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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-003 **Dated: 09-01-2015**

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 – 003 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 – 003 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 003 for IP 2014

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

to pdh-pub. on our web-site
14/1/15
Sr Exec (Pub.)
14/01/15

ERRATA- 003 TO IP-2014

2.4.26. Solubility

Page 202. Insert before **Undecenoic Acid**.

Ulipristal Acetate. Freely soluble in *dichloromethane*, soluble in *methanol*, *acetone*, *ethanol* and insoluble in *water*.

4.2 General Reagents

Page 785 Insert before **Ferrous Ammonium Sulphate.**

Ferric Sulphate Pentahydrate. Iron (III) Sulphate Pentahydrate; $Fe_2(SO_4)_3,5H_2O$ = 489.9

Analytical reagent grade of commerce.

White to yellowish powder.

Store in well-closed, light-resistant containers.

Tablets. Page 959

Effervescent Tablets.

Disintegration. Line 2

Change **from**: containing water

to: containing 200 ml of water

Acesulphame Potassium. Page 984, 3798

Identification B. line 2

Change **from**: *cellulose.*

to: *cellulose* F254.

Impurity A. line 2

Change **from**: *silica gel.*

to: *silica gel G.*

Acitretin Page 993

Heavy Metals. Line 2.

Change **from** : Method C

T o : Method B

Adenosine. Page 997

Appearance of solution. Line 1,

Change **from**: solution (Solution A)

to : solution in hot *water* (Solution A)

Related substances. After chromatographic system.

Adenosine impurity G, Correction factor,

Change **from** : 0.4

to: 1.4

Allopurinol. Page 1012

Related substances. Insert after chromatographic system.

The elution order of the peaks is allopurinol impurity A, allopurinol impurity B, allopurinol impurity C and allopurinol.

The retention time for allopurinol is about 10 minutes.

Allopurinol Tablets. Page 1013

Related substances. Insert after chromatographic system.
The elution order of the peaks is allopurinol impurity A, allopurinol impurity B, allopurinol impurity C and allopurinol. The retention time for allopurinol is about 10 minutes.

Alprazolam Prolonged-release Tablets. Page 1016

Uniformity of content.
Test solution.
Change **from**: ultrasound for 2 minutes.
to: ultrasound.

Aminocarproic Acid. Page 1031

Assay. lines 2 and 3,
Delete. and add 15 ml of *mercuric acetate* solution.

Aminocarproic Acid Injection. Page 1032

Assay. lines 4 and 5,
Delete. and add 15 ml of *mercuric acetate* solution.

Aminocarproic Acid Tablets. Page 1032

Assay. line 4 .
Delete. and add 15 ml of *mercuric acetate* solution.

Amioradone Hydrochloride. Page 1037

Heavy metals.
Change **from**: Method C
to: Method B

Amlodipine Tablets. Page 1046

Dissolution. Medium, line 2,
Change **from**: 900 ml
to: 500 ml
Line 3
Change **from**: 45 minutes
to: 30 minutes
Line 10
Change **from**: 70 per cent
to: 75 per cent

Amoxycillin Trihydrate. Page 1054

Labelling. Delete.

Amoxycillin Dispersible Tablets. Page 1056

Insert at the end
Labelling.

The label states (1) the strength in terms of the equivalent amount of amoxycillin; (2) that the tablets should be dispersed in water immediately before use.

Anticogulant Citrate Phosphate Dextrose Adenine Solution. Page 1075

Assay. *For dextrose.* last line
Change **from**: $C_6H_{12}O_6$.
to: $C_6H_{12}O_6.H_2O$.

Atorvastatin Calcium. Page 1099

Description. Insert at the end.
It shows polymorphism.
Water.
Change **to**: **Water** (2.3.43). Not more than 6.0 per cent.

Betahistine Tablets. Page 1166

Uniformity of content. *Test solution.*
Change **to**: Disperse one tablet to a 25 ml volumetric flask and add about 15 ml of mobile phase, mix with the aid of ultrasound and dilute to 25.0 ml with the mobile phase, filter.

Bezafibrate. Page 1185

Chlorides. Change **to**:
Chlorides (2.3.12). Boil 0.83 g with 30 ml of *water* for 5 minutes, cool and filter. The filtrate complies with the limit test for chlorides (300 ppm).

Bisacodyl. Page 1194

Related substance. *Test solution,* Line 1.
Change **from**: 50 g
to: 50 mg

Carbamazepine. Page 1266

Chlorides(2.3.12).
Change **to**: Boil 1.5 g in 30 ml of *water* for 5 minutes, cool and filter. The filtrate complies with the limit test for chlorides (165 ppm).

