



# **NEW BIOLOGICAL MONOGRAPHS OF INDIAN PHARMACOPOEIA**

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# Biological Monographs of IP 2007

- Specific importance are given for biological monographs.
- They are kept in Volume III in separate chapters.
- They are marked with coloured strips for easy reference.

# Biological Monographs

## Categories of Biological Monographs :

- Vaccines and Immunoserum for Human Use
- Blood and Blood Related Products
- Biotechnology Products
- Biological monographs of veterinary products

# Vaccines

## General requirements

Vaccines are preparations of antigenic substances that are administered for the purpose of inducing in the recipient a specific and active immunity against the infective agent or toxin produced by it.

Vaccines may contain living micro-organisms suitably treated to attenuate their virulence but retain their antigenic potency or they may consist of pathogenic organisms which have been killed or inactivated. Some vaccines consist of antigenic fractions or substances produced by the same pathogenic organisms but rendered harmless whilst retaining their antigenic efficiency. Vaccines may be prepared from one species only or from a mixture of two or more species.

# Bacterial Vaccines

Bacterial vaccines are either sterile suspensions of live or killed bacteria or sterile extracts of derivatives of bacteria. They may be simple vaccines prepared from one species or may be mixed vaccines prepared by blending two or more simple vaccines from different species or strains.

# **Bacterial toxoids**

Bacterial toxoids are toxins or material derived therefrom, the toxicity of which has been reduced to a very low level or completely eliminated by chemical or physical means without destroying their immunizing potency. The toxins are obtained from selected strains of specific micro-organisms, grown in media free from ingredients known to cause toxic, allergic or other undesirable immunological reactions in humans. Toxoids produced by the action of formaldehyde are known as formol toxoids.

# **Viral and rickettsial vaccines**

Viral and rickettsial vaccines are suspensions of viruses or rickettsiae and are prepared from infected tissues or blood obtained from artificially infected animals, from cultures in fertile eggs, or from cell or tissue culture. Viral vaccines may be live or killed and they may be freeze-dried. Live vaccines are usually prepared using attenuated strains of the specific organisms. Killed vaccines may be inactivated by suitable chemical or physical means.

# Mixed Vaccines

Mixed vaccines are mixtures of two or more vaccines. A suitable antibacterial substance may be added to inactivated or live viral and rickettsial vaccines provided that it has no action against the specific organisms.

# Production

**General provisions.** Requirements for production including in-process testing are included in individual monographs. Where justified and authorized, certain tests may be omitted where it can be demonstrated, for example by validation studies, that the production process consistently ensures compliance with the following tests.

**Substrates for propagation**

**Seed lot**

**Culture media**

**Propagation and harvest**

**Control cells**

**Control eggs**

**Purification**

**Inactivation**

**Intermediates**

**Final bulk**

**Adsorbents**

**Antimicrobial preservative**

**Final lot**

**Stability**

**Degree of adsorption**

- **Tests**
- Vaccines, reconstituted where necessary, comply with the following requirements unless otherwise stated in the individual monograph.
- **Phenol**
- **Thiomersal**
- **Free formaldehyde**
- **Aluminium**
- **Sterility**
- **Abnormal toxicity**
- **Storage**
- **Labelling**

## **Antisera**

Antisera are native (unconcentrated) sera or preparations from native sera containing specific immunoglobulins that have prophylactic or therapeutic action when injected into persons exposed to or suffering from a disease caused by a specific micro-organism.

## **Tests**

The following tests refer to liquid antisera and to the reconstituted freeze-dried preparations.

- **pH**
- **Total protein**
- **Foreign proteins**
- **Phenol**
- **Sterility**
- **Abnormal toxicity**
- **Storage**
- **Labelling**

# Vaccines and Immunoserum for Human Use

- A large number of Vaccines and Immunoserum monographs of IP 96 was upgraded in IP 2007.
- Total available monographs in IP 2007 are 57 out of which 32 New Monographs are introduced in IP 2007.

