



INDIAN PHARMACOPOEIA COMMISSION

(Ministry of Health & Family Welfare, Government of India)

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F. No. T.11013/02/2018-AR&D

Date: 15th July, 2020
22nd

To,

1. The Drugs Controller General (India)
2. CDSCO Zonal Offices
3. All State Drug Controllers
4. Members of the Scientific Body of IPC
5. Members of Sub-Committees of the Scientific Body of IPC
6. Directors of Drugs Testing Laboratories
7. Government Analysts
8. IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations

Subject: Amendment List-06 to IP 2018

The 8th Edition of Indian Pharmacopoeia (IP) 2018 has become effective from 1st January, 2018. Based on scientific inputs, some IP monographs needed up-gradation and accordingly Amendment List-06 to IP 2018 is issued containing such amendments.

This is for notice and compliance with the IP 2018.

(Dr. Jai Prakash) 22/07/2020
Secretary-cum-Scientific Director (I/c)

Encl. Amendment List-06 to IP 2018

Amendment List 06 to IP-2018

Anti-A Blood Grouping Serum. Page 3887

Tests

Avidity

Change from:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-A	A ₁	3 – 4 seconds
(Monoclonal)	A ₂	5 - 6 seconds
	A ₂ B	5 – 6 seconds

to:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-A	A ₁	4 seconds
(Monoclonal)	A ₂	6 seconds
	A ₂ B	6 seconds

Anti-B Blood Grouping Serum. Page 3888

Tests

Avidity

Change from:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-B	B	3 – 4 seconds
(Monoclonal)	A ₁ B	5 – 6 seconds

to:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-B	B	4 seconds
(Monoclonal)	A ₁ B	6 seconds

Anti-AB Blood Grouping Reagent. Page 3890

Tests

Avidity

Change from:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-AB	A ₁	3 – 4 seconds
(Monoclonal)	A ₂	5 – 6 seconds
	B	3 – 4 seconds

to:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-AB	A ₁	4 seconds
(Monoclonal)	A ₂	6 seconds
	B	4 seconds

Anti-D (IgM) Monoclonal Blood Grouping Reagent. Page 3894

Tests

Avidity

Change from:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-D (IGM)	O+ve (R ₁ r or R ₁ R ₂)	5 – 10 seconds
(Monoclonal)		

to:

<i>Types of Reagent</i>	<i>Test Red Blood Cells</i>	<i>Avidity</i>
Anti-D (IGM)	O+ve (R ₁ r or R ₁ R ₂)	10 seconds
(Monoclonal)		

Diphtheria and Tetanus Vaccine (Adsorbed). Page 3599

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents.

Page 3601

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Diphtheria, Tetanus and Pertussis Vaccine (Adsorbed). Page 3602

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Each final lot shall be tested for abnormal toxicity by injecting intraperitoneally one human dose, but not more than 0.25 ml into each of the five mice weighing between 17 to 22 g and at least one human dose but not more than 1.0 ml into each of the two guinea-pigs weighing between 250 and 350 g. The preparation passes the test if none of the animals dies or shows signs of ill health in 7 days following the injection. If one of the animal dies or shows the sign of ill health, repeat the test. The preparation passes the test if none of the animals in the second group dies or shows signs of ill health in the time interval specified.

Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus influenza Type b Conjugate Vaccine (Adsorbed). Page 3604

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Each final lot shall be tested for abnormal toxicity by injecting intraperitoneally 0.25 ml of the vaccine into each of the five mice weighing between 17 to 22 g and at least one human dose but not more than 1.0 ml into each of the two guinea-pigs weighing between 250 and 350 g. The preparation passes the test if none of the animals dies or shows signs of ill health in seven days following the injection. If one of the animals dies or shows the sign of ill health, repeat the test. The preparation passes the test if none of the animals in the second group dies or shows signs of ill health in the time interval specified.

