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INDIAN PHARMACOPOEIA COMMISSION
MIN. OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD - 201002

No. IPC/7021/IP-2014/ER-009 **Dated**: 13-05-2016

To,

1. **DCG (I)/ 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**

ERRATA – 009 for IP 2014

As you are aware that the 7th edition of Indian Pharmacopoeia has become official from 1st April, 2014. Based on scientific inputs, some monographs, appendices needed corrections, accordingly an Errata – 009 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 009 for IP 2014

CC to: Publication Division to put up on IPC website.

Errata-009 to IP-2014

2.4.26 Solubility. Page 191,

Insert before **Metoprolol tartrate**

Metoprolol Succinate. Freely soluble in *water*, soluble in *methanol*, sparingly soluble in *ethanol (95 percent)*, slightly soluble in *isopropyl alcohol*.

4.2 General Reagents. Page 762

Insert before **Acetic Anhydride-Dioxan Solution**

Acetic anhydride solution. Dilute 25 ml of *acetic anhydride* in *anhydrous pyridine* and dilute to 100.0 ml with *anhydrous pyridine*.

Store protected from light and air.

4.4. Standard Solutions. Page 833

Add after **Lead Standard Solution (0.1 percent Pb)**

Mercury Standard Solution (100 ppm Hg) Dissolve 0.108 g of *yellow mercuric oxide* in the minimum volume of *2 M hydrochloric acid*, add sufficient *water* to produce 1000.0 ml.

Betamethasone Valerate Cream. Page 1181

Assay. After chromatographic System, para1, line1

Change **from:** Inject test solution (a).

to: Inject reference solution.

Bumetanide Injection. Page 1211

Add. After Bacterial endotoxin**.**

Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Calcium Stearate. Page 1260

Compositions of fatty acids. Under Chromatographic system

Change **from**: a glass column 30 m x 0.32 mm packed with silanised diatomaceous support coated with macrogol 20000 (film thickness 0.5 µm),

to: a capillary column 30 m x 0.32 mm, packed with fused silica coated with macrogol 20000 (film thickness 0.5 µm);

Chlorthalidone. Page 1381

Change **to:**

Assay. Determine by liquid chromatography (2.4.14).
Test solution. Dissolve 50 mg of the substance under examination in 50.0 ml of *methanol*. Take 5.0 ml of the resulting solution, dilute with *water* to 50.0 ml and mix.

Reference solution. A 0.1 per cent w/v solution of *chlorthalidone RS* in *methanol*. Take 5.0 ml of this solution dilute with 50.0 ml of *water* and mix.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 60 volumes of 0.01 M of *dibasic ammonium phosphate* and 40 volumes of *methanol* with the pH adjusted to 5.5 with *orthophosphoric acid*,
- flow rate: 1.0 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 25 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2 and the relative standard deviation for replicate injections is not more than 2.0 per cent.
Inject the reference solution and the test solution.
Calculate the content of $C_{14}H_{11}ClN_2O_4S$.

Clobetasone Cream. Page 1427

Usual strength.

Change **from**: 0.05 per cent w/v

to: 0.05 per cent w/w

Divalproex Sodium. Page 1601

Identification A.
Change **from:** Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *valproic acid RS* or with the reference spectrum of valproic acid.

to: Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *divalproex sodium RS* or with the reference spectrum of divalproex sodium.

Docetaxel Anhydrous. Page 1606,

Bacterial endotoxins.
Change **from**: Not less than 0.3 IU per mg of docetaxel
to : Not more than 0.3 Endotoxin Unit per mg of docetaxel

Doxorubicin Injection. Page 1628

Add. After Bacterial endotoxins.
Other tests. Comply with the tests stated under Parenteral Preparations (Injections).

Etoposide. Page 1722

Appearance of solution. Last Line.
Change **from**: Y6 or BY6
to: YS6 or BYS6

Isopropyl Palmitate. Page 2011

Assay. *Reference solution.*

Change **from:** A 0.02 per cent w/v solution of *isopropyl hexadecanoate RS* in the internal standard solution and dilute to 100.0 ml with the same solution.

to: A 0.02 per cent w/v solution of *isopropyl hexadecanoate RS* in the internal standard solution.

