

**Quality Control (QC) Tests conducted on Biologicals at
National Institute of Biologicals, NOIDA**

S. No.	Name of test & Method	Blood Grouping reagents
1	Appearance (Macroscopically)	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin 18. Bovine Serum Albumin 19. Microplate for Forward Grouping 20. Microplate for Forward & Reverse Grouping 21. Blood Grouping cards for Forward Grouping 22. Gel cards for Forward Grouping 23. Gel cards for Forward & Reverse Grouping 24. Gel cards for Forward Grouping for Newborns 25. Gel cards for Subgrouping 26. Gel cards for Direct Antiglobulin Test
2	Color (Macroscopically)	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti Human Globulin 16. Bovine Serum Albumin

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3	Potency, (Tube Method)	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG)
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S. No.	Name of test & Method	Blood Grouping reagents
3 contd.	Potency, contd. (Tube Method)	<ol style="list-style-type: none"> 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin
4	Specificity, Slide Method	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin 18. Bovine Serum Albumin 19. Microplate for Forward Grouping 20. Microplate for Forward & Reverse Grouping 21. Blood Grouping cards for Forward Grouping 22. Gel cards for Forward Grouping 23. Gel cards for Forward & Reverse Grouping 24. Gel cards for Forward Grouping for Newborns 25. Gel cards for Subgrouping 26. Gel cards for Direct Antiglobulin Test

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5	Avidity Slide Method	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin)
6	Intensity, Tube method	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk)

S. No.	Name of test & Method	Blood Grouping reagents
6 contd	Intensity, contd. Tube method	<ol style="list-style-type: none"> 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin

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7	Rouleaux	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin 18. Bovine Serum Albumin
8	Haemolysis	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk) 6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A₁(Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin 18. Bovine Serum Albumin
9	Prozone	<ol style="list-style-type: none"> 1. Anti-A 2. Anti-A (Bulk) 3. Anti-A (Concentrate Bulk) 4. Anti-B 5. Anti-B(Bulk)

S. No.	Name of test & Method	Blood Grouping reagents
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9 contd	Prozone, contd	6. Anti-B (Concentrate Bulk) 7. Anti-A,B 8. Anti-D(IgM) 9. Anti-D(IgM) (Bulk) 10. Anti-D(IgM) (Concentrate Bulk) 11. Anti-D(IgM+IgG) 12. Anti-D(IgM+IgG) Bulk) 13. Anti-D(IgM+IgG) (Concentrate Bulk) 14. Anti-D(IgG) 15. Anti-A ₁ (Lectin) 16. Anti-H(Lectin) 17. Anti Human Globulin 18. Bovine Serum Albumin
10	Potentiating Ability	1. Bovine Serum Albumin
11	IgG Contamination	1. Bovine Serum Albumin

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S. No.	Name of test & Method	Blood Products
1	Test for pH by Potentiometry	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV , Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM, Human Coagulation Factor VIII, Human Coagulation Factor IX, Human Fibrinogen, Fibrin sealant Kit, Anti-Thrombin III Concentrate, Anti-Inhibitor Coagulant Complex
2	Test for identification by Double immunodiffusion Method	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV , Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM
3	Test for total protein by Kjeldahl Method	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV, Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM
4	Test for total protein by Biuret Method	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV , Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM
5	Test for Molecular Size Distribution by Size Exclusion Chromatography	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV, Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM
6	Test for Purity by SDS-PAGE	<ol style="list-style-type: none"> Human Albumin, Human Normal Immunoglobulin IV , Human Normal Immunoglobulin IM, Specific Immunoglobulin IV/IM
7	Test for Haem Content by UV- Vis Spectrophotometry	<ol style="list-style-type: none"> Human albumin
8	Test for stability by visual inspection after heating at 57°C for 50 hours	<ol style="list-style-type: none"> Human albumin
9	Test for Osmolality by Osmometry	<ol style="list-style-type: none"> Human albumin, Human Normal Immunoglobulin IV, Specific Immunoglobulin IV, Human Coagulation Factor VIII, Human Coagulation Factor IX, Anti-Thrombin III concentrate,

