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

No. IPC/7035/IP-2014/ER-006 **Dated**: 20-07-2015

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/FFSAI/Small Scale Industry Associations**

ERRATA – 006 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 – 006 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 006 for IP 2014

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

Mr K.K. Singh pl do the needful
27.7.15

27/7/15

Errata 006 to IP-2014

4.4 Standard Solutions. Page 832.

Perchloric Acid, 0.1 M. (Regarding water content) Lines 7, 10 and 12.
Change **from:** 0.05 Per cent
to : 0.5 Per cent

Aspartame. Page 1089

5-Benzyl-3,6-dioxo-2-piperazineacetic acid. After chromatographic system. Para 1.
Change **to**: Inject the reference solution. The test is not valid unless the relative standard deviations for replicate injections is not more than 4.0 per cent and the tailing factor of the principal peak is not more than 2.0.

Betahistine Hydrochloride. Page 1165.

Assay. After reference solution.
Change **from**: Use chromatographic system as described under Related substances.

to: Chromatographic system

- a stainless steel column 15 cm x 3.0 mm packed with octadecylsilane chemically bonded to porous silica (5 µm),
- mobile phase: dissolve 0.45 g *ammonium acetate* and 0.4 ml *glacial acetic acid* in 650 ml of *water*, add 350 ml of *acetonitrile* and add 2.88 g of *sodium laurylsulphate* and mix,
- flow rate: 0.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 10 µl.

Betahistine Tablets. Page 1166

Uniformity of content. *Test solution*,
Change **to**: Disperse one tablet to a 25 ml volumetric flask with about 15 ml of mobile phase, mix with the aid of ultrasound and dilute to 25.0 ml with the mobile phase, filter. Dilute with mobile phase to achieve concentration of 0.032 per cent w/v of betashistine hydrochloride.

Betamethasone. Page 1169

Related Substances. Under chromatographic condition. After injection volume.

Change **from:**

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
15	0	100
40	100	0
46	0	100
48	100	0

to:

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
15	100	0
40	0	100
41	100	0
46	100	0

Bleomycin Injection. Page 1198

Usual strength.
Change **from** : 15 mg per ml.
to: 15 units per vial; 30 units per vial.

Bortezomib. Page 1200, 3812

Specific optical rotation. Line 1.
Change **from:** -50.0° to -55.0°
to: -45.0° to -55.0°

Bumetanide Tablets. Page 1213

Related substances.. *Test solution*. line 1
Change **from:** Dissolve 0.125 g of substance under examination in 20 ml of a mixture……..

to: weigh and transfer a quantity of the powdered tablets containing 0.0125 g of bumetanide in 20 ml of a mixture……..

Buspirone Hydrochloride. Page 1219.

Assay. Last line.
Change **from**: 1 ml of *0.1 M perchloric acid* is equivalent to 0.021 g of $C_{21}H_{32}ClN_5O_2$.

to: 1 ml of *0.1 M perchloric acid* is equivalent to 0.0211 g of $C_{21}H_{32}ClN_5O_2$.

Buspirone Tablets. Page 1220.

Uniformity of Content. Para 2. Test solution.
Change **from**: Disperse one tablet in the minimum amount of *1 M hydrochloric acid* and dilute to 25.0 ml with *water*, and filter.

to: Disperse one tablet in the minimum amount of *1 M hydrochloric acid* and dilute with water to produce a solution containing 0.005 per cent w/v of buspirone, shake and filter.

Carbomer. Page 1275

Heavy metals.
Change **to**: 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Docetaxel Anhydrous. Page 1606.

Related substances. *Reference solution (c)*

Change **from**: Dissolve 5 mg of *docetaxel impurity E RS* in 2.5 ml of *ethanol* and dilute to 50.0 ml with the solvent mixture.

to: Dissolve 5 mg of *docetaxel impurity E RS* in 2.5 ml of *ethanol* and dilute to 50.0 ml with the solvent mixture. Dilute 1.0 ml of this solution to 100.0 ml with the solvent mixture.

Erlotinib Tablets. Page 1681

Dissolution. *Test solution***.**
Change to**:**
Test solution. Dilute the filtrate if necessary, with the mobile phase.

Etidronate Disodium. Page 1716.

Water (2.3.43). Line 3

Change **from.** Method 1

to. Method 3

. Losartan Tablets. Page 2123

Related substances. Under chromatographic system. Line 2.

Change **from**: 5 mm

to: 5 µm

Maleic Acid. Page 2146.

Appearance of solution. Line 1

Change **from:** A 0.01 percent w/v solution is clear

to: A 10.0 percent w/v solution is clear

Mefenamic Acid. Page 2162, 3890

Related substances. After chromatographic system. Para 2, last line .

Delete.

"and ignore the peak due to mefenamic acid impurity A".

Methylprednisolone Acetate Injection. Page 2209.

Assay. Chromatographic system. Line 1.

Change **from**: – "octadecylsilane chemically bonded to porous silica (5 to 10 µm),"

to: – "silica gel for chromatography (5 to 10 µm) ,"

Assay. After Chromatographic system. Para 3, line 1.

Change **from**: $C_{22}H_{29}FO_5$

to: $C_{24}H_{32}O_6$

Metronidazole Benzoate. Page 2216, 3903

Related substances. Para 1

Change **from**: Inject reference solution (b). The test is not valid unless the resolution between the peaks due to metronidazole benzoate impurity A and B is not less than 2.0.

to: Inject reference solution. The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Para 2, lines 1, 4, 7, 10.

Change **from**: reference solution (a)

to: reference solution

Monothioglycerol. Page 2246

Refractive index.