# New Monographs

- Adsorbed Diphtheria, Tetanus and Hepatitis B (rDNA) Vaccine
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Haemophilus Type b Conjugate Vaccine
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Hepatitis B (rDNA) Vaccine
- Adsorbed Diphtheria, Tetanus and Pertussis (Acellular Component), Inactivated Poliomyelitis Vaccine and Haemophilus Type b Conjugate Vaccine

## New Monographs

- Adsorbed Diphtheria, Tetanus, Pertussis and Poliomyelitis (Inactivated) Vaccine
- Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine
- Adsorbed Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus Type b Conjugate Vaccine
- Adsorbed Pertussis Vaccine (Acellular Component)
- Adsorbed Pertussis Vaccine (Acellular, Co-purified)

# New Monographs

- Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents
- Diphtheria Vaccine (Adsorbed)
- Diphtheria, Tetanus, Pertussis (Whole Cell) and Haemophilus Type b Conjugate Vaccine (Adsorbed)
- Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus Type b Conjugate Vaccine (Adsorbed)

# New Monographs

- Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed)
- Haemophilus Type b Conjugate Vaccine
- Hepatitis A (Inactivated) and Hepatitis B (rDNA) Vaccine (Adsorbed)
- Inactivated Influenza Vaccine (Split Virion)
- Inactivated Influenza Vaccine (Surface Antigen)

# New Monographs

- Inactivated Influenza Vaccine (Whole Virion)
- Measles and Rubella Vaccine (Live)
- Measles, Mumps and Rubella Vaccine (Live)
- Meningococcal Polysaccharide Vaccine
- Mumps Vaccine (Live)
- Pertussis Vaccine

# New Monographs

- Pneumococcal Polysaccharide Vaccine
- Poliomyelitis Vaccine (Inactivated)
- Rubella Vaccine (Live)
- Tick-Borne Encephalitis Vaccine (Inactivated)

# New Monographs

- Typhoid (Strain Ty 21a) Vaccine, Live (Oral)
- Typhoid Polysaccharide Vaccine
- Typhoid Vaccine (Freeze Dried)
- Varicella Vaccine, Live

# Blood and Blood Products

IPC introduced New Monographs with the deep consent of the eminent scientists of India and Abroad.

- Some of the monographs of IP 96 was also upgraded in IP 2007.
- Total available monographs - 21
- 15 New Monographs are introduced in IP 2007.

# New Monographs

- Anti-A Blood Grouping Serum
- Anti-B Blood Grouping Serum
- Anti-D (Rh<sub>0</sub>) Immunoglobulin
- Anti-D Immunoglobulin for Intravenous Use
- Anti-Human Globulin Serum
- Blood Grouping Serums Anti-D, Anti-C, Anti-E, Anti-c, Anti-e
- Cryoprecipitated Antihæmophilic Factor

# New Monographs

- Fibrin Sealant Kit
- Human Coagulation Factor IX
- Human Coagulation Factor VII
- Human Coagulation Factor VIII (r DNA)
- Human Normal Immunoglobulin for Intravenous Use
- Human Prothrombin Complex
- Plasma for Fractionation
- Platelet Concentrate

# Biotechnology Products

- The monographs of this category is first time introduced in IP 2007.
- An utmost care is taken for preparation of these monographs with the consultation of industries, academia and eminent scientists.
- 04 New Monographs appeared in IP 2007

# New Monographs

- Erythropoietin Concentrated Solution
- Filgrastim Concentrated Solution
- Interferon Alfa-2 Concentrated Solution
- Streptokinase Bulk Solution

# Biological Monographs of Veterinary Products

Veterinary products monographs, which were in veterinary supplement earlier has been merged in IP and kept in a separate chapter of IP 2007. The veterinary monographs are marked with yellow coloured strips for easy reference.

# Biological Monographs of Veterinary Products

- Some of the monographs of IP 96 were also upgraded in IP 2007.
- Total available monographs - 41
- 05 New Monographs are introduced in IP 2007.

## New Monographs

- Clostridium Multicomponent Vaccine, Inactivated
- Inclusion Body Hepatitis (IBH) Vaccine, Inactivated
- Infectious Coryza Vaccine
- Laryngotracheitis Vaccine, Live
- Peste Des Petitis Ruminants Vaccine, Live

# Indian Pharmacopoeia Commission

IPC is keen for collaboration, co-ordination and co-operation in all related fields of pharmacopoeia with the stake holder, academia and scientists.

- Suggestions are also invited.



THANKS