Laboratory	**Central Quality Control Department, Reliance Life Sciences Pvt. Ltd., DALC, Thane Belapur Road, Rabale, Navi Mumbai, Maharashtra**		
Accreditation Standard	**ISO/IEC 17025: 2005**		
Certificate Number	**TC-7158**	**Page 1 of 24**	
Validity	**13.04.2018 to 12.04.2020**	**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.	**DRUGS AND AGRICULTURAL PRODUCTS**			
	Finished Product			
1.	**Human Normal Albumin(I.P/E.P)**	Sterility	I.P 2018 , 2.2.11, Page 3921, Vol. III SOP:RLS-CQC-SOP-0134-03 date : 09 Mar 2018	Complies/ Does not comply
		Bacterial endotoxin	I.P 2018,2.2.3, Page 3921, Vol. III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.65 IU/ml Max:1.3 IU/ml NMT:1.3 IU/ml
2.	**Religrast (Filgrastim injection)**	Identification (Bioassay)	I.P 2018, Page 3981, Vol.III SOP:RLS2/QC/GTP/027 date 07 Aug 2012	Qualitative
		Assay (Bioassay)	I.P 2018, Page 3983, Vol. III SOP:RLS2/QC/GTP/027 Date 07 Aug 2012	Minimum 24 MIU Maximum 36 MIU
		Bacterial endotoxin	I.P 2018,2.2.3, Page 3983, Vol. III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Filgrastim per 0.5 ml Min: 1 IU/mg Max: 2 IU/mg Limit: NMT 2IU/mg
		Sterility	I.P 2018,2.2.11, Page 3983, Vol. III SOP:RLS-CQC-SOP-0134-03 : date 09 Mar 2018	Complies/ Does not comply
3.	**Reliferon 3MIU, 5MIU (Recombinant Human Interferon Alpha 2b Injection)**	Identification (Bioassay)	I.P 2018, Page 4027,Vol. III RLS-CQCQ-SOP-0296-01 Date 22 Jun 2018	Qualitative

Bhumi Rajyaguru
Convenor

Alok Jain
Program Director

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Assay (Bioassay)	I.P 2018, Page 4029,Vol. III RLS-CQCQ-SOP-0296-01 Date 22 Jun 2018	Potency: Minimum 80 per cent Maximum 125 per cent of the stated potency
		Bacterial Endotoxin	I.P 2018,2.2.3, Page 4029, Vol.III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:1 EU/MIU Max:2 EU/MIU Limit: NMT 2EU/MIU
		Sterility	I.P 2018,2.2.11, Page 4029, Vol.III SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
4.	**Relipoietin (Recombinant Human Erythropoietin injection)**	Identification (Bioassay)	I.P 2018, Page3973, Vol. III SOP: RLS-CQC-SOP-0141-03 date 07 Apr 2018	Qualitative
		Assay (Bioassay)	I.P 2018, Page3975, Vol.III SOP: RLS-CQC-SOP-0141-03 date 07 Apr 2018	Potency: Minimum 80% Maximum 125% of the stated Potency Activity Minimum 1600 IU Maximum 2500IU of 2000IU, Minimum 3200 IU Maximum 5000IU of 4000IU, Minimum 8000IU Maximum 12500IU of 10000IU.