Change **from:** 11.521 to 1.526 at 25º

to: 1.521 to 1.526 at 25º

Phenytoin Injection. Page 2486

Bacterial endotoxins. Line 2.

Change **from**: phenytoin

to: phenytoin sodium.

Prazosin Hydrochloride. Page 2536, 3919

Assay. After chromatographic system . para 1.

Change **to**

"Inject the reference solution. The relative standard deviation for replicate injections is not more than 2.0 per cent."

Trandolapril Tablets. Page 2900

Assay. *Test solution.*

Change **to**: Transfer 10 intact tablets in a 100.0 ml volumetric flask, and disperse in about 80 ml of mobile phase with the aid of ultrasound for about 30 minutes, cool and dilute to volume with the mobile phase. Mix well and filter, dilute suitably with mobile phase to obtain a solution containing 0.005 per cent w/v trandolapril and filter.

Triamcinolone Tablets. Page 2907

Related substances. After chromatographic system. Para 1, line 3.

Change **from**: 10,000 theoretical plates.

to: 2000 theoretical plates.

Budesonide Inhalation. Page 3815

Assay. *Test solution*. Line 11

Change **from**: 0.01 per cent w/v

to: 0.002 per cent w/v

Reference solution (a).

Change **from**: 0.01 per cent w/v

to: 0.002 per cent w/v

Delete reference solution (b).

After chromatographic system. Para 1. line1.

Change **from**: Inject reference solution (b).

to: Inject reference solution (a).

Epimer A. Last line

Change **from**: reference solution (b).

to: test solution

Illoperidone Tablets. Page 3874

Dissolution. After reference solution. Line 1.

Change **to.** Use chromatographic system as described in the Assay using injection volume 100 µl.

Lacidipine Tablets. Page 3883

Assay. *Test solution.*

Change **from**: Weigh and powder 20 tablets. Disperse a quantity of the powder containing 20 mg of lacidipine in 35 ml ethanol with the aid of ultrasound for 30 min. Cool and filter through a 0.45 - µm membrane filter and dilute to 50 ml with ethanol.

to: Weigh and powder 20 tablets. Disperse a quantity of the powder containing 20 mg of lacidipine in 50 ml ethanol with the aid of ultrasound for 30 min. Cool and filter through a 0.45 - µm membrane filter and dilute to 200 ml with mobile phase.

Rabeprazole Injection. Page 3921.

Assay. Under Chromatographic Condition. Insert after Line 2.

- Sample temperature: 5°,

Tadalafil Tablets. Page 3934

Uniformity of content.

Line 5.

Change **from**: dilute with the solvent mixture to volume and filter. Measure the absorbance of the resulting solution at the maximum at about 285 nm (2.4.7)

to: dilute with the solvent mixture to volume and filter. Dilute 5.0 ml of the filtrate to 50.0 ml using solvent mixture. Measure the absorbance of the resulting solution at the maximum at about 285 nm (2.4.7)

Terazosin Tablets. Page 3938.

Insert after Dissolution.

Uniformity of content.

Determine by liquid chromatography (2.4.14), as described in the Assay using following modification.

Test solution. Transfer one tablet to 20 ml of solvent mixture, disperse with the aid of ultrasound for about 20 minutes, cool and dilute, with sufficient of the solvent mixture, to produce a solution containing 0.005 percent w/v tearzosin, mix and shake well, filter.

Torsemide Tablets. Page 3945.

Related Substances. *Reference solutions (a),* lines 2 and 3.

Change **from:** 0.008 per cent w/v of *torsemide impurity A RS*

to: 0.04 per cent w/v *torsemide impurity A RS*.

Herbs and Herbal Products

Mirch. Page 3978

Tests. Insert before **Loss on Drying** (2.4.19)

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Asthisamhrta. Page 3967

Tests. Insert before **Loss on Drying** (2.4.19)

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm)

Bassant. Page 3969

Tests. Insert before **Loss on Drying** (2.4.19)

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Assay. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel GF254*.

Reference solution

Change: **from:** A 1.0 per cent w/v solution of *hypericin RS* in *methanol.*
to: A 0.01 per cent w/v solution of *hypericin RS* in *methanol.*

Bassant Dry Extract. Page 3969

Tests. Insert before **Loss on Drying** (2.4.19)

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Assay. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel GF254*.

***Reference solution*.**
Change **from :** A 0.6 per cent w/v solution of *hypericin RS* in *methanol.*
to : A 0.006 per cent w/v solution of *hypericin RS* in *methanol.*

Shankhpushpi. Page 3980

Tests. Insert before **Loss on Drying** (2.4.19)
Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm)

Veterinary Monographs

Frusemide Injection. Page 3528

Insert before Usual Strength.

Frusemide Injection is a sterile solution of Frusemide in Water for Injection prepared with the aid of Diethanolamine or Monoethanolamine.

Frusemide Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of Frusemide $C_{12}H_{11}ClN_2O_5S$.

Insert after Dose

Tests, pH. 7.0 to 7.8, if it contains diethanolamine; or between 8.0 to 9.3, if it contains monoethanolamine.

Labelling. The label states whether preparation is prepared using Diethanolamine or with Monoethanolamine

Niclosamide Veterinary Oral Powder. Page no.3551

2-chloro-4-nitroaniline. Line 9 10 and 11.

Change **from:** The colour produced is not more than that produced by simultaneously treating 10 mg of *2-chloro-4-nitroaniline* in the same manner.

to: Any pinkish violet colour produced is not more intense than that obtained in a solution prepared simultaneously using 10.0 ml of a solution prepared by diluting 2.0 ml of a 0.0002 percent w/v solution of *2-chloro-4-nitroaniline* in *methanol* to 20 ml with *1 M hydrochloric acid*