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		7. Human Coagulation Factor IX, 8. Anti-Inhibitor Coagulant Complex
10	Test for potency by Chromogenic Method	1. Human Coagulation Factor VIII
11	Physical Characteristics by Visual Inspection	1. Human Coagulation Factor VIII, 2. Fibrin Sealant Kit

S. No.	Name of test & Method	Blood Products
12	Test for solubility by Visual Inspection	1. Human Coagulation Factor VIII, 2. Human Coagulation Factor IX, 3. Anti-Thrombin III concentrate, 4. Anti-Inhibitor Coagulant Complex
13	Test for Anti-A Anti-B by haemagglutination method	1. Human Normal Immunoglobulin IV, Specific 2. Immunoglobulin IV, 3. Human Coagulation Factor VIII(plasma derived)
14	Test for sterility by Membrane filtration/ Direct Inoculation	1. Human Albumin, 2. Human Normal Immunoglobulin IV, 3. Human Normal Immunoglobulin IM, 4. Specific Immunoglobulin IV/IM, 5. Human Coagulation Factor VIII, 6. Human Coagulation Factor IX, 7. Human Fibrinogen, 8. Fibrin sealant Kit, 9. Anti-Thrombin III Concentrate, 10. Anti-Inhibitor Coagulant Complex
15	Test for Abnormal toxicity : Mice and Guinea Pig	1. Human Albumin, 2. Human Normal Immunoglobulin IM, 3. Specific Immunoglobulin IM, 4. Human Coagulation Factor VIII (Plasma Derived)
16	Test for Pyrogen: Rabbit inoculation	1. Human Albumin, 2. Human Normal Immunoglobulin IV , 3. Human Normal Immunoglobulin IM, 4. Specific Immunoglobulin IV/IM, 5. Human Coagulation Factor VIII, 6. Human Coagulation Factor IX, 7. Human Fibrinogen, 8. Anti-Thrombin III Concentrate
17	Bacterial Endotoxin Test by Gel Clot method	1. Human Recombinant Coagulation Factor VIII

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18	Test for Viral markers : Anti HIV 1 &2, HBsAg , Anti-HCV by Immunoassay	<ol style="list-style-type: none"> 1. Human Albumin, 2. Human Normal Immunoglobulin IV , 3. Human Normal Immunoglobulin IM, 4. Specific Immunoglobulin IV/IM, 5. Human Coagulation Factor VIII, 6. Human Coagulation Factor IX, 7. Human Fibrinogen, 8. Fibrin sealant Kit, 9. Anti-Thrombin III Concentrate, 10. Anti-Inhibitor Coagulant Complex
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S. No.	Name of QC tests	Biochemical Kit
1.	Precision at Normal Glucose level	1. Glucose Reagent (Analyzer- based)
2.	Precision at Pathological Glucose level	1. Glucose Reagent (Analyzer- based)
3.	Repeatability at Low glucose level	1. Blood Glucose Test Strips
4.	Repeatability at Normal glucose level	1. Blood Glucose Test Strips
5.	Repeatability at High glucose level	1. Blood Glucose Test Strips
6.	Intermediate Precision at Normal Glucose level	1. Blood Glucose Test Strips
7.	Intermediate Precision at High Glucose level	1. Blood Glucose Test Strips
8.	Bias at Medical decision level for Glucose	<ol style="list-style-type: none"> 1 Glucose Reagent 2 Blood Glucose Test Strips
9.	System Accuracy	1. Blood Glucose Test Strips
10.	Linearity and Range	1. Glucose Reagent (Analyzer- based)

