

Description of content□

The Minimum Requirements for Biological Products shall be partially amended as follows□

1. To revise the following articles under The Minimum Requirements for Biological Products

Influenza Vaccine

Influenza HA Vaccine

Adsorbed New Influenza Vaccine (H5N1 Strain)

Freeze-dried Live Attenuated Mumps Vaccine

Inactivated Rabies Vaccine

Freeze-dried Inactivated Tissue Culture Rabies Vaccine

Cholera Vaccine

Varicella Antigen

Freeze-dried Live Attenuated Varicella Vaccine

Typhoid-paratyphoid Vaccine

Purified Tuberculin

Smallpox Vaccine Prepared in Cell Culture

Freeze-dried Smallpox Vaccine Prepared in Cell Culture

Japanese Encephalitis Vaccine

Freeze-dried Japanese Encephalitis Vaccine

Pertussis Vaccine

Adosorbed Purified Pertussis Vaccine

Diphtheria-pertussis Combined Vaccine

Diphtheria-pertussis-tetanus Combined Vaccine

Adosorbed Diphtheria-purified Pertussis-tetanus Combined Vaccine

Freeze-dried Live Attenuated Rubella Vaccine

Freeze-dried Haemophilus Type b Vaccine (Tetanus Toxoid Conjugate)

Freeze-dried Live Attenuated Measles Vaccine

Freeze-dried Live Attenuated Measles, Mumps, Rubella Combined Vaccine

Freeze-dried Live Attenuated Measles, Rubella Combined Vaccine

Weil's Disease and Akiyami Combined Vaccine

Human Serum Albumin

Freeze-dried Human Fibrinogen

Freeze-dried Human Blood Coagulation Factor VIII

Freeze-dried Concentrated Blood Coagulation Factor VIII

Freeze-dried Human Blood Coagulation Factor IX Complex

Freeze-dried Concentrated Human Blood Coagulation Factor IX

Normal Human Immunoglobulin
Freeze-dried Ion-exchange-resin-treated Normal Human Immunoglobulin
Freeze-dried Sulfonated Normal Human Immunoglobulin
pH 4-treated Normal Human Immunoglobulin
Freeze-dried pH 4-treated Normal Human Immunoglobulin
Freeze-dried Pepsin-treated Normal Human Immunoglobulin
Polyethylene Glycol-treated Normal Human Immunoglobulin
Freeze-dried Polyethylene Glycol-treated Normal Human Immunoglobulin
Human Anti-HBs Immunoglobulin
Freeze-dried Human Anti-HBs Immunoglobulin
Polyethylene Glycol-treated Anti-HBs Immunoglobulin
Freeze-dried Human Anti-D(Rho) Immunoglobulin
Human Anti-tetanus Immunoglobulin
Freeze-dried Human Anti-tetanus Immunoglobulin
Polyethylene Glycol-treated Human Anti-tetanus Immunoglobulin
Human Haptoglobin

2. To add the following 1 test toxin and 4 test solutions under the section of GENERAL TESTS

Standards, Reference Preparations, Test Toxins and Units

Diphtheria Test Toxin (for Cell Culture)

Reagents, test solutions, etc.

0.2 mol/L Sodium Chloride Test Solution

Folin's Test Solution, Diluted

Acetic Acid-Pyridine Test Solution

Dimethyl Barbiturate Test Solution

3. To eliminate the following 1 standard under the section of GENERAL TESTS

Standards, Reference Preparations, Test Toxins and Units

Reference Standard Activated Protein C for Potency Test

4. To revise the following 1 test, 1 standard and 5 test solutions under the section of GENERAL TESTS

Test Procedures

Test for Moisture Content

Standards, Reference Preparations, Test Toxins and Units

Standard Mamushi (*Agkistrodon halys*) Antivenin

Reagents, test solutions, etc.

0.05 mol/L Calcium Chloride Test Solution

Stilbazo

Thromboplastin Solution

1 g/l Phenol Standard Solution

Potassium Hexacyanoferrate (□) Solution