		Bacterial Endotoxin	I.P 2018,2.2.3, Page 3975, Vol.III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:10EU/10000IU Max:20EU/10000IU Limit: NMT 20EU/10000IU

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Sterility	I.P 2018,2.2.11, Page 3975, Vol.III SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
5.	**MIRel (Reteplase-Recombinant tissue plasminogen activator)**	Bacterial Endotoxin	I.P 2018,2.2.3, Page 28, Vol.I SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:4.5EU/mg Max: 9EU/mg Limit: NMT 9EU/mg
		Sterility	I.P 2018, 2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
6.	**Human Normal Immunoglobulin (I.P/E.P)**	Sterility	I.P 2018,2.2.11, Page 3936 , Vol.III SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
		Bacterial endotoxin	I.P 2018, 2.2.3, Page 3936, Vol.III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.3IU/ml Max: 0.5IU/ml Limit: NMT 0.5IU/ml
7.	**ReliBeta 30µg (Recombinant Interferon Beta 1a injection)**	Identification (Bioassay)	SOP:RLS-CQCQ-SOP-0296-01 Date 22 Jun 2018	Qualitative
		Assay (Bioassay)	SOP:RLS-CQCQ-SOP-0296-01 Date 22 Jun 2018	Potency Minimum 1.6×10^8 IU/mg Maximum 2.5×10^8 IU/mg
		Bacterial Endotoxin	I.P 2018,2.2.3, Page 28,Vol.I SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:25EU/dose Max: 50EU/dose Limit: NMT 50EU/dose
		Sterility	I.P 2018,2.2.11,Page 59,Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
8.	**RituxiRel 100 & 500mg (Rituximab)**	Identification (Activity: Invitro bioassay)	SOP:RLS-CQC-SOP-0284-03 date 18 Apr 2018	Qualitative
		Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.17EU/mg Max:0.35EU/mg LIMIT: NMT 0.35 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
		Activity (Invitro bioassay)	SOP:RLS-CQC-SOP-0284-03 date 18 Apr 2018	Potency Minimum 80% Maximum 125% of the reference standard
9.	**TrastuRel 150mg & 440mg (Trastuzumab)**	Identification (Bioassay)	SOP: RLS-CQC-SOP-0140-01date :10 Oct 2016	Qualitative
		Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.4EU/mg Max: 0.8EU/mg Limit: NMT 0.8 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
		Bioassay: Anti proliferation Assay	SOP: RLS-CQC-SOP-0140-01 date :10 Oct 2016	Potency of Minimum 80% and Maximum 125% of the reference standard
10.	**BevaciRel 100mg & 400mg (Bevacizumab)**	Identification (VEGF Binding assay by ELISA)	SOP:RLS-CQC-SOP-0253-01 Date 12 Jan 2017	Qualitative
		Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I	Min:0.85EU/mg Max: 1.75EU/mg

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Limit: 1.75 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
11.	**HemoRel-A Dried Factor VIII Fraction, B.P – 250 I.U. (Double Viral Inactivated) (IP/BP)**	Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
12.	**FostiRel 75 IU, 150 IU,300 IU/ 900 IU/1200 IU/2000 IU (Recombinant Human Follicle Stimulating Hormone)**	Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP:RLS-CQC-SOP-0156- date : 13 Dec 2016	Min: 10 IU/ml Max: 20 IU/ml Limit: NMT 20 IU/ml
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
		In Vivo potency assay	SOP:RLS-CQC-SOP-0273-01 date 17 Apr 2018	Minimum:60 IU/ml Maximum :600 IU/ml
13.	**Infimab 100 mg (Infliximab powder for concentrate for solution for infusion)**	Identification (L929 Cell based bioassay)	SOP:RLS-CQC-SOP-0072-02 Date 22 Mar 2018	Qualitative
		Assay (Potency in L929 cell protection assay)	SOP;RLS-CQC-SOP-0072-02 Date 22 Mar 2018	Potency Minimum 73% Maximum 137% of the reference standard
		Bacterial Endotoxins	I.P 2018 ,2.2.3,Page 28, Vol.I SOP:RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.5EU/mg Max: 1EU/mg Limit: NMT 1.0 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I	Complies/ Does not comply

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	
14.	**DarbeRel 25 µg, 40µg, 60µg, 100µg, 150µg, 200µg, 300µg and 500µg (Darbepoetin Alfa for Injection)**	Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP:RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.05EU/µg Max: 0.10EU/µg Limit: NMT 0.10 EU/ µg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
15.	**AbcixiRel (Abciximab Injection)**	Identification (Activity: Receptor binding assay)	RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	Qualitative
		Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP:RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:17.5EU/mg Max: 35EU/mg Limit: NMT 35 EU/mg
16.	**Pegfilgrastim 6mg injection**	Identification (Invitro Potency)	RLS-CQC-SOP-0295-01 date 20 Jun 2018	Qualitative
		Bacterial Endotoxin	I.P 2018 ,2.2.3,Page 28, Vol.I SOP:RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:25EU/mg Max: 50EU/mg Limit: NMT 50 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
17.	**AdaliRel 20mg, 40mg (Adalimumab)**	Identification (L929 cytotoxicity inhibition bioassay)	SOP:RLS-CQC-SOP-0035-01date 27 Jul 2016	Complies/ Does not comply
		Assay(Potency in L929 cell protection assay)	Assay(Potency in L929 cell protection assay)	Potency Minimum 80.00% Maximum 125.00% of the reference standard.
