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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-002 **Dated**: 17-10-2014

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 – 002 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 – 002 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 002 for IP 2014

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

Errata – 002 to IP-2014

4.1 Buffer solutions. Page 760

Insert before **Phosphate buffer pH 4.9**

Phosphate buffer pH 4.4. Dissolve 7.8 g of *monobasic sodium phosphate* in 900 ml of *water*, adjusted to pH 4.4 with *10 M sodium hydroxide* or *orthophosphoric acid* and diluting with *water* to 1000.0 ml.

4.4. Standard Solutions. Page 833

Insert before **Formaldehyde Standard Solution (5 ppm CH_2O)**

Ferrocyanide Standard Solution (100 ppm $Fe(CN)_6$): Immediately before use, dilute with *water* to 10 times its volume a solution containing *potassium ferrocyanide* equivalent to 0.2 g of $K_4Fe(CN)_6,3H_2O$ in 100.0 ml.

Adefovir Tablets. Page 996

Assay. After chromatographic system, para 1, line 2

Change **from**: 9000

to: 5000

Amiodarone Intravenous Infusion. Page 1038

Assay. After chromatographic system, para 1

Change **to**: Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent and the tailing factor is not more than 2.0.

Amoxycillin and Potassium Clavulanate Injection. Page 1057

Assay. Chromatographic system, mobile phase

Change **to**: mobile phase: a mixture 5 volumes of *methanol* and 95 volumes of phosphate buffer pH 4.4.

Amoxycillin and Potassium Clavulanate Oral Suspension. Page 1058

Assay. Chromatographic system, mobile phase

Change **to**: mobile phase: a mixture 5 volumes of *methanol* and 95 volumes of phosphate buffer pH 4.4.

Amoxycillin and Potassium Clavulanate Tablets. Page 1059

Assay. Chromatographic system, mobile phase

Change **to**: mobile phase: a mixture 5 volumes of *methanol* and 95 volumes of phosphate buffer pH 4.4.

Atropine Injection. Page 1109

Bacterial endotoxins. Last line

Change **from**: atropine.

to: atropine sulphate

Calcium Carbonate. Page 1248

Identification. A. Line 2.

Change **from**: 0.2 ml of the filtrate (solution A).

to: the filtrate (solution A).

Carboplatin Injection. Page 1277

Usual strength.

Change **from**: 100 IU per ml

to: 10 mg per ml

Clotrimazole Cream. Page 1443

2-Chlorotritanol. After chromatographic system, para 1, line 2
Change **from**: 9000 theoretical plates.
to: 6000 theoretical plates .

Clotrimazole Pessaries. Page 1444

Related substances. After chromatographic system, para 1, line 3
Change **from**: 9000 theoretical plates.
to: 6000 theoretical plates.

Assay. After chromatographic system, para 1, line 3
Change **from**: 9000 theoretical plates.
to: 6000 theoretical plates.

Gemcitabine Injection. Page 1850

Usual strengths.
Change **to**: 40 mg per ml

Identification. Change **to**: Line 2
Identification. In the Assay, the principal peak in the chromatogram obtained with the test solution (b) corresponds to the peak in the chromatogram obtained with the reference solution (b).

Assay. Last line
Change **from**: $C_9H_{12}ClF_2N_3O_4$
to: $C_9H_{11}F_2N_3O_4$

Ethambutol Tablets. Page 1697

Assay. Chromatographic system, insert after mobile phase
- flow rate: 1 ml per minute

Gliclazide. Page 1862

Gliclazide Impurity B.
Reference solution. Insert at the end,
To 1.0 ml of the solution, add 12 ml of *dimethyl sulphoxide* and dilute to 50.0 ml with *water*.

Racecadotril Capsules. Page 2634

Related substances. *Reference solution*. line 4
Change **from** : 100.0 ml
to : 50.0 ml

Ramelteon. Page 2639.

Heavy metals.
Change **from** : 2.0 g
to : 1.0 g

Ribavirin. Page 2655.

Assay. Line 4

Change **from** : test solution (b).
to : test solution.

Safinamide Methane Sulphonate. Page 2697

Related Substances. *Reference solution.* Line 1
Change **from**: 0.0001 per cent
to: 0.01 per cent

Salbutamol. Page 2698

Related Substances.*Reference solution*.Line 1
Change **from**: 0.02 per cent
to: 0.03 per cent

Last paragraph, line 9 to 11
Change **to**: Ignore any peak with an area less than 0.17 times the area of the principal peak in the chromatogram obtained with the reference solution (0.05 per cent).

Salicylic Acid Ointment. Page 2706

Para 1, Change **to**:
Salicylic Acid Ointment contains Salicylic Acid in a suitable water-emulsifying basis.