Cefadroxil Tablets. Page 1295

Related substances. Para2, lines 2 and 3
Change **from**: Run the chromatogram 6 times the retention times of the principal peak.
to: For test solution, run the chromatogram 6 times the retention times of the principal peak.

Clotrimazole Pessaries. Page 1444, 3836

Assay.
Reference solution.
Change **to:** Dissolve 20 mg of *clotrimazole RS* in 70 ml of *methanol*, add sufficient *0.02 M phosphoric acid* to produce 100.0 ml and dilute 1.0 ml of the resulting solution to 5.0 ml with methanol.

Disodium Edetate. Page 1594

Impurity A.
Reference solution. Line 1
Change **from**: *nitrilotriacetic acid*
to: *nitrilotriacetic acid* (disodium edetate impurity A)

Para 2, line 6.
Change **from**: principal peak
to: corresponding peak

Docusate Sodium. Page 1610

Heavy metals.
Change **to**: Dissolve 4.0 g in 20 ml of *ethanol (80 per cent v/v)*. 12 ml of the solution complies with the limit test for heavy metals, Method D (10 ppm), using 10 ml of *lead standard solution (2 ppm Pb*).

Entacapone. Page 1662

Related substances. After chromatographic system, para 3, line 5
Change **from** : more than twice
to : more than

para 3, line 11
Change **from** : not more than the area
to : not more than twice the area

Loss on drying. line 3
Change **from** : 49 mm of mm Hg
to : 49 mm of Hg

Assay. para 2
Change **to:** Inject reference solution (a). The test is not valid unless the resolution between the peaks corresponding to entacapone impurity A and entacapone is not less than 2.0.

Inject reference solution (b). The tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more than 1.0 per cent for entacapone peak.

Flumazenil. Page 1779

N,N – dimethylformamide diethyl acetate.
Reference solution (a). Line 2
Change **from**: 0.00006 per cent w/v
to: 0.6 µl per ml

Diluted Glyceryl Trinitrate. Page 1872

Related substances. *Test solution (a).*
Change **to**: Dissolve a quantity of the substance under examination in *methanol* to obtain a solution containing 1.0 per cent w/v of nitroglycerin and centrifuge, if necessary, to obtain a clear liquid solution or apply directly 1.0 per cent w/v nitroglycerin.

Para 1, line 1,
Change **from**: 20 µl
to: 40 µl

Griseofulvin. Page 1876

Related substances. last para. line 1.
Change **from**: ratio (r)
to: ratio (R).

last para. line 6.
Change **from**: is less than 0.6

to: is less than 0.6 R.

last para. line 10.
Change **from**: is less than 0.15
to: is less than 0.15 R.

Griseofulvin Tablets. Page 1877

Related substances. last para. line 1.
Change **from**: ratio (r)
to: ratio (R).

last para. line 6.
Change **from**: is less than 0.6
to: is less than 0.6 R.

last para. line 10.
Change **from**: is less than 0.15
to: is less than 0.15 R.

Hydroxyzine Oral Solution. Page 1923

Identification B
Test Solution. line 3
Change **from**: dilute to 10.0 ml with solvent mixture,
to: dilute to 50.0 ml with solvent mixture,

Irbesartan and Hydrochlorothiazide Tablets. Page 1995, 3878

Assay. Chromatographic system, mobile phase.
Change **from**: 1.36 g of *monobasic potassium phosphate*
to: 1.36 g of *monobasic potassium phosphate* in 900 ml of *water*

Meclofenamic Acid. Page 3542

Related substance. After chromatographic system, para 1. line 2
Change **from**: 4500 theoretical plates.
to: 900 theoretical plates.

Heavy metals.
Change **from**: Method D
to: Method B

Metformin Hydrochloride. Page 2186

Related Substances. Chromatographic system. Line 2.
Change **from** : 10 mm.
to : 10 µm.

Mifepristone. Page 2234

Optical rotation (2.4.22).

Change **to**: **Specific optical rotation** (2.4.22). 124° to 135°, determined in a 0.5 per cent w/v solution in *dichloromethane,* when determined at 20°.

Mupirocin. Page 2265

Related substances. After chromatographic system, para1
Change **to**: Inject reference solution (b). This test is not valid unless resolution between the second of the 2 peaks due to hydrolysis products and the peak due to mupirocin is not less than 7.0 in the chromatogram obtained with reference solution (b).

