromogenic Assay	NIB/BPL/SOP/33/R2 dt.09.04.18 Reference IP 2014; .	80-120% of stated Potency (Factor VIII plasma derived) (IP 2014)
92.	**1. Human Normal immunoglobulin IV** **2. Human Normal Immunoglobulin IM**	Antibody to Hepatitis B Surface Antigen	NIB/BPL/SOP/61/R1 dt. 01.08.2017 Reference IP 2014; .	0-150 mIU/ml Minimum 0.5IU per gm of Immunoglobulin(IP 2014)
93.	**1. Human Coagulation factor VIII (plasma derived)** **2. Human**	Residual Moisture by KF Method	NIB/VVL/SOP/006/R2 dt 23.05.2017 Reference IP 2014; And Manufacturer's specifications	≤3% ≤ 2%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Coagulation Factor VIII Recombinant **3. Human Coagulation Factor IX** **4. Fibrin sealant kit** **5. Anti-inhibitor coagulant complex**			
B.	**Parenteral Preparations:Bacterial Vaccine**			
1.	**1. Haemophilusinfluenzae type b TT conjugate vaccine** **2. Bacillus Calmette Guerin (BCG) Vaccine**	Test for Identity (Immunochemical Assay) Identification	**1.** NIB/BVL/SOP/02/R3;-. 09.10.17 References:IP 2014;Pg No. 67-69 **2.** NIB/BVL/SOP/13/R4;-. 31.07.17 IP 2014;Pg 3059	Qualitative
2.	1. **Haemophilusinfluenzae type b TT conjugate vaccine**	pH Test (Potentiometric Method)	NIB/BVL/SOP/01/R5;-. 04.07.17 References:IP 2014 Pg No. 169-170	1-11
3.	**1. Haemophilusinfluenzae type b TT conjugate vaccine**	Thiomersol content- Antimicrobial preservative	NIB/BVL/SOP/09/R4;-.09.10.17 References:IP 2014;Pg No. 119	NLT 85% and NMT 115 % of the intended amount
4.	**1. Bacillus Calmette Guerin (BCG) vaccine** **2. Haemophilusinfluenzae type b TT conjugate**	Test for water content	NIB/BVL/SOP/20/R3;-. 31.07.17 Ref IP 2014, Pg No.113-115 & 3059 NIB/VVL/SOP/006/R2;-.23.05.17	Not more than 3%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	vaccine		NIB/BVL/SOP/06/R1;-.09.10.17 Ref IP 2014 Pg No. 113-115	
5.	**1. Haemophilusinfluenzae type b TT conjugate vaccine**	PRP (Ribose Assay)	NIB/BVL/SOP/03/R1;-.02.05.17 Ref IP 2014, Pg No.282-283	80-120%
6.	**1. Haemophilusinfluenzae type b TT conjugate vaccine**	Free PRP (Ribose Assay)	NIB/BVL/SOP/05/R1;-.02.05.17 Ref IP 2014, Pg No.282-283	Less than 20%
7.	**Oral cholera Vaccine**	Identification (Immunochemical Assay)	NIB/BVL/SOP/23/R0;dt.26.03.18 References:BP 2016;Pg No. 558	Qualitative
		pH Test (Potentiometric Method)	NIB/BVL/SOP/23/R0;dt.26.03.18 References:BP 2016;Pg No. 558	1-11
		Assay (Antigen content) (Immunochemical Assay)	NIB/BVL/SOP/23/R0;dt.26.03.18 References:BP 2016;Pg No. 558	Total LPS content not less than 600µg/ml
8.	**Oral cholera Vaccine**	Free formaldehyde	NIB/BVL/SOP/23/R0;dt.26.03.18 References:BP 2016;Pg No. 558	Maximum 0.2g/L
9.	**1. Live Attenuated Measles Vaccine 2. Live Attenuated Rubella Vaccine**	Moisture content	NIB/VVL/SOP/006/R2; dt 23.05.17 Reference:IP 2014, Pg. No:113	NMT 3%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	3. Live Attenuated MMR Vaccine 4. Cell Culture Rabies Vaccine 5. Live Attenuated Measles & Rubella Vaccine			