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S. No.	Name of QC tests	Enzymes And Hormones
1.	Particulate matter and Clarity	1. Streptokinase injection, 2. r-Streptokinase injection, 3. hCG (Bulk), 4. hCG injection, 5. hMG(Bulk), 6. hMG injection, 7. FSH(Bulk), 8. FSH injection , 9. r-FSH, 10. r-FSH(PFS)
2.	Identification by clot lysis	1. Streptokinase Injection, 2. r-Streptokinase injection, 3. Streptokinase(Bulk), 4. Urokinase
3.	pH determination by Potentiometry	1. Streptokinase injection, 2. r-Streptokinase injection, 3. Streptokinase(Bulk), 4. Urokinase, 5. Enoxaparin (Bulk), 6. Enoxaparin injection, 7. hCG (Bulk), 8. hCG injection, 9. hMG(Bulk), 10. hMG injection, 11. FSH(Bulk), 12. FSH injection , 13. r-FSH, 14. r-FSH(PFS)
4.	Streptodornase activity	1. Streptokinase injection , 2. Streptokinase(Bulk)
5.	Streptolysin activity	1. Streptokinase injection , 2. Streptokinase(Bulk)
6.	Potency by Chromogenic method	1. Streptokinase injection, 2. r-Streptokinase injection, 3. Streptokinase(Bulk),
7.	Sterility	1. Streptokinase injection, 2. r-Streptokinase injection, 3. Streptokinase(Bulk), 4. Urokinase, 5. hCG (Bulk),

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		6. hCG injection, 7. hMG(Bulk), 8. hMG injection, 9. FSH(Bulk), 10. FSH injection , 11. r-FSH, 12. r-FSH(PFS)
S. No.	Name of QC tests	Enzymes And Hormones
8.	Abnormal toxicity	1. Streptokinase(Bulk), 2. Urokinase, 3. hCG (Bulk), 4. hCG injection
9.	Bacterial Endotoxin	1. Streptokinase injection, 2. r-Streptokinase injection, 3. Streptokinase(Bulk), 4. Urokinase , 5. hCG (Bulk), 6. hCG injection, 7. hMG(Bulk), 8. hMG injection
10.	Hepatitis-B surface antigen marker	1. Urokinase, 2. Enoxaparin, 3. hCG (Bulk), 4. hCG injection, 5. hMG(Bulk), 6. hMG injection, 7. FSH(Bulk), 8. FSH injection
11.	HIV- antibody testing	1. Enoxaparin, 2. hCG (Bulk), 3. hCG injection, 4. hMG(Bulk), 5. hMG injection, 6. FSH(Bulk), 7. FSH injection
12.	HCV-antibody testing	1. Enoxaparin , 2. hCG (Bulk), 3. hCG injection, 4. hMG(Bulk), 5. hMG injection, 6. FSH(Bulk),

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		7. FSH injection
13.	Total Protein content by Kjeldahl method	1. Urokinase
14.	Potency by in-vivo method	1. hCG (Bulk), 2. hCG injection, 3. hMG (Bulk), 4. hMG injection, 5. FSH(Bulk), 6. FSH injection
15.	Luteinizing hormone activity	1. hMG

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S. No.	QC test & Method	Diagnostic kit
1.	Rapid test	<ol style="list-style-type: none"> 1. HIV 1&/2 antibody 2. HCV antibody 3. HBs Antigen 4. Syphilis 5. HIV-HCV combo 6. HIV/HCV/HBc combo
2.	ELISA test	<ol style="list-style-type: none"> 1. HIV 1&/2 antibody 2. HCV antibody 3. HBs Antigen 4. Anti HBs 5. Anti HBc total (IgG & IgM) 6. Anti HBc IgM 7. HBeAg-Ab
3.	CLIA test	<ol style="list-style-type: none"> 1. HIV 1&/2 2. HCV antibody
4.	ELISA 4 th Generation test	<ol style="list-style-type: none"> 1. HIV Ag/Ab 2. HCV Ag/Ab
5.	Confirmatory test	<ol style="list-style-type: none"> 1. HIV 1 2. HIV 2 3. HIV 1&/2 4. HCV

S. No.	QC test & Method	Recombinant Products
1.	Identification- HPLC Reverse Phase	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection 7. Insulin Lispro injection 8. Biphasic Insulin Lispro25/75 injection 9. Biphasic Insulin Lispro 50/50 injection 10. Insulin Aspart injection 11. Biphasic Insulin Aspart 30/70 injection 12. Biphasic Insulin Aspart 50/50 injection 13. Insulin Glulisine injection 14. Insulin Detemir injection 15. Exenatide injection 16. Liraglutide injection 17. Human insulin Bulk 18. Interferon injection