Assay. After chromatographic system, para 1,
Change **to**: Inject reference solutions (a) and (b). This test is not valid unless resolution between the second of the 2 peaks due to hydrolysis products and the peak due to mupirocin is not less than 7.0 in the chromatogram obtained with reference solution (b). The relative standard deviation for replicate injections is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Nalidixic Acid Tablets. Page 2293

Assay. Lines 3 and 4
Change **from**: *0.1 M sodium hydroxide*
to: *1.0 M sodium hydroxide*
Line 7
Change **from**: *0.1 M sodium hydroxide*
to: *0.01M sodium hydroxide*

Naltrexone Hydrochloride. Page 2298

Ethanol. line 1
Change **from**: 3.0 per cent v/v
to: 3.0 per cent

Nandrolone Decanoate Injection. Page 2301

Identification. *Test solution*. Line 2
Change **from**: *carbon tetrachloride*
to: *chloroform*

Reference solution. Line 2
Change **from**: *carbon tetrachloride*
to: *chloroform*

Naphazoline Nitrate. Page 2303

Identification C. Line 1
Change **from**: Dissolve about 0.5 mg in 1 ml of *methanol*
to: To 1 ml of 0.05 per cent w/v in *methanol*
Naphthylacetylethylenediamine. Delete the test.

Naproxen. Page 2305

Identification B. line 1
Change **from**: 0.04 per cent w/v.
to: 0.004 per cent w/v.
line 3
Change **from**: absorbance
to: specific absorbance

Nevirapine. Page 2324

Line 1
Change **to** : $C_{15}H_{14}N_4O$ Mol. Wt. 266.3

(anhydrous)

$C_{15}H_{14}N_4O.1/2H_2O$ Mol. Wt. 275.3
(hemihydrate)

Nicotinic Acid. Page 2334.

Heavy metals. Line 4

Change **from**: Method B

to: Method A

Nortriptyline Tablets. Page 2356

Uniformity of content. *Test solution*.

Change **to**:

Test solution. Transfer one tablet to 100.0 ml volumetric flask, add about 5 ml of *water* and disperse with the aid of ultrasound. Add about 50.0 ml of *methanol*, mix with the aid of ultrasound for 30 minutes and dilute to 100.0 ml with *water*. Centrifuge and use the supernatant liquid, dilute if necessary.

Octyldodecanol. Page 2365

Assay.

Chromatographic system, temperature:

Change **to**:

column time (min)	temperature (°)
0 - 2	180
2 - 22	180 – 280
22 - 52	280

Ondansetron Hydrochloride. Page 2376

Assay. After chromatographic system, para 1, line 2

Delete. for ondansetron is about 1.0

Ondansetron Injection. Page 2377

Assay. After chromatographic system, para 1, line 2

Delete. for ondansetron is about 1.0

Ondansetron Orally Disintegrating Tablets. Page 2377

Related substances. Last para, line 4

Change **form**: 0.5

to: 1.89

Line 6

Change **form**: 1.2

to: 0.77

Uniformity of content.

Test solution. Lines 2 and 3

Change **from**: and filter.

to: filter, dilute if necessary.

Ondansetron Tablets. Page 2380

Dissolution. Para 1, line 9

Change **from**: *ondansetron hydrochloride dihydrate RS*
to: *ondansetron hydrochloride RS*

Ornidazole. Page 2385

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Ornidazole Injection. Page 2385

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Ornidazole Tablet. Page 2386

Related subsatances. *Reference Solution (c).* Line 2
Change **form**: 1.0 ml
to: 10.0 ml

Oseltamivir Capsules. Page 2391

Related substances. *Reference solution (a).*
Change **from**: A 0.1 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.
to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.1per cent w/v of oseltamivir.

Assay. *Reference solution.*
Change **from**: A 0.02 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.
to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.02 per cent w/v of oseltamivir.

Oseltamivir Oral Suspension. Page 2392

Related substances. *Reference solution (a).*
Change **from**: A 0.1 per cent w/v solution of *oseltamivir phosphate RS* in the mobile phase.

to: Dissolve a quantity of *oseltamivir phosphate RS* in the mobile phase to obtain a solution equivalent to 0.1per cent w/v of oseltamivir.

Oxazepam. Page 2395

Identification A. line 2
Change **from**: *oxazepam RS*.
to: *oxazepam RS* or with the reference spectrum of oxazepam.

Identification B. First para, line 3
Change **from**: Dilute 10.0 ml of solution A to 100.0 ml with *ethanol (95 per cent)* (solution B).
to: Dilute 5.0 ml of solution A to 20.0 ml with *ethanol (95 per cent)* (solution B).