		Bacterial Endotoxins	I.P 2018 ,2.2.3,Page 28, Vol.I	Min:2.5EU/mg Max: 5EU/mg

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			SOP:RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Limit: NMT 5 EU/mg
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Qualitative
18.	**HepaRel-Hepatitis B**	Immunoglobulin (100 IU / 200 IU)	I.P 2018,2.2.11, Page 59, Vol.I RLS-QC-01-FPSTP-0009-03 date 11 Oct 2017	Potency Minimum 80.00% Maximum 125.00% of the reference standard.
		Sterility	I.P 2018,2.2.11, Page 59, Vol.I SOP:RLS-CQC-SOP-0134-03 date 09 Mar 2018	Complies/ Does not comply
II.	**WATER**			
1.	**Water for Injection**	Bacterial Endotoxin	I.P 2018, 2.2.3, Page 3517, Vol.III SOP: RLS-CQC-SOP-0156-03 date : 13 Dec 2016	Min:0.125 EU/ml Max:0.25 EU/ml
		Microbial Monitoring (per100 ml)(Total Viable aerobic count)	I.P 2018,2.2.9, Page 3517, Vol.III RLS-CQC-RMSTP-0026-01 date:- 19 Jan 2016 RLS-CQC-RMSPC-0055-01 date:- 19 Jan 2016	Minimum:01 CFU/100ml Maximum:10 cfu/100 ml Limit: Not More than10 CFU / 100 ml
		Pathogens : E.coli Salmonella spp. Pseudomonas spp. S.aureu)	I.P 2018,2.2.9, Page 3517, Vol.III RLS-CQC-RMSTP-0026-01 date:- 19 Jan 2016 RLS-CQC-RMSPC-0055-01 date:- 19 Jan 2016	Absent or present / gm or ml
2.	**Water purified**	Microbial Monitoring (per ml)(Total Viable aerobic count)	I.P 2018,2.2.9, Page 3516, Vol.III RLS-CQC-RMSTP-0025-01	Minimum: 1 CFU/ml. Maximum: 100 CFU/ml Limit: Not More than100

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			date:- 19 Jan 2016 RLS-CQC-RMSPC-0054-01 date:- 19 Jan 2016	CFU / ml
		Pathogens (per100 ml) E.coli Salmonella spp. Pseudomonas spp. S.aureus	I.P 2018,2.2.9, Page 3516, Vol.III RLS-CQC-RMSTP-0025-01 date:- 19 Jan 2016 RLS-CQC-RMSPC-0054-01 date:- 19 Jan 2016	Absent or present / gm or ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		CHEMICAL TESTING		
I.	**DRUGS &PHARMACEUTICALS**			
1.	**RAW MATERIALS (API)**			
a.	**Acetonitrile**	Identification by UV-Visible - Spectrophotometry	IP 2018 Vol I Pg.890	UV-VIS 230 nm to 420 nm
b.	**Glycine**	Identification by IR - Spectrophotometry	Ph Eur Vol II Pg. 2608	4000 to 650 cm-1
c.	**Sodium acetate trihydrate**	Chloride Reducing substances Arsenic Iron Sulphate	IP 2018 Vol II Pg. 2188 IP 2018 Vol III Pg.3200 IP 2018 Vol III Pg. 3200 IP 2018 Vol III Pg. 3200 IP 2018 Vol III Pg. 3200	Qualitative Qualitative Qualitative Qualitative Qualitative
d.	**Sodium chloride**	Appearance Loss on drying Bromides Iodides	IP 2018 Vol III Pg. 3208 IP 2018 Vol III Pg.3209 IP 2018 Vol III Pg.3209 IP 2018 Vol III Pg. 3209	Qualitative 0.1 % to 10.0 % Qualitative Qualitative
e.	**Kanamycin sulphate**	Melting point/Melting Range (Part of Identification test)	IP 2018 Vol II Pg. 2345	40 to 320 °C
f.	**Sodium Hydroxide**	pH	IP 2018 Vol III Pg. 3220	1.0 to 12.8
g.	**Isopropyl alcohol**	Refractive index	IP 2018 Vol II Pg. 2326	1.3 to 1.7
h.	**Ethanol**	Relative density	IP 2018 Vol II Pg.1993	0.6 to 1.0
i.	**Sucrose**	Sulphated ash	IP 2018 Vol III Pg. 3274	0.01% to 30%
j.	**Sorbitol**	Water	IP 2018 Vol III Pg. 3248	0.05 to 61 %
k.	**Purified water**	Nitrate	IP 2018 Vol III Pg. 3516	Qualitative
l.	**Monosodium phosphate monohydrate**	Phosphates (Part of identification test)	IP 2018 Vol III Pg. 3232	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
m.	**Sodium carbonate**	Carbonates	IP 2018 Vol III Pg. 3208	Qualitative
2	**Finished Products**			