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2.	Identification (peptide mapping)- HPLC Reverse Phase	1. Human insulin Bulk
3.	Identification- SDS- PAGE	1. Erythropoietin injection 2. G-CSF
4.	Identification- HPLC Size exclusion	1. Erythropoietin injection
5.	Total Potency- HPLC Reverse Phase	1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Human Insulin Bulk 7. Insulin Glargine injection 8. Insulin Lispro injection 9. Biphasic Insulin Lispro 25/75 injection 10. Biphasic Insulin Lispro 50/50 injection 11. Insulin Aspart injection 12. Biphasic Insulin Aspart 30/70 injection 13. Biphasic Insulin Aspart 50/50 injection 14. Insulin Glulisine injection 15. Insulin Detemir injection 16. Exenatide injection 17. Liraglutide injection
6.	Potency in supernatant- HPLC Reverse Phase	1. Isophane insulin injection
7.	Soluble insulin human content- HPLC Reverse Phase / Soluble insulin Lispro content- HPLC Reverse Phase / Insulin Aspart in solution- HPLC Size Exclusion	1. Biphasic isophane insulin 25/75 injection 2. Biphasic isophane insulin 30/70 injection 3. Biphasic isophane insulin 50/50 injection 4. Biphasic Insulin Lispro 25/75 injection 5. Biphasic Insulin Lispro 50/50 injection 6. Biphasic Insulin Aspart 30/70 injection 7. Biphasic Insulin Aspart 50/50 injection

S. No.	QC test & Method	Recombinant Products
8.	In vitro Biological activity- ELISA	1. Erythropoietin injection
9.	In vitro Biological activity- Cell proliferation based assay	1. G-CSF injection
10.	In vitro Biological activity- Cytopathic inhibition assay	1. Interferon injection
11.	Related proteins – HPLC Reverse Phase	1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Human Insulin Bulk 7. Insulin Glargine injection 8. Insulin Lispro injection

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		<ul style="list-style-type: none"> 9. Biphasic Insulin Lispro25/75 injection 10. Biphasic Insulin Lispro 50/50 injection 11. Insulin Aspart injection 12. Biphasic Insulin Aspart 30/70 injection 13. Biphasic Insulin Aspart 50/50 injection 14. Insulin Glulisine injection 15. Insulin Detemir injection 16. Exenatide injection 17. Liraglutide injection 18. G-CSF injection 19. Interferon injection
12.	Higher molecular weight proteins – HPLC Size Exclusion	<ul style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Human Insulin Bulk 7. Insulin Glargine injection 8. Insulin Lispro injection 9. Biphasic Insulin Lispro25/75 injection 10. Biphasic Insulin Lispro 50/50 injection 11. Insulin Aspart injection 12. Biphasic Insulin Aspart 30/70 injection 13. Biphasic Insulin Aspart 50/50 injection 14. Insulin Glulisine injection 15. Insulin Detemir injection 16. Exenatide injection 17. Liraglutide injection 18. G-CSF injection
13.	Impurities with molecular masses differing from that of the product- SDS- PAGE	<ul style="list-style-type: none"> 1. G-CSF injection 2. Interferon injection
14.	Zinc metal ion estimation- Atomic Absorption spectrometry	<ul style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection 7. Insulin Lispro injection 8. Biphasic Insulin Lispro 25/75 injection 9. Biphasic Insulin Lispro 50/50 injection

S. No.	QC test & Method	Recombinant Products
14 contd	Zinc metal ion estimation- Atomic Absorption spectrometry Contd.	<ul style="list-style-type: none"> 10. Insulin Aspart injection 11. Biphasic Insulin Aspart 30/70 injection 12. Biphasic Insulin Aspart 50/50 injection 13. Insulin Detemir injection 14. Human Insulin Bulk