Ketorolac Tromethamine. Page 2037, 3880

Related substances.. After Chromatographic System,

Change **from:**

Name	Relative retention time	Correction factor
Unknown impurity [1]	0.54	0.45
Unknown impurity [2]	0.66	1.1
ketorolac 1-hydroxy analog	0.63	1.49
ketorolac 1-keto analog	0.89	1.92
ketorolac	1.0	----

to:

Name	Relative retention time	Correction factor
Unknown impurity [1]	0.54	2.2
Unknown impurity [2]	0.66	0.91
ketorolac 1-hydroxy analog	0.63	0.67
ketorolac 1-keto analog	0.89	0.52
ketorolac	1.0	----

Levocetirizine Tablets. Page 2078

Delete. Labelling statement.

Levonorgestrel and Ethinyloestradiol Tablets. Page 2091

Dose.

Change **to**: One tablet daily for 21 days, subsequent courses repeated after 7- day pill free interval (during which withdrawal bleeding occurs).

Levosalbutamol Sulphate. Page 2095

Enantiomeric purity. *Test solution.*

Change **to**: Dissolve about 10 mg of the substance under examination in 4 ml of methanol and dilute to 10.0 ml with the mobile phase.

Reference solution.

Change **to:** Dissolve 10 mg of *Salbutamol sulphate RS* in 4 ml of *methanol* and dilute to 10.0 ml with the mobile phase

Under chromatographic system. Injection volume.
Change **from**: 15 µl
to: 10 µl

Meropenem. Page 2178.

Acetone . *Internal standard solution*. Last line.
Change **from.** 0.000005 percent
To. 0.005 percent

Phenindione. Page 2465

Related substances. Last Paragraph, lines 1 and 2.
Change **from.** Apply to the plate 10 µl of each solution .Allow the mobile Phase to rise 4 cm**.**
To. Allow the mobile phase to ascend 4 cm, remove the plate and dry it in a current of cold air for 1 minute. Immediately apply 10 µl of each solution.

Phenindione Tablets. Page 2465

Related substances. Last Paragraph, lines 1 and 2.
Change **from.** Apply to the plate 10 µl of each solution .Allow the mobile Phase to rise 4 cm**.**
To. Allow the mobile phase to ascend 4 cm, remove the plate and dry it in a current of cold air for 1 minute. Immediately apply 10 µl of each solution.

Phenoxyethanol. Page. 2474

Related substances. *Test solution (b).*

Change **from**: Dissolve 5 g of the substance under examination in 10.0 ml of *dichloromethane* and add 1.0 ml of the internal standard solution.

to: Dissolve 5.0 g of the substance under examination in sufficient quantity of *dichloromethane,* add 1.0 ml of internal standard solution and dilute to 10.0 ml with *dichloromethane.*

Progesterone. Page 2565

Related substances.

Delete. *Reference solution (a).* A solution containing 0.004 per cent w/v each of *progesterone RS* and *progesterone impurity C RS ((20R)-20-hydroxypregn-4-en-3-one RS)* in *methanol.*

Reference solution (b).

Change **to**: *Reference solution.*

After chromatographic system.

Para 1.

Change **to**: Inject reference solution. The test is not valid unless the column efficiency is not less than 4000 theoretical plates, tailing factor is not more than 2.0, and the relative standard deviation for replicate injections is not more than 5.0 per cent.

Rabeprazole Injection. Page 3921

pH

Change **to:** 10.8 to 12.5, determine in a 0.8 per cent w/v of Rabeprazole Sodium solution.

Related substances.

Test solution.

Change **from**: Reconstitute 1 vial with 5.0 ml of sterile water for injections and dilute a volume to obtain a solution containing 0. 1 per cent w/v of rabeprazole sodium in the solvent mixture.

to: Reconstitute 1 vial with 5.0 ml of *water*, shake. Reconstitute 4 more vials. Pool the contents of 5 vials to prepare a composite sample. Dilute a suitable volume of pooled sample with solvent mixture to obtain a solution containing 0.1 per cent w/v of rabeprazole sodium

Reference solution (a).