a.	**Human Normal Albumin I.P. /B.P. 20% Total protein**	Acidity or Alkalinity / pH	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.544	(-)1.0 to12.8
		Total protein by Kjeldhal method	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.544	0.05 % to 31%
		Identification test by precipitation test & Immunoelectrophoresis	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.544	Qualitative
		Identification test by SDS PAGE / Protein composition by zone electrophoresis	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.544	Qualitative
		Haem content	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.54	0.01 to 1.00
		Molecular Size Distribution	IP 2018 vol. III Page.No.3920 BP 2018 vol. IV Page No.544	0 % to 10%
b.	**Human Normal Immunoglobulin I.P./B.P**	Distribution of molecular size	IP 2018 vol. III Page.No.3931 BP 2018 vol. IV Page.No.572	0 % to 3%
		Anti-complementary activity	IP 2018 vol. III Page.No.3932 BP 2018 vol. IV Page.No.572	1% to 100%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Anti-A & anti-B Haemagglutinins	IP 2018 vol. III Page.No.3935 BP 2018 vol. IV Page.No.572	Qualitative
		Anti-D antibodies	IP 2018 vol. III Page.No.3935 BP 2018 vol. IV Page.No.572	Qualitative
		IgA content	IP 2018 vol. III Page.No.3936 BP 2018 vol. IV Page.No.572	0.5 mg/L to 160 mg/L
		Antibody to hepatitis B surface antigen	IP 2018 vol. III Page.No.3936 BP 2018 vol. IV Page.No.572	0.1 IU/g to 100 IU/g
c.	**Religrast (Filgrastim injection)**	Total protein by Kjeldhal method	IP 2018 vol. III Page.No.3931 BP 2018 vol. IV Page No.572	0.05 % to 31%
		Identification by SEC HPLC	(IP 2018 Vol. III Page No. 3981	Qualitative
		Identification by SDS PAGE	(IP 2018 Vol. III Page No. 3981)	Qualitative
		pH (at 20-25°C)	(IP 2018 Vol. III Page No. 3981)	1.0 to 12.8
		Related proteins (by RP-HPLC)	(IP 2018 Vol. III Page No. 3981-3982)	Total impurity: Minimum : 0 % Maximum: 3.5% Single impurity Minimum : 0 % Maximum: 2.0%
		Dimers and Related Substances of Higher Molecular Mass	(IP 2018 Vol. III Page No. 3982-3983)	Minimum : 0 % Maximum :2.0%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Assay (Protein: by RP -HPLC)	(IP 2018 Vol. III Page No. 3983)	Minimum: 480 µg/ml Maximum: 750 µg/ml
		Impurities by SDS PAGE	(IP 2018 Vol. III Page No. 3981)	Qualitative
d.	**Reliferon 3MIU, 5MIU (Recombinant Human Interferon Alpha 2b Injection)**	Identification by RP-HPLC	(IP 2018 Vol. III Page No. 4027)	Qualitative
		Identification by SDS PAGE	(IP 2018 Vol. III Page No. 402	Qualitative
		pH (at 20-25°C)	(IP 2018 Vol. III Page No. 4027)	1 to 12.8
		Impurities by SDS PAGE	(IP 2018 Vol. III Page No. 4027-4028) (8th Edition)	Qualitative
		Related proteins by RP HPLC	(IP 2018 Vol. III Page No. 4028-4029)	Total impurity: Minimum: 0 % Maximum: 3 % Single impurity: Minimum: 0 % Maximum: 5 %
e.	**Relipoietin (Recombinant Human Erythropoietin injection)**	Identification (by Immunoblotting)	(IP 2018 Vol. III Page No. 3973-3974	Qualitative
		Identification (by RP-HPLC)	(IP 2018 Vol. III Page No. 3974)	Qualitative
		pH (at 20-25°C)	(IP 2018 Vol. III Page No. 3974)	1 to 12.8
		Dimers and Related Substances of Higher Molecular Mass	(IP 2018 Vol. III Page No. 3974-3975)	Minimum: 0 % Maximum:2.0%
f.	**MIRel (Reteplase-Recombinant tissue plasminogen activator)**	Reconstitution time	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018	Qualitative