Diphtheria, Tetanus, Pertussis (Whole Cell) and Hepatitis B (rDNA) Vaccine (Adsorbed). Page 3607

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Each final lot shall be tested for abnormal toxicity by injecting intraperitoneally one human dose, but not more than 0.25 ml into each of the five mice weighing between 17 to 22 g and at least one human dose but not more than 1.0 ml into each of the two guinea-pigs weighing between 250 and 350 g. The preparation passes the test if none of the animals dies or shows signs of ill health in 7 days following the injection. If one of the animals dies or shows the sign of ill health, repeat the test. The preparation passes the test if none of the animals in the second group dies or shows signs of ill health in the time interval specified.

Diphtheria, Tetanus, Pertussis (Whole Cell) and *Haemophilus influenza* Type b Conjugate Vaccine (Adsorbed). Page 3609

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Each final lot shall be tested for abnormal toxicity by injecting intraperitoneally a maximum of one human dose, but not more than 0.25 ml into each of the five mice weighing between 17 to 22 g and at least one human dose but not more than 1.0 ml into each of the two guinea-pigs weighing between 250 and 350 g. The preparation passes the test if none of the animals dies or shows signs of ill health in 7 days following the injection. If one of the animals dies or shows the sign of ill health, repeat the test. The preparation passes the test if none of the animals in the second group dies or shows signs of ill health in the time interval specified.

Diphtheria Vaccine (Adsorbed). Page 3612

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Diphtheria Vaccine (Adsorbed) for Adults and Adolescents. Page 3615

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

***Haemophilus influenza* Type b Conjugate Vaccine.** Page 3621

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Inactivated Hepatitis A Vaccine (Adsorbed). Page 3628

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Inactivated Influenza Vaccine (Split Virion). Page 3632

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Inactivated Influenza Vaccine (Surface Antigen). Page 3634

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Inactivated Influenza Vaccine (Whole Virion). Page 3636

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Inactivated Influenza Vaccine (Human, Live Attenuated). Page 3638

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Japanese Encephalitis Vaccine (Human). Page 3640

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Japanese Encephalitis Live Vaccine (Human). Page 3642

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human). Page 3645

Para 1,

Change **from**: Japanese Encephalitis vaccine-adsorbed for human use is a liquid preparation with 0.1 per cent Alum of Japanese Encephalitis virus grown in approved substrate and inactivated by a validated method.

to: Japanese Encephalitis vaccine-adsorbed for human use is a liquid preparation of Japanese Encephalitis virus grown in approved substrate and inactivated by a validated method.

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Measles and Rubella Vaccine (Live). Page 3648

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Measles Vaccine (Live). Page 3649

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Measles, Mumps and Rubella Vaccine (Live). Page 3650

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Group A Meningococcal Conjugate Vaccine. Page 3652

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Meningococcal Polysaccharide Vaccine. Page 3656

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Mumps Vaccine (Live). Page 3661

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Plague Vaccine. Page 3665

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity but injecting into each mouse 1.0 ml and into each guinea-pig 3.0 ml.

Rabies Vaccine, Human. Page 3682

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Rubella Vaccine (Live). Page 3689

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Tetanus Vaccine (Adsorbed). Page 3693

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity for antisera and vaccine.

Typhoid Polysaccharide Vaccine. Page 3704

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Typhoid Paratyphoid A Vaccine. Page 3706

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity injecting subcutaneously, intramuscularly or intraperitoneally.

Typhoid Vi Conjugate Vaccine. Page 3708

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity. Animal should show no signs of illness and show no weight loss for a period of 7 days.

Typhus Vaccine. Page 3712

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity injecting subcutaneously, intramuscularly or intraperitoneally.

Varicella Vaccine, Live. Page 3712

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.

Yellow Fever Vaccine. Page 3714

FINAL LOT

Tests

Delete the following requirement

Abnormal toxicity (2.2.1). Complies with the test for abnormal toxicity.