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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-011 **Dated**: 05-08-2016

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 – 011 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 – 011 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 011 for IP 2014

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

Errata-011 to IP-2014

2.3.43. **Water.** Page 113

Karl Fischer (KF) reagent

Change **to**: KF reagent is an iodosulphurous compound containing basic substances like pyridine, piperidine etc and may contain imidazole. The reagent and solutions used for preparing the KF should be kept anhydrous and care should be taken throughout the determination to prevent exposure to atmospheric moisture. The reagent should be protected from light and stored in a bottle to which is fitted an automatic burette.

The composition of commercially available Karl Fischer reagents often differs from that above by the replacement of pyridine with other basic compounds. The use of these reagents must be validated in order to verify in each individual case the stoichiometry and the absence of incompatibility between the substance under test and the reagent.

Ear Drops. Page 931,

Para 4, Last Line.

Change from: 5.9

to: 2.2.9.

Gels. Page 933,

Para 2, Last Line.

Change from: 5.9

to: 2.2.9.

Nasal Preparations. Page 951,

Para 3, Last Line.

Change **from**: 5.9

to: 2.2.9

Ointments. Page 951,

Para 3, Last Line.

Change **from**: 5.9

to: 2.2.9.

Oral Liquids. Page 952,

Para 3, Last Line.

Change **from**: 5.9

to: 2.2.9.

Oral Powders. Page 953,

Para 4, Last Line.

Change **from**: 5.9

to: 2.2.9.

Atracurium Besylate Injection. Page 1105

Assay. After chromatographic system. Para1. Line 4.

Change from: not less than 2.0

to: not less than 1.5

Butylparaben. Page 1223

Identification B. Line 1**.**

Change **from:** Related substances

to: Assay

Cefoperazone Sodium. Page 1308

Related substances. *Reference solution (a).* line 2.

Change **from:** *cefoperazone dihydrate RS.*

to: *cefoperazone sodium RS.*

Assay. *Reference solution* . line 2.

Change **from:** *cefoperazone dihydrate RS.*

to: *cefoperazone sodium RS.*

After Chromatographic system. Para 3.

Change **from:** Calculate the content of $C_{25}H_{26}N_9NaO_8S_2$ by multiplying the content of cefoperazone by 1.034.

to: Calculate the content of $C_{25}H_{26}N_9NaO_8S_2$.

Cefoperazone Injection. Page 1309

Assay. *Reference solution* . line 2.

Change **from:** *cefoperazone dihydrate RS.*

to: *cefoperazone sodium RS.*

Clarithromycin Tablets. Page 1413

Dissolution. Medium

Change **from**: 900 ml of *acetate buffer pH 5.0*,

to: Use 900 ml of a solution containing 1000 volumes of a 1.361 per cent w/v solution of *sodium acetate* and 350 volumes of 0.1M *acetic acid*, adjusted to pH 5.0 with 0.1M *acetic acid* , at a temperature of 37º ± 0.5º, as the medium.

Desferrioxamine Injection. Page 1517

Storage.

Change **from:** Store protected from light in a refrigerator (2° to 8°). Do not freeze.

to: Store protected from light at a temperature not exceeding 30°.

Diclofenac Prolonged-release Tablets. Page 1553

Assay. After chromatographic system. Para 1, last line.

Change **from**: 6.5

to: 2.0

Fasoterodine Fumarate . Page 1739

Change title **to**: **Fesoterodine Fumarate**

In the entire monograph change the word **fasoterodine fumarate**

to: fesoterodine fumarate

Imipenem. Page 1951

Water (2.3.43).

Change From: 5.0 per cent to 8.0 per cent, determined on 0.2 g.

To: 5.0 per cent to 8.0 per cent, determined on 0.1 g. Use an iodosulfurous reagent containing imidazole instead of pyridine and a clean container for each determination.

Nifedipine Prolonged release Tablets. Page 2338, 3914

Para 1.

Delete. *Nifedipine Prolonged – release Tablets manufactured…….. may not be the same***.**

Dissolution A. Delete the letter "D"

Ofloxacin. Page 2367

Related substances. Under chromatographic system, Mobile Phase, Line 3.

Change **from**: 27.2 g

to: 2.72 g

Ofloxacin Oral Suspension. Page 2369

Assay. Under chromatographic system, Mobile Phase, Line 2.

Change **from**: 27.2 g

to: 2.72 g

Ofloxacin Tablets. Page 2369

Assay. Under chromatographic system, Mobile Phase, Line 2

Change **from**: 27.2 g

to: 2.72 g

Oxytocin. Page 2408

Assay.

Change **from:** *Reference solution.* A 0.025 per cent w/v solution of *oxytocin RS* in mobile phase A.

to: *Reference solution.* Dissolve the contents of one vial of *oxytocin RS* in mobile phase A to produce a solution containing the same concentration as in test solution.

Oxytocin Injection. Page 2410

Assay.

Change **from**: Injection Volume : 200 µl

to: Injection Volume : 100 µl

After chromatographic system, Para 1.

Change **from**: Inject the reference solution. The test is not valid unless the theoretical plates are not less than 50, 000.

to: Inject the reference solution. The test is not valid unless the theoretical plates are not less than 2, 000.

