INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
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To,

1. **Drug Controller General (India)/CDSCO, Zonal Offices**
2. **All State Drug Controllers**
3. **Members of Scientific body of the IPC**
4. **Members of Sub-committee of Scientific Body of the IPC**
5. **Government Analysts**
6. **Director of Drug Laboratories**
7. **IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations**

AMENDMENT LIST – 001 for IP-2018

As you are aware that 8th edition of Indian Pharmacopoeia will be effective from 1st April, 2018. Based on Scientific inputs some monographs needed up-gradation, accordingly an Amendment List-001 is issued containing such amendment.

This is for notice and compliance with IP-2018.

(Dr. G.N. Singh)
Secretary-cum-Scientific Director

Encl:- Amendment List – 001 for IP-2018
Cc to:- Publication Division to put up on IPC website.

Amendment List 001 to IP-2018

2.4.26. Solubility. Page 224

Busulphan.

Change **from**: Freely soluble in *acetone*, in *chloroform*, and in *acetonitrile*; very slightly soluble in *water*, in *ethanol (95 per cent)* and in *ether*.

to: Sparingly soluble in *acetone*; slightly soluble in *ethanol (95 per cent)*; very slightly soluble in *water*.

Aminophylline Prolonged-release Tablets. Page. 1209

Para 1, line 1

Change **from**: *Alprazolam Prolonged-release Tablets*

to: *Aminophylline Prolonged-release Tablets*

Carboxymethylcellulose Sodium. Page 1491

Labelling.

Change **from**: The label states (1) the apparent viscosity in millipascal seconds of a 2 per cent w/v solution or, where the viscosity is low, the concentration of the solution to be used and the apparent viscosity in mPa s; (2) that the contents are not intended for use in the manufacture of an injectable preparation.

to: The label states the apparent viscosity in millipascal seconds of a 2 per cent w/v solution or, where the viscosity is low, the concentration of the solution to be used and the apparent viscosity in mPa s.

Corn Oil. Page 1698

Labelling.

Change **from**: The label states (1) the name and quantity of any added antioxidant; (2) whether the content are suitable for use in the manufacture of parenteral preparations.

to: The label states the name and quantity of any added antioxidant.

Cottonseed Oil. Page 1704

Labelling.

Change **from**: The label states (1) the name and quantity of any added antioxidant, (2) whether the contents are suitable for use in the manufacture of parenteral preparations.

to: The label states the name and quantity of any added antioxidant.

Dextromethorphan Hydrobromide. Page. 1792

Related substances, under Chromatographic system

-mobile phase:

Change **from**: dissolve 3.11 g of *docusate sodium* in a mixture of 400 ml of *water* and 600 ml of *acetonitrile*. Add 0.56 g of *ammonium nitrate*, adjusted to pH 2.0 with *glacial acetic acid*,

to: dissolve 3.11 g of *docusate sodium* in a mixture of 400 ml of *water* and 600 ml of *acetonitrile*. Add 0.56 g of *sodium nitrate*, adjusted to pH 2.0 with *glacial acetic acid*,

Dextromethorphan Hydrobromide Syrup. Page. 1793

Assay, under Chromatographic system

-mobile phase:

Change **from**: a filtered and degassed solution of *0.007 M ammonium nitrate* in a mixture of 70 volumes of *acetonitrile* and 30 volumes of *water* adjusted to pH 3.4 with *glacial acetic acid*,

to: a filtered and degassed solution of *0.007 M sodium nitrate* in a mixture of 70 volumes of *acetonitrile* and 30 volumes of *water* adjusted to pH 3.4 with *glacial acetic acid.*

Diclofenac Sodium and Paracetamol Tablets. Page 1811

4-Aminophenol: *Test solution*

Change **from**: Weigh and powder 20 tablets. Weigh and transfer a quantity of powder containing 25 mg of paracetamol to 25.0 ml volumetric flask. Add 6.3 ml of solvent mixture A, sonicate for 10 minutes and dilute to volume with a mixture of equal volumes of solvent mixture A and solvent mixture B.

to: Weigh and powder 20 tablets. Weigh and transfer a quantity of powder containing 25 mg of paracetamol to 25.0 ml volumetric flask. Add 6.3 ml of solvent mixture A, sonicate for 10 minutes and dilute to volume with a mixture of equal volumes of solvent mixture B and solvent mixture C.