		pH after reconstitution (at 20-25°C)	RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	1 to 12.8
		Identification (by SDS-Page)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Identification (by Western blot)	RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Qualitative
		Identification (by RP-HPLC)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018	Qualitative
		Identification (by Isoelectric Focusing)	RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Qualitative
		Purity (by SEC- HPLC)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018 RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Monomer content : Minimum: 95.0% Maximum:100.0%
		Assay (Protein concentration by SEC-HPLC	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018 RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Total impurity: Minimum: 0 % Maximum:5.0
		Assay (Activity by chromozym enzymatic assay)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018 RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Minimum:1.44 mg/ml Maximum:2.16 mg/ml
		Assay (Specific activity: Activity by chromozym assay / protein concentration by SEC-HPLC)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018 RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Minimum: 0.80 Units/ml Maximum: 1.25 Units/ml Minimum: 0.44 Units/mg Maximum: 0.66 Units/mg
		Moisture content (By KF)	RLS-CQC-FPSPC-0035-02 date 31 Mar 2018 RLS-CQC-FPSTP-0024-02 date 31 Mar 2018	Minimum: 0% Maximum:6.50 %
g.	**ReliBeta 30µg (Recombinant Interferon Beta 1a injection)**	Identification (Examine by SDS-Page)	RLS-CQC-FPSPC-0015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	Qualitative
		Identification (Examine by Western blot)	RLS-CQC-FPSPC-0015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Purity By (RP-HPLC)	RLS-CQC-FPSPC-0015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	Single impurity Minimum: 0% Maximum:5.0 % Total impurities: Minimum: 0% Maximum:7.0%
		Assay (Protein concentration)	RLS-CQC-FPSPC-00150015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	Purity: Minimum:93.0% Maximum:100.0%
		pH (20-25ºC)	RLS-CQC-FPSPC-00150015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	48 µg/ml to 75 µg/ml
		Arginine hydrochloride content	RLS-CQC-FPSPC-00150015-05 date 28 Mar 2018 RLS-CQC-FPSTP-0013-03 date 26 Aug 2016	1 to 12.8 Minimum:120.0 mM Maximum:300.0 mM
h.	**RituxiRel 100 & 500mg (Rituximab)**	pH	RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg) RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg)	1 to 12.8
		Identification (by SEC-HPLC)	RLS-CQC-FPSTP-0004-01 date 11 May 2015 RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg)	Qualitative
		Identification (by Reducing and Non-Reducing SDS PAGE)	RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg) RLS-CQC-FPSTP-0004-01 date 11 May 2015	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Identification (by Western blotting reducing and non-reducing)	RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg) RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg)	Qualitative
		Identification (by SCX-HPLC)	RLS-CQC-FPSTP-0004-01 date 11 May 2015 RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg)	Qualitative
		Assay: Protein Concentration (by A280nm)	RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg) RLS-CQC-FPSTP-0004-01 date 11 May 2015	Minimum:9.0mg/ml Maximum:11.0 mg/ml