Para 2, Change **to**:
Salicylic Acid Ointment contains not less than 95.0 per cent and not more than 105.0 per cent w/w of the stated amount of salicylic acid, $C_7H_6O_3$.

Silver Sulphadiazine. Page 2727

Insert before **Identification**
Description. White to creamy-white powder, odourless to having a slight odour. Stable in air, but turns yellow on exposure to light.

Sodium Aminosalicylate. Page 2735

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

Sorafenib Tosylate. Page 2774

Assay. Last line
Change **to**: Calculate the content of $C_{21}H_{16}ClF_3N_4O_3.C_7H_8SO_3$.

Sorafenib Tablets. Page 2775

Related substances. *Reference solution*. last line
Change **from**: 0.05 per cent w/v of *sorafenib RS* in the solvent mixture.
to: 0.00005 per cent w/v of *sorafenib tosylate RS* equivalent to sorafenib in the solvent mixture.

Assay. *Reference solution.* Line 1,

Change **from**: *sorfenib tosylate RS*
to: *sorafenib tosylate RS*.

After chromatographic system, para1, last line
Change **from**: is more than 2.0 per cent.
to: is not more than 2.0 per cent.

Succinylcholine Injection. Page 2801

Bacterial endotoxins. Last line
Change **from**: succinylcholine.
to: succinylcholine chloride

Sulpiride. Page 2809.

Impurity A. *Reference solution (b)*, line 1,
Change **from**: 0.0002 per cent
to : A 0.002 per cent

Tamoxifen tablets. Page 2823

Identification. A; para 2, last line
Change **from**: tamoxifen citrate
to: tamoxifen

Terbutaline Injection. Page 2843

Bacterial endotoxins. Line 2
Change **from**: terbutaline
to: terbutaline sulphate

Theophylline Injection. Page 2852

Assay. *For dextrose.* Line 2
Change **from**: 5 mg
to: 5 g
Line 8
Change **from**: ratio 200
to: ratio of 200

Labelling. Last line
Change **from**: Dextrose
to: Dextrose monohydrate

Thiamine Injection.Page 2857

Bacterial endotoxins.Line 2
Change **from**: thiamine
to: thiamine hydrochloride

Thiotepa.Page 2865

Related Substances.*Reference solution (a)*
Change **to**: *Reference solution (a).* Dilute 1.0 ml of the test solution to 100.0 ml with *water*. Further dilute 1.0 ml to 10.0 ml with *water*.

Thiocolchicoside Capsule. Page 2861.

Identifiaction B. Para 1, Line 1.
Change **from**: 10 ml
to: 10 µl

Thyroxine Tablets. Page 2869

Uniformity of content. *Reference solution*. Lines 4 and 5
Delete. Further dilute 1.0 ml of this solution to 10.0 ml with the solvent mixture.

Ulipristal Acetate. Page 2938

Description. Change **to**: A white to yellow powder.

Verapamil Injection. Page 2965

Bacterial endotoxins. Line 2
Change **from**: verapamil
to: verapamil hydrochloride

Vinblastine Sulphate. Page 2967

Bacterial endotoxins. Line 2
Change **from**: vinblastine
to: vinblastine sulphate

Zolmitriptan. Page 3017

Related substances. *Reference solution (a)*. Line 1
Change **from**: 0.0001 per cent
to: 0.001 per cent

(R)- 4-[(3[2-(dimethyl amino)ethyl]-1H-indol-5-yl]methyl)]-2-oxazolidinone (R-isomer). *Test solution.*
Change **to**: Dissolve 10 mg of the substance under examination in mobile phase and dilute to 20 ml with the mobile phase.

Zolmitriptan Tablets. Page 3018

Related substances. *Reference solution*. line 1
Change **from**: 0.0125 per cent
to: 0.0025 per cent

(R)- 4-[(3[2-(dimethyl amino)ethyl]-1H-indol-5-yl]methyl)]-2-oxazolidinone (R-isomer). *Test solution.*
Change **to**: Dissolve 10 mg of the substance under examination in mobile phase and dilute to 20 ml with the mobile phase.

Uniformity of content. *Test solution*.
Change **to**: *Test solution*. Disperse one tablet in the mobile phase and dilute to obtain a solution containing 0.0025 per cent w/v of zolmitriptan and filter.

Assay. *Test solution*. Lines 3 and 4
Change **from**: buffer solution
to: the mobile phase

Reference solution(a). Lines 3 and 4
Change **from**: buffer solution
to: the mobile phase

Reference solution(b). Lines 3 and 4
Change **from**: buffer solution
to: the mobile phase