10.	**1. Cell Culture Rabies Vaccine 2. Hepatitis A Inactivated Vaccine 3. Hepatitis B (r-DNA) Vaccine**	Aluminium Content	NIB/BVL/SOP/12/R1; dt-05.07.17 Reference IP 2014, Pg. 95-96, 3136	NMT1.25mg per single human dose
11.	**Rotavirus Vaccine Rotarix Oral Suspension**	pH potentiometric	NIB/VVL/SOP/047/R0 dt 06.01.17 Reference IP 2014, Pg. No:3139	6.3 to 8.5
12.	**1. Inactivated Polio Vaccine 2. Hepatitis A Inactivated Vaccine 3. Hepatitis B (r-DNA) Vaccine**	Free formaldehyde	NIB/BVL/SOP/34/R2 dt. 04.08.17 Reference IP 2014, Pg. No:3126	Maximum 0.2gm/L
13.	**1. Hepatitis A Inactivated Vaccine 2. Hepatitis B (r-DNA) Vaccine**	Anti-microbial preservative test	NIB/BVL/SOP/09/R4 dt:09.10.17 Reference:Hep A, BP 2017 Pg. IV-593 IP 2014 Pg. 3088 Hep B, BP 2017 PG IV-599	NLT 85% and NMT 115% of the quantity stated on the label

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			IP 2014, Pg 3090	
C.	**Parenteral Preparations:Therapeutics Monoclonal Antibody**			
1.	**1) Rituximab**	Identification (SEC-HPLC)	NIB/TMA/SOP/20/R1, dt. 01.08.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol MethodVerification Doc. ID:NIB/TMA/MV/Mab-SEC	a) 0.02mg/ml to 10mg/ml
2.	**2) Adalimumab**			b) 1.25mg/ml to 50mg/ml
3.	**3) Bevacizumab**			c) 0.78mg/ml to 25mg/ml
4.	**1) Rituximab**	Identification (CEX-HPLC)	NIB/TMA/SOP/33/R1, dt. 05.05.17 References: Manufacturer'sdrugproduct releasespecifications(Doc.ID:NIB/TMA/ProductSpecifications/01) &Method of Analysisprotocol MethodVerification Doc. ID:NIB/TMA/MV/Rituximab-IEC	a) 0.25mg/ml to 2.0mg/ml
5.	**2) Adalimumab**	Identification (CEX-HPLC)		b) 0.25mg/ml to 2.0mg/ml
6.	**3) Bevacizumab**	Identification (CEX-HPLC)		c) 0.125mg/ml to 1.5mg/ml
7.	**4) Trastuzumab**	Identification (CEX-HPLC)		d) 0.125mg/ml to 1.5mg/ml
8.	**Rituximab**	Identification (SDS-PAGE)	NIB/TMA/SOP/34/R0, dt. 27.09.16 References: Manufacturer's drugproductreleasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol	0.2µg/ml
9.	**1. Rituximab 2. Bevacizum**	Identification (Capillary Zone	NIB/TMA/SOP/043/R1, dt. 29.01.18	0.5mg/mL

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	ab **3. Trastuzumab**	Electrophoresis)	References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol	
10.	**1. Rituximab**	Purity (SEC-HPLC)	NIB/TMA/SOP/20/R1, dt. 01.08.16 Acceptancecriteria at thegivenconcentrationrangeis % Monomerpeakarea NLT 95%	a) 0.02mg/ml to 10mg/ml
11.	**2. Adalimumab**	Purity (SEC-HPLC)	NIB/TMA/SOP/20/R1, dt. 01.08.16 Acceptancecriteria at thegivenconcentrationrangeis % Monomerpeakarea NLT 95%	b) 1.25mg/ml to 50mg/ml
12.	**3. Bevacizumab**	Purity (SEC-HPLC)	NIB/TMA/SOP/20/R1, dt. 01.08.16 Acceptancecriteria at thegivenconcentrationrangeis % Monomerpeakarea NLT 92%	c) 0.78mg/ml to 25mg/ml
13.	**4. Trastuzumab**	Purity (SEC-HPLC)	NIB/TMA/SOP/20/R1, dt. 01.08.16 Acceptancecriteria at thegivenconcentrationrangeis % Monomerpeakarea NLT 98%	d) 0.625mg/ml to 22mg/ml
14.	**1. Rituximab**	Purity (CEX-HPLC)	NIB/TMA/SOP/33/R1, dt. 05.05.17 Acceptancecriteria at thegivenconcentrationrang	a) 0.25mg/ml to 2.0mg/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			eisrelativeretention time should be 1 ±0.1	