		Purity (by SEC-HPLC)	RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg) RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg) RLS-CQC-FPSTP-0004-01 date 11 May 2015 RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg) RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg) RLS-CQC-FPSTP-0004-01 date 11 May 2015 RLS-CQC-FPSPC-0005-03 date 18 May 2017 (100mg)	Monomer content : Minimum: 95% Maximum:100 % High molecular weight species: Minimum: 0% Maximum:3% Low molecular weight species: Minimum: 0% Maximum:2%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			RLS-CQC-FPSPC-0006-02 date 03 Sep 2015 (500mg) RLS-CQC-FPSTP-0004-01 date 11 May 2015	
i.	**TrastuRel 150mg & 440mg (Trastuzumab)**	Reconstitution time	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Qualitative
		Identification (by Weak Cation Exchange HPLC)	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Qualitative
		Identification (by SEC HPLC)	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Qualitative
		pH	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	1 to 12.8
		Purity (by WCX HPLC)	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Acidic variants: Minimum:0.00 % Maximum:35.00 % Basic variants: Minimum:0.00 % Maximum:20.00 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Assay (Protein concentration by A280nm)	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Protein Conc: Minimum:18.90 Maximum:23.10 mg/mL
		Moisture content (By KF)	RLS-CQC-FPSPC-0023-03 date 16 May 2017 (440mg) RLS-CQC-FPSPC-0022-04 date19 May 2017 (150mg) RLS-CQC-FPSTP-0020-05 date 15 May 2017	Minimum: 0% Maximum: 5%
j.	**BevaciRel 100mg & 400mg (Bevacizumab)**	pH (20-25°C)	RLS-CQC-FPSPC-0028-02 date 03 May 2018 (100mg) RLS-CQC-FPSPC-0027-02 date 03 May 2018 (400mg) RLS-CQC-FPSTP-0018-03 date 03 May 2018	1 to 12.8
		Identification (Examine by SEC-HPLC)	RLS-CQC-FPSPC-0028-02 date 03 May 2018 (100mg) RLS-CQC-FPSPC-0027-02 date 03 May 2018 (400mg) RLS-CQC-FPSTP-0018-03 date 03 May 2018	Qualitative
		Protein concentration by A280nm	RLS-CQC-FPSPC-0028-02 date 03 May 2018 (100mg) RLS-CQC-FPSPC-0027-02 date 03 May 2018 (400mg) RLS-CQC-FPSTP-0018-03 date 03 May 2018	Minimum: 20.0 mg/ml Maximum:30.0 mg/ml (100mg) Minimum: 25.0 mg/ml Maximum: 26.3 mg/ml (400mg)
		Purity (by SEC-HPLC)	RLS-CQC-FPSPC-0028-02 date 03 May 2018 (100mg) RLS-CQC-FPSPC-0027-02 date 03 May 2018 (400mg) RLS-CQC-FPSTP-0018-03	Monomer content : Minimum: 92.0% Maximum:100.0%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			date 03 May 2018	High molecular weight species: Minimum: 0.0% Maximum:6.0% Low molecular weight species: Minimum: 0.0% Maximum: 2.0%
k.	**HemoRel-A Dried Factor VIII Fraction, B.P – 250 I.U./500 I.U. (Double Viral Inactivated) (IP/BP)**	Identity(By Potency assay)	IP 2018 vol. III Page.No.3915 BP 2018 vol. IV Page.No.556	Qualitative
		Solubility	IP 2018 vol. III Page.No.3913 BP 2018 vol. IV Page.No.555	Qualitative
		pH (at 20-25°C)	IP 2018 vol. III Page.No.3913 BP 2018 vol. IV Page.No.555	1 to 12.8
		Assay: Potency (By chromogenic method)	IP 2018 vol. III Page.No.3915 BP 2018 vol. IV Page.No.556	0.015 IU-600 IU