Change **from**: A solution containing 0.01 per cent w/v solution of *rabeprazole sulphide RS* and *rabeprazole sulphone RS* in the solvent mixture

to: Weigh about 2.5 mg each of *rabeprazole sulphide RS* and *rabeprazole sulphone RS* dissolve in 2.5 ml of *methanol* and dilute to 25.0 ml with the solvent mixture

Abiraterone Acetate. Page 4151

Related substances. Under chromatographic system.

Change **from**: - a stainless steel column 15 cm x 4.6 mm, packed with phenyl group (3.5 mm)(Such as Zorbax SB-Phenyl),

to: - a stainless steel column 15 cm x 4.6 mm, packed with phenyl group (3.5 µm)(Such as Zorbax SB-Phenyl),

Change **from**: - Injection volume: 10 ml

to: - Injection volume: 10 µl

Assay. Under chromatographic system.

Change **from**: - a stainless steel column 15 cm x 4.6 mm, packed with phenyl group (3.5 mm)(Such as Zorbax SB-Phenyl),

to: - a stainless steel column 15 cm x 4.6 mm, packed with phenyl group (3.5 µm)(Such as Zorbax SB-Phenyl),

Benzoyl Peroxide. Page 4161

Change the Title **to**: **Hydrous Benzoyl Peroxide**

Under the Structure

Insert (Anhydrous Substances)

Para 1.

Change **from**. Benzoyl Peroxide contains not less than 70.0 per cent and not more than 77.0 per cent of $C_{14}H_{10}O_4$, calculated on the anhydrous basis.

To. Hydrous Benzoyl Peroxide contains not less than 70.0 per cent and not more than 77.0 per cent of $C_{14}H_{10}O_4$.

Water. Line 1.

Change **from**: Not more than 20.0 per cent ,…….

to: Not less than 20.0 per cent ,…….

Captopril. Page 4167

Change title **to**: **Captopril Tablets**.

Menotropin for Injection. Page 4215.

Para 2. Line 1 to 3.

Change **from** : The injection is reconstituted by dissolving the contents of the sealed container in the requisite amount of *Water for Injection*, immediately before use.

to : The injection is reconstituted by dissolving the contents of the sealed container in the requisite amount of *Sterile Water for Injection* or a suitable diluent supplied by the manufacturer, immediately before use.

Metoprolol Succinate. Page 4220

Assay. After Chromatographic System,

Change **from:** Inject reference solution (a). The test is not valid unless the resolution between the peaks due to Metoprolol Impurity A and Metoprolol Impurity B is not less than 2.5 and the resolution between Metoprolol Impurity B and Metoprolol Impurity C is not less than 1.5 and the relative standard deviation of replicate injection is not more than 2.0 per cent.

to: Inject reference solution (a). The test is not valid unless the resolution between the peaks due to Metoprolol Impurity A and Metoprolol Impurity B is not less than 2.5 and the resolution between Metoprolol Impurity B and Metoprolol Impurity C is not less than 1.5.

Inject reference solution (b) the relative standard deviation of replicate injection is not more than 2.0 per cent.

Olmesartan Medoxomil. Page 4228

Acetone. Under Chromatographic System. -temperature:

Change **from**:

column	time (min)	temperature (°)
	5	50
	5-18	50-80
	18-23	180

to:

column	time	temperature

(min)	(°)
5	50
5-18	50-180
18-23	180

Flow rate

Change **from**: 4 ml per minute, using nitrogen as the carrier gas.
to: 4 ml per minute, using nitrogen or Helium as the carrier gas.

Pemetrexed Injection. Page 4234

Related substances. Under chromatographic system. Column temperature.
Change **from**: 2^0 to 8^0
to: 35^0
Add after column temperature.
Autosampler temperature : 2^0 to 8^0
Assay. Under chromatographic system. Insert after Line 2.
Column temperature. 30^0

,

Sucralose. Page 4244

Change title **to**: **Sucrose**. Page 2802

Tacrolimus. Page 4244

Insert after **category**
Description. White Crystals or white crystalline powder.

Zolmitriptan Nasal Spray. Page 4263

Para 1
Change **from.** Zolmitriptan Nasal Spray is a suspension of Zolmitriptan in a suitable liquid in a container fitted with an appropriate nasal delivery system.

to. Zolmitriptan Nasal Spray is a solution of Zolmitriptan in a suitable liquid in a container fitted with an appropriate nasal delivery system.