15.	**2. Bevacizumab**	Purity (CEX-HPLC)	NIB/TMA/SOP/46/R0, dt. 30.03.17 Acceptancecriteria at thegivenconcentrationrangeisrelativeretention time should be 1 ±0.1	b) 0.125mg/ml to 1.5mg/ml
16.	**3. Trastuzumab**	Purity (CEX-HPLC)	NIB/TMA/SOP/41/R1, dt. 13.06.17 Acceptancecriteria at thegivenconcentrationrangeisrelativeretention time should be 1 ±0.1	c) 0.125mg/ml to 1.5mg/ml
17.	**Rituximab**	Purity (SDS-PAGE-Reducing/Non Reducing)	NIB/TMA/SOP/34/R0, dt. 27.09.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol	0.2µg/ml
18.	**Trastuzumab**	Purity (CE-SDS under Reducing & Non-reducing conditions)	NIB/TMA/SOP/16/R2, dt. 23.04.18 References: Manufacturer'sdrugproduct releasespecifications(Doc.ID:NIB/TMA/ProductSpecifications/01) &Method of Analysisprotocol	1mg/ml
19.	**1. Rituximab 2. Adalimumab 3. Bevacizum**	Protein Content	NIB/TMA/SOP/06/R1, dt. 23.08.16 References: Manufacturer'sdrugproduct	0.5mg/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	ab **4. Trastuzumab**		releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol	
	1. Rituximab	pH	NIB/TMA/SOP/03/R1, dt. 05.09.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01)&Method of Analysisprotocol	1) 6.2-6.8
20.	**2. Adalimumab**	pH		2) 4.7-5.7
21.	**3. Bevacizumab**	pH		3) 5.7-6.7
22.	**4. Trastuzumab**	pH		4) 5.4-6.6
23.	**1. Rituximab**	Osmolality	NIB/TMA/SOP/04/R1, dt. 06.09.16 References: Manufacturer'sdrugproduct releasespecifications (Doc.ID:NIB/TMA/Product Specifications/01) &Method of Analysisprotocol	1) 240-400 mOsmol/Kg
24.	**2. Adalimumab**			2) 310-380 mOsmol/Kg
25.	**3. Bevacizumab**			3) 200-350 mOsmol/Kg
26.	**4. Trastuzumab**			4) 450-750 mOsmol/Kg
27.	**Trastuzumab**	Moisture Content	NIB/VVL/SOP/006/R2 dt:23.05.17 Reference: Manufacturer'sdrugproduct releasespecifications	NMT 5.0%
D.	**Parenteral Preparations:Enzymes**			
1.	**1. Streptokinase Bulk/Inj.** **2.Recombinant Streptokinase Inj.**	Assay/Potency (Chromogenic method)	NIB/EHL/SOP/10/R3; Dt 20.02.18 NIB/EHL/SOP/23/R3; dt.20.02.18 References: IP 2014 addendum 2015	0.5 IU/ml to 4.0 IU/ml Applicable Range of Measurement: 90-111 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Pg No:3931,3932	
2.	**1.Streptokinase Bulk/Inj.**	Streptodornase activity (UV Vis Spectrophotometry)	NIB/EHL/SOP/07/R4; Dt 02.01.17 References:IP-2014, Pg No. 2794,2795	Qualitative
3.	**1. Streptokinase Inj. 2. Recombinant Streptokinase Inj.**	Particulate Matter (Visual Observation)	NIB/EHL/SOP/17/R3; Dt. 20.02.18 References: IP 2014, Pg No:956	Qualitative
4.	**1. Streptokinase Bulk/Inj. 2. Recombinant Streptokinase Inj.**	pH determination (Potentiometry).	NIB/EHL/SOP/06/R3;dt 20.02.18 NIB/EHL/SOP/20/R3;dt 26.10.17 Ref:IP 2014, Pg No:2794. 3380	pH 4.0-9.0
5.	**1. Streptokinase inj. 2. Recombinant Streptokinase Inj.**	Clarity (Visual Observation)	NIB/EHL/SOP/16/R3; dt 20.02.18 References: IP 2014, Pg No,.957	Qualitative