l.	**FostiRel 300 IU/ 900 IU/1200 IU/2000 IU 150IU 75 IU (Recombinant Human Follicle Stimulating Hormone)**	Identification (Examine by SDS-Page)	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU) RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051-01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Identification (Examine by Western blot)	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU) RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051-01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	Qualitative
		Benzyl alcohol content	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU) RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051-01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	Minimum: 8.0 mg/ml Maximum: 12.0 mg/ml
		Purity (by SEC-HPLC)	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU) RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051-01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	A: Monomer content : Minimum:92.0% Maximum:100.0% B:Low molecular weight: Minimum:0.0% Maximum:6.0% C High molecular weight: Minimum:0.0% Maximum:2.0%
		pH (20-25°C)	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU)	1 to 12.8

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051 -01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	
		Assay (Protein Concentration by SEC-HPLC)	RLS-CQC-FPSPC-0050-01 date 12 Dec 2015 (300 IU) RLS-CQC-FPSPC-0048-01 date 12 Dec 2015 (900 IU) RLS-CQC-FPSPC-0049-01 date 12 Dec 2015 (1200 IU) RLS-CQC-FPSPC-0051-01 date 12 Dec 2015 (2000 IU) RLS-CQC-FPSTP-0034-01 date 12 Dec 2015	10 to 150 µg/ml
m.	**Infimab 100 mg (Infliximab powder for concentrate for solution for infusion)**	Reconstitution time	RLS-CQC-FPSPC-0019-03 date 06 Sep 2017 RLS-CQC-FPSTP-0017-03 date 06 Sep 2017	Qualitative
		pH after reconstitution	RLS-CQC-FPSPC-0019-03 date 06 Sep 2017	1 to 12.8
		Identification (by Weak Cation Exchange HPLC)	RLS-CQC-FPSTP-0017-03 date 06 Sep 2017	Qualitative
		Purity by SE-HPLC	RLS-CQC-FPSPC-0019-03 date 06 Sep 2017 RLS-CQC-FPSTP-0017-03 date 06 Sep 2017	Minimum: 98.0%. Maximum:100.0 %
		Assay (Protein concentration by A280nm)	RLS-CQC-FPSPC-0019-03 date 06 Sep 2017 RLS-CQC-FPSTP-0017-03 date 06 Sep 2017	Minimum: 9.0 mg/ml Maximum: 11.0 mg/ml

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Moisture content by KF	RLS-CQC-FPSPC-0019-03 date 06 Sep 2017 RLS-CQC-FPSTP-0017-03 date 06 Sep 2017	Minimum: 0.00% Maximum:5.00%
n.	**DarbaRel 25 µg, 40µg, 60µg, 100µg, 150µg, 200µg, 300µg and 500µg (Darbepoetin Alfa for Injection)**	pH (20-25°C)	RLS-CQC-FPSPC-0018-03 date 22 Oct 2016 RLS-CQC-FPSTP-0015-03 date 22 Oct 2016	1 to 12.8
		Identification (Examine by Polyacrylamide gel electrophoresis)	RLS-CQC-FPSPC-0018-03 date 22 Oct 2016 RLS-CQC-FPSTP-0015-03 date 22 Oct 2016	Qualitative
		Identification (Examine by RP-HPLC	RLS-CQC-FPSPC-0018-03 date 22 Oct 2016 RLS-CQC-FPSTP-0015-03 date 22 Oct 2016	Qualitative
		Purity (by SEC-HPLC)	RLS-CQC-FPSPC-0018-03 date 22 Oct 2016 RLS-CQC-FPSTP-0015-03 date 22 Oct 2016	Minimum:95.00 % Maximum:100.00%
		Protein Concentration (by RP-HPLC)	RLS-CQC-FPSPC-0018-03 date 22 Oct 2016 RLS-CQC-FPSTP-0015-03 date 22 Oct 2016	25 µg/ml to 600 µg/mL
o.	**AbcixiRel (Abciximab Injection)**	Identification (Examine by SDS-Page)	RLS-CQC-FPSPC-0024-01 date 30 Sep 2015 RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	Qualitative
		Identification (Examine by Western blot)	RLS-CQC-FPSPC-0024-01 date 30 Sep 2015 RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	Qualitative Qualitative
		Identity test (By SCX-HPLC)	RLS-CQC-FPSPC-0024-01 date 30 Sep 2015	Monomer content : Minimum: 95.0% Maximum:100.0%