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15.	Bacterial Endotoxin- Gel clot	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection 7. Insulin Aspart injection 8. Biphasic Insulin Aspart 30/70 injection 9. Biphasic Insulin Aspart 50/50 injection 10. Insulin Glulisine injection 11. Exenatide injection 12. Liraglutide injection 13. Erythropoietin injection 14. G-CSF injection 15. Interferon injection
16.	Bacterial Endotoxin- Kinetic Chromogenic	<ol style="list-style-type: none"> 1. Insulin Lispro injection 2. Biphasic Insulin Lispro25/75 injection 3. Biphasic Insulin Lispro 50/50 injection 4. Insulin Detemir injection
17.	Sterility- Membrane Filtration	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection 7. Insulin Lispro injection 8. Biphasic Insulin Lispro25/75 injection 9. Biphasic Insulin Lispro 50/50 injection 10. Insulin Aspart injection 11. Biphasic Insulin Aspart 30/70 injection 12. Biphasic Insulin Aspart 50/50 injection 13. Insulin Glulisine injection 14. Insulin Detemir injection 15. Exenatide injection 16. Liraglutide injection
18.	Sterility- Direct inoculation	<ol style="list-style-type: none"> 1. Erythropoietin injection G- 2. CSF injection 3. Interferon injection
19.	Abnormal toxicity- Mice	<ol style="list-style-type: none"> 1. Erythropoietin injection G- 2. CSF injection
20.	Particulate analysis- Light Obscuration	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Insulin Glargine injection 3. Insulin Lispro injection 4. Insulin Aspart injection 5. Insulin Glulisine injection 6. Insulin Detemir injection

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21.	Particulate analysis- Microscopy	<ol style="list-style-type: none"> 1. Isophane insulin injection 2. Biphasic isophane insulin 25/75 injection 3. Biphasic isophane insulin 30/70 injection 4. Biphasic isophane insulin 50/50 injection 5. Biphasic Insulin Lispro25/75 injection 6. Biphasic Insulin Lispro 50/50 injection 7. Biphasic Insulin Aspart 30/70 injection 8. Biphasic Insulin Aspart 50/50 injection
22.	Loss on drying	<ol style="list-style-type: none"> 1. Human Insulin Bulk
23.	Appearance & Color- visual	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection 7. Insulin Lispro injection 8. Biphasic Insulin Lispro25/75 injection 9. Biphasic Insulin Lispro 50/50 injection 10. Insulin Aspart injection 11. Biphasic Insulin Aspart 30/70 injection 12. Biphasic Insulin Aspart 50/50 injection 13. Insulin Glulisine injection 14. Insulin Detemir injection 15. Exenatide injection 16. Liraglutide injection 17. Erythropoietin injection 18. G-CSF injection 19. Interferon injection
24.	Clarity- visual	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Insulin Glargine injection 3. Insulin Lispro injection 4. Insulin Aspart injection 5. Insulin Glulisine injection 6. Insulin Detemir injection 7. Exenatide injection 8. Liraglutide injection 9. Interferon injection
25.	Visible particle- visual	<ol style="list-style-type: none"> 1. Erythropoietin injection
26.	Volume tolerance- Gravimetric	<ol style="list-style-type: none"> 1. Erythropoietin injection G- 2. CSF injection 3. Interferon injection
27.	pH- potentiometric	<ol style="list-style-type: none"> 1. Soluble insulin injection 2. Isophane insulin injection 3. Biphasic isophane insulin 25/75 injection 4. Biphasic isophane insulin 30/70 injection 5. Biphasic isophane insulin 50/50 injection 6. Insulin Glargine injection

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		<ul style="list-style-type: none"> 7. Insulin Lispro injection 8. Biphasic Insulin Lispro25/75 injection 9. Biphasic Insulin Lispro 50/50 injection 10. Insulin Aspart injection
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S. No.	QC test & Method	Recombinant Products
28.	pH- potentiometric contd	<ul style="list-style-type: none"> 11. Biphasic Insulin Aspart 30/70 injection 12. Biphasic Insulin Aspart 50/50 injection 13. Insulin Glulisine injection 14. Insulin Detemir injection 15. Exenatide injection 16. Liraglutide injection 17. Erythropoietin injection 18. G-CSF injection 19. Interferon injection
29.	Osmolality- osmometry	<ul style="list-style-type: none"> 1. Exenatide injection 2. Interferon injection
30.	Viral marker-Anti HIV 1 & 2, Anti HCV, HBsAg ELISA	<ul style="list-style-type: none"> 1. Erythropoietin injection