6.	**1. Recombinant Streptokinase Inj.**	Residual Moisture Content (Karl Fisher Coulometric method)	NIB/VVL/SOP/006/R2 dt. 23.05.17 Ref:IP 2014, Page:3380	Maximum 3.0%
F.	**Hormones**			
1.	**1. Human Chorionic Gonadotropin Inj. 2. Menotropin (Human Menopausal Gonadotropin) Inj. 3. Urofollitropin (Human follicle stimulating Hormone) Inj.**	Particulate Matter by (Visual observation)	NIB/EHL/SOP/49/R1; dt 20.02.18 Ref:IP 2014, Pg. No. 957	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	4. Recombinant Human Follicle Stimulating Hormone Inj. **5. Somatropin Inj. (Recombinant Human Growth Hormone)**			
2.	**1. Human Chorionic Gonadotropin Inj.** **2. Menotropin (Human Menopausal Gonadotropin) Inj.** **3. Urofollitropin (Human follicle stimulating Hormone) Inj.** **4. Recombinant Human Follicle Stimulating Hormone Inj.** **5. Somatropin Inj. (Recombinant Human Growth Hormone)**	Clarity (Visual observation)	NIB/EHL/SOP/50/R1;dt.20.02.18 Ref:IP 2014, Pg No.957.	Qualitative
3.	**1. Human Chorionic Gonadotropin Inj.** **2. Menotropin (Human Menopausal Gonadotropin) Inj.**	pH determination	NIB/EHL/SOP/38/R2;dt 20.02.18 NIB/EHL/SOP/42/R2;dt. 26.10.17 Ref:IP 2014, Pg No.:1388	pH.4.0 to 9.0

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	3. Urofollitropin (Human follicle stimulating Hormone) Inj. **4. Recombinant Human Follicle Stimulating Hormone Inj**			
4.	**Somatropin Inj. (Recombinant Human Growth Hormone)**	Identification (SE-HPLC)	NIB/EHL/SOP/56/R1; dt 10.05.18 Ref:IP Addendum 2016, Page no-4320	Qualitative
5.	**Somatropin Inj. (Recombinant Human Growth Hormone)**	Assay (SE-HPLC)	NIB/EHL/SOP/56/R1; dt 10.05.18 Ref:IP Addendum 2016, Page no.-4320	89.0-105 %
6.	**Somatropin Inj. (Recombinant Human Growth Hormone)**	Dimer and related substances of higher molecular weight (SE-HPLC)	NIB/EHL/SOP/56/R1; dt 10.05.18 Ref:IP Addendum 2016, Page no.-4320	Maximum 6.0%
7.	**Somatropin Inj. (Recombinant Human Growth Hormone)**	Residual Moisture Content(Karl Fisher Coulometric method)	NIB/VVL/SOP/006/R2 dt. 23.05.17 EP 2014, Page.2960 IP Addendum 2016, Page no.-4321	Maximum 3.0%
8.	**Somatropin Inj. (Recombinant Human Growth Hormone)**	Identification (RP-HPLC)	NIB/EHL/SOP/58/R0; dt 16.01.18 Ref:IP Addendum 2016, Page no.-4320	Qualitative
9.	**Somatropin Inj. (Recombinant Human Growth**	Related Protein (RP-HPLC)	NIB/EHL/SOP/58/R0; dt 16.01.18 Ref:IP Addendum 2016,	Maximum 13.0%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	Hormone)		Page no.-4320	
10.	**Heparin Sodium injection**	Assay/Potency by Anti factor IIa activity chromogenic method	NIB/EHL/SOP/48/R1;-. 26.01.17 Ref:USP 37 pg no: 3406-3407	90-110%
11.	**Heparin Sodium injection**	Particulate Matter by (Visual observation)	NIB/EHL/SOP/17/R3;dt 20.02.18 Ref:IP 2014, Page 957	Qualitative
12.	**Heparin Sodium injection**	Clarity (Visual observation)	NIB/EHL/SOP/16/R3; Dt. 20.02.18 Ref:IP 2014, Page 957	Qualitative
		pH determination	NIB/EHL/SOP/51/R2;-. 19.06.17 Ref:IP 2014, Page:1888	pH.4.0 to 9.0