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	High molecular weight species: Minimum: 0.0% Maximum:3.0%
		Purity (by SEC-HPLC)	RLS-CQC-FPSPC-0024-01 date 30 Sep 2015 RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	Low molecular weight species: Minimum: 0.0% Maximum:2.0%
		Assay (Protein Concentration by A 280nm)	RLS-CQC-FPSPC-0024-01 date 30 Sep 201 RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	Minimum: 1.9 mg/ml Maximum: 2.2 mg/ml
		pH (20-25°C)	RLS-CQC-FPSPC-0024-01 date 30 Sep 2015 RLS-CQC-FPSTP-0019-01 date 30 Sep 2015	1 to 12.8
p.	**Pegfilgrastim 6mg injection**	Identification (by SDS-Page)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Qualitative
		Identification (by SDS PAGE (PEG Staining))	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Qualitative
		Identification (by SEC-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Qualitative
		Identification (by RP-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Qualitative
		Related Proteins (Purity by RP-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017	Minimum:0.0 % Maximum:5.0 %

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
			RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Monomer content : Minimum: 95.0% Maximum:100.0 %
		Related Proteins (Purity by SEC-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	High molecular weight species: Minimum: 0.0% Maximum:3.0 % Low molecular weight species: Minimum: 0.0% Maximum:2.0 %
		Related Proteins (Purity of Un-conjugated GCSF by RP-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Minimum: 0.0% Maximum:2.0 %
		Assay (Protein Concentration by RP-HPLC)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	Minimum: 9.2 mg/ml Maximum: 11.3 mg/ml
		pH (20-25 °C)	RLS-CQC-FPSPC-0002-02 date 21 Sep 2017 RLS-CQC-FPSTP-0002-02 date 21 Sep 2017	1 to 12.8
q.	**AdaliRel 20mg, 40mg (Adalimumab)**	pH(20-25°C)	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	1 to 12.8
		Identification (Examine by SEC HPLC)	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	Qualitative
		Identification (Examine by Weak Cation Exchange (WCX-HPLC))	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	Qualitative

Sl.	Product / Material of Test	Specific Test Performed	Test Method Specification against which tests are performed	Range of Testing / Limits of Detection
		Assay protein concentration by A280nm	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	Minimum: 48.69 mg/ml Maximum:53.81 mg/ml
r.	**HepaRel- Hepatitis B Immunoglobulin (100 IU / 200 IU)**	Purity(by SEC HPLC)	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	A: Monomer content: Minimum:95.0% Maximum: 100.0 %
		Purity (by WCX HPLC)	RLS-CQC-FPSPC-0025-03 date 20 Sep 2017 RLS-CQC-FPSTP-0016-04 date 20 Sep 2017	B: High molecular weight species: Minimum:0.0% Maximum: 3.0 % C: Low Molecular weight Species: Minimum:0.0% Maximum: 2.0 % Acidic variants: Minimum: 0 % Maximum: 15% and Basic variants: Minimum: 0 % Maximum: 30%
		Immunoelectrophoresis	IP 2018 vol. III Page.No.3930	Qualitative
		pH	IP 2018 vol. III Page.No.3930	1 to 12.8
		Hepatitis B immunoglobulin Potency	IP 2018 vol. III Page.No.3919	80-220 IU/ml
		Protein Composition	IP 2018 vol. III Page.No.3931	Qualitative
		Total Protein	IP 2018 vol. III Page.No.3931	10%-50%
		Molecular Size	IP 2018 vol. III Page.No.3931	0-10%