Under Chromatographic system

After line 2, add the following

– column temperature: 35º,

Diethylene Glycol Monoethyl Ether. Page 1826

Related substances, under Chromatographic system
Change **from**: injection volume: 1 µl.
to: injection volume: 1 ml.
Labelling. Delete the requirement.

Escitalopram Oxalate and Clonazepam Tablets. Page 1977

Dissolution. *Reference solution.* line 1

Change **from**: Dissolve an accurately weighed quantity of *escitalopram oxalate RS* and *clonazepam RS* in the dissolution medium and dilute with the dissolution medium to …….

to: Dissolve an accurately weighed quantity of *escitalopram oxalate RS* and *clonazepam RS* in 5.0 ml *methanol* and dilute with the dissolution medium to……

Gelatin. Page 2155

Labelling.
Change **from**: The label states, where applicable, that the material is suitable for the preparation of pessaries and suppositories and, if so, the jelly strength.

to: The label states the jelly strength.

Levetiracetam. Page 2407

Enantiomeric purity. After chromatographic system, para 2, line 4
Change **from**: 2.0
to: 2.4

Levofloxacin Hemihydrate. Page 2422

Water (2.3.43)

Change **from**: Not more than 3.0 per cent, determined on 0.1 g.

to: Not more than 3.0 per cent, determined on 0.2 g.

Levonorgestrel and Ethinyloestradiol Tablets. Page 2429

Uniformity of content.

Change **from**: Complies with the test stated under Tablets.

Carry out the procedure described under Assay using the following solutions.

Test solution. Disperse one tablet in 5 ml of mobile phase with the aid of ultrasound for 30 minutes, cool and dilute to 10.0 ml with the mobile phase. Shake to mix and centrifuge, use the clear supernatant liquid.

Reference solution (a). Weigh accurately a quantity of *levonorgestrel RS* containing 100 times the stated amount of Levonorgestrel per tablet, dissolve in sufficient *methanol (70 per cent)* to produce 200.0 ml. Take 2.0 ml of this solution, add 2.0 ml of the internal standard solution and use the resulting solution.

Reference solution (b). Weigh accurately a quantity of *ethinyloestradiol RS* containing 100 times the stated amount of Ethinyloestradiol per tablet, dissolve in sufficient *methanol (70 per cent)* to produce 200.0 ml. Take 2.0 ml of the solution, add 2.0 ml of the internal standard solution and use the resulting solution.

to: Complies with the test stated under Tablets.

Carry out the procedure described under Assay using the following solutions.

Test solution. Disperse one tablet in 5 ml of mobile phase with the aid of ultrasound for 30 minutes, cool and dilute to 10.0 ml with the mobile phase. Shake to mix and centrifuge, use the clear supernatant liquid.

Assay. After chromatographic system, para 1, line 1.
Change **from**: Inject the reference solution.
to: Inject the reference solution (c).

Para 2, line 1.
Change **from**: Inject the reference solution and the test solution.
to: Inject the reference solution (c) and the test solution.

Metoprolol Succinate Prolonged- release and Amlodipine Tablets. Page 2585

Identification, line 3
Change **from**: reference solution.
to: reference solution (c).

Oleic Acid. Page 2774

Labelling.

Change **from**: The label states (1) where applicable, that it is used for external use only; (2) the name and concentration of any added antioxidant.

to: The label states the name and concentration of any added antioxidant.

Rosuvastatin Calcium and Ezetimibe Tablets. Page 3143

Para 1, line 3.

Change **from**: rosuvastatin calcium,

to: rosuvastatin,

Soyabean Oil. Page 3250

Labelling.

Change **from**: The label states (1) the name and quantity of any added antioxidant, (2) whether the contents are suitable for use in the manufacture of parenterals.

to: The label states the name and quantity of any added antioxidant.

Telmisartan and Amlodipine Tablets. Page 3321

Assay. *Reference solution (a)*. line 1
Change **from**: 0.008
to: 0.08

Telmisartan and Hydrochlorothiazide Tablets. Page 3323

Related substances. Last para**,** line 14
Change **from**: 0.002 times
to: 0.005 times

Last para**,** line 15
Change **from**: 0.2 per cent
to: 0.5 per cent

Arachis Oil. Page 3739

Labelling.

Change **from**: The label states (1) whether the contents are suitable for use in the manufacturer of parenteral preparations; (2) when the addition of antioxidants is authorised, the name and quantity of the added antioxidants.

to: The label states name and quantity of the added antioxidants.