		Identification by Method B-Reaction A of sodium Salt	NIB/EHL/SOP/57;dt. 20.03.17 Ref:IP 2014, Page:1888	Qualitative
G.	**Blood Grouping Reagents**			
1.	**1. Anti-A (Monoclonal)**	Color (Visual observation)	NIB/BRL/SOP/18/R2,- .22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
2.	**2. Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
3.	**3.Anti-A,B (Monoclonal)**		NIB/BRL/SOP/20/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specification	Qualitative
4.	**4. Anti-D (IgM)**		NIB/BRL/SOP/22/R2;-.	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
	(Monoclonal)		22.09.17 Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specification	
5.	**5.Anti-D (IgM + IgG) (Monoclonal)**		NIB/BRL/SOP/23/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specification	Qualitative
6.	**6. Anti-D (IgG) (Monoclonal)**		NIB/BRL/SOP/21/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specification	Qualitative
7.	**1. Anti-A (Monoclonal)**	Physical Appearance (Visual observation)	NIB/BRL/SOP/18/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
8.	**2. Anti-B (Monoclonal)**		NIB/BRL/SOP/19/R2;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
9.	**3. Anti-A,B (Monoclonal)**		NIB/BRL/SOP/20/R2;-. 22.09.17, Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Qualitative
10.	**4. Anti-D (IgM) (Monoclonal)**		NIB/BRL/SOP/22/R2;-. 22.09.17, Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
11.	5. Anti-D (IgM +IgG) (Monoclonal)		NIB/BRL/SOP/23/R2;-. 22.09.17, Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Qualitative
12.	6. Anti-D(IgG) (Monoclonal)		NIB/BRL/SOP/21/R2;-. 22.09.17, Reference:Indian Pharmacopoeia 2014 and as per manufacturer's specifications	Qualitative
13.	7. Gel card Forward grouping		NIB/BRL/SOP/055/R2;-. 22.09.17,Reference:Transfusion Medicine Technical Manual 2003 and as per manufacturer's specifications	Qualitative
14.	8. Anti-Fy^a reagent	Physical Appearance (Visual observation)	NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
15.	9. Anti-Jk^a reagent		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
16.	10. Anti-K reagent		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
17.	11.Anti-k reagent		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
18.	12. Anti-Le^a reagent		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			Pharmacopoeia 2014	
19.	**13. Anti-Le^b reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
20.	**14. Anti-Pi reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
21.	**15. Anti-M reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
22.	**16. Anti-N reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
23.	**17.Anti-S reagent**		NIB/BRL/SOP/066/00;-. 22.09.17 Reference:Indian Pharmacopoeia 2014	Qualitative
24.	**1.Anti-A_1 (Lectin)**	Clarity (Visual observation)	NIB/BRL/SOP/24/ R2,22.09.17, References:Based on NIB data and recommendation of experts	Qualitative
25.	**2.Anti-H (Lectin)**		NIB/BRL/SOP/25/R1;-. 22.09.17, References:Based on NIB data and recommendation of experts	Qualitative