Paracetamol. Page 2429

Related substances. Chromatographic system, line 1
Change **from**: 4.0 mm,
to: 4.6 mm,

Paracetamol Tablets. Page 2434

Related substances. chromatographic system. line 1
Change **from** : 4.0 mm,
to: 4.6 mm,

Penicillamine. Page 2443

Heavy metals. line 1
Change **from**: 10.0 ml
to: 12.0 ml

Phenylmercuric Nitrate. Page 2481

Inorganic mercuric compounds. Lines 7 and 8
Change **from**: Method A (2.3.13). Use *lead standard solution (1 ppm Pb)*
to: Method D (2.3.13). Use 10 ml of *lead standard solution (1 ppm Pb)*

Phenytoin. Page 2483

Heavy metals. line 2
Change **from** : Method D
to : Method B

Polysorbate 20. Page 2516

Identification A. lines 2 and 3.
Change **from**: *polysorbate RS* or with the reference spectrum of polysorbate.
to: *polysorbate 20 RS* or with the reference spectrum of polysorbate 20.

Polysorbate 80. Page 2517

Identification A. lines 2 and 3.
Change **from**: *polysorbate RS* or with the reference spectrum of polysorbate.
to: *polysorbate 80 RS* or with the reference spectrum of polysorbate 80.

Potassium Clavulanate Diluted. Page 2525

Assay. Chromatographic system, injection volume
Change **from** : 20 µl
to : 10 µl

Progesterone Injectable Suspension. Page 2567

Assay.
Reference solution. Line 2
Change **from** : 4.0
to : 10.0 ml

Line 4,
Change **from** : 10 ml
to : 25 ml

Propionic acid. Page 2576

Heavy metals. line 4
Change **from**: 10.0 ml
to: 12.0 ml

Rizatriptan Tablets. Page 2681

Related substances. *Reference solution (a).*
Change **from**: A 0.0001 per cent w/v solution of *rizatriptan benzoate RS* in the solvent mixture.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.0001 per cent w/v of rizatriptan in the solvent mixture.

Uniformity of content.
Test solution. Line 3
Change **from**: Rizatriptan Benzoate.
to: Rizatriptan Benzoate equivalent to Rizatriptan.

Reference solution.
Change **from**: A 0.005 per cent w/v solution of *rizatriptan benzoate RS* in the mobile phase.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.005 per cent w/v of rizatriptan in the mobile phase.

Assay. *Reference solution.*
Change **from**: A 0.005 per cent w/v solution of *rizatriptan benzoate RS* in the mobile phase.
to: A solution of *rizatriptan benzoate RS* equivalent to 0.005 per cent w/v of rizatriptan in the mobile phase.

Saquinavir Mesylate Tablets. Page 2712.

Dissolution. Line 2,
Change **from** : 5.82 mg,
to : 5.82 g.

Line 2,
Change **from** : 16.7 mg,
to : 16.7 g.

Related substances. *Reference solution (a).*Line 2,
Change **from** : *saquinavir mesylate RS*
to : *saquinavir mesylate RS* equivalent to *saquinavir*

Assay.*Reference solution*. Lines 1 and 2,
Change **from** : *saquinavir mesylate RS*
to : *saquinavir mesylate RS* equivalent to *saquinavir*

Sildenafil Tablets. Page 2726

Assay. After chromatographic system, para 1, line 4
Change **from**: 5.0 per cent.
to: 2.0 per cent

Sisomicin Sulphate Injection. Page 2733

Identification. *Test Solution.*
Change **to** : Dilute a suitable volume of injection (if required) to contain 1.0 percent w/v solution of sisomicin sulphate.

Sorafenib Tosylate. Page 2774

Paratoluenesulphonic acid. Line 1
Change **from**: 26.4 per cent to 27.6 per cent.
to: 25.6 per cent to 28.3 per cent.

Heavy metals.
Change **from**: 2.0 g complies with the limit test for heavy metals, Method B (10 ppm).
to: 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Loss on drying. Line 1
Change **from**: Not more than 0.5 per cent,
to: Not more than 1.0 per cent,

Tadalafil Tablets. Page 3934

Dissolution. Speed and time.
Change **from**: 50 rpm and 30 minutes.
to: 50 rpm ,10 minutes and 30 minutes.

D. Lines 1 and 2
Change **to**: Not less than 40 per cent of the stated amount of $C_{22}H_{19}N_3O_4$ at 10 minutes and not less than 80 per cent of the stated amount of $C_{22}H_{19}N_3O_4$ at 30 minutes.

Veterinary Monographs.

Flunixin Meglumine. Page 3527

Identification. line 2
Change **from**: *flunixin RS*
to: *flunixin meglumineRS*

Related Substance.
Reference Solution (a). line 1
Change **from**: *flunixin RS*
to: *flunixin impurity B RS*

Reference Solution (c). line 1
Change **from**: *flunixin RS*
to: *flunixin impurity C RS*

last para, lines 1 to 4
Change **from**: The area of the peak is not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.2 per cent).
to: In the chromatogram obtained with the test solution, the area of any peak corresponding to flunixin impurity A and flunixin impurity B is not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.2 per cent).