Sodium Phosphate. Page 2764

Water. Line 1
Change **from** : 0.1 g
to: 50 mg
Line 3.
Change **from**: *dimethylformamide*
to: *formamide*

Sorbitan Oleate. Page 2777

Composition of fatty acids.
Line1.
Change **from:** Determine by gas chromatography (2.4.13).
to: Determine Fatty Acid Composition by gas chromatography (2.3.50, Method C).

Thymol. Page 2867

Related substances. After chromatographic system, Line 1.

Change **from.** Inject reference solutions (a), (b), (c) and the test solution.

to. Inject 1 µl of the reference solutions (a), (c) and the test solution

Last Para. Line 1 &2.

Change **from.** …. the sum of the areas of any secondary peaks…….

to. …. the sum of the areas of all the secondary peaks…….

Trospium Chloride. Page 4258

Impurity C.Last para, line 8.
Change **from**: The area of any spot due to impurity C….
to: Any spot corresponding to impurity C….

Abiraterone Acetate. Page 4151

Category.
Change **from.** Antiandrogen
to. Anticancer

Bendamustine Injection. Page 4160

After Title, Delete the following
Bendamustine for Injection**.**

Gabapentin Capsules. Page 4196

Related substances. Test solution, line 1.
Change **from**: Weigh and powder 20 tablets….
to: Weigh a quantity of mixed content of 20 capsules……

Assay. Test solution, line 1.
Change **from**: Weigh and powder 20 tablets….
to: Weigh a quantity of mixed content of 20 capsules……

Duloxetine Gastro- resistant Tablets. Page 4181

Assay. *Test solution*

Change **from:** Weigh and Dissolve 60 mg of duloxetine equivalent to *duloxetine hydrochloride RS* in 70 ml mobile phase and mix with the aid of ultrasound and make up the volume to 100.0 ml with the same solvent. Dilute 5.0 ml of this solution to 50.0 ml with the mobile phase.

to: Weigh and powder 20 tablets. Weigh a quantity of the powder containing 60 mg of duloxetine, add 70 ml of the mobile phase, mix with the aid of ultrasound and dilute to 100.0 ml with the mobile phase. Dilute 5.0 ml of this solution to 50.0 ml with the mobile phase.

Reference solution

Change **from:** Weigh and Dissolve 60 mg of duloxetine equivalent to *duloxetine hydrochloride RS* in 70 ml mobile phase and mix with the aid of ultrasound and make up the volume to 100.0 ml with the same solvent. Dilute 5.0 ml of this solution to 50.0 ml with the mobile phase.

to: A 0.0065 percent w/v solution of duloxetine hydrochloride RS in mobile phase.

Glucosamine Sulphate Sodium Chloride. Page 4199

Heavy metals. Last line.

Change **from**: *lead standard solution (2 ppm pb)*

to: *lead standard solution (1 ppm pb)*

Levetiracetam. Page 4209

Related substances. After chromatographic system. RRT Table

Change **to:**

Name	Relative Retention time	Correction factor
Levetiracetam impurity A[1]	0.5	_
Levetiracetam (Retention time: about 10 minute)	1.0	_
2-pyrrolidone	1.1	_
Levetiracetam impurity B[2]	1.2	0.5

[1] *(2RS)-2-(2-oxopyrrolidin-1-yl)butanoic acid,*

[2] *(2Z)-2-(2-oxopyrrolidin-1-yl)but-2-enamide*

Metoprolol Succinate Prolonged-Release Tablets. Page 4221

Under Labelling. Line 2.&3

Change **from**: tertrate $(C_{15}H_{25}NO_3)_2,C_4H_6O_4$.

to: tartrate

Olmesartan Medoxomil. Page 4228

Related substances. Under chromatographic system. After RRT Table, Lines 3.

Change **from**: 3 (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(1-methylethenyl)-2-propyl-1-[[2'-(1*H*- tetrazol-5-yl)biphenyl-4-yl]methyl]-1*H*,

to: (5-methyl-2-oxo-1,3-dioxol-4-yl)methyl 4-(1-methylethenyl)-2-propyl-1-[[2'-(1*H*- tetrazol-5-yl)biphenyl-4-yl]methyl]-1*H*-imidazole-5-carboxylate,

Pemetrexed Injection. Page 4234

Related substance. *Reference solution*

Change **from**: A 0.0001 per cent w/v solution of *pemetrexed disodium RS* in *water*.

to: A 0.00001 per cent w/v solution of pemetrexed in water.

Pioglitazone and Metformin Hydrochloride Tablets. Page 4236

Add after storage.

Labelling. The label states the strength in terms of the equivalent amount of pioglitazone and metformin hydrochloride.

Zidovudine. Page3003,3953 4261

Related substances. Change **to**:

Related substances A.

Zolmitriptan Tablets. Page 3018, 4264

(R)- 4-[(3[2-(dimethyl amino)ethyl]-1H-indol-5-yl]methyl)]-2-oxazolidinone (R-isomer).

Test solution.

Change **from**: Dissolve 10 mg of the substance under examination in mobile phase and dilute to 20 ml with the mobile phase.

to: Weigh a quantity of the powdered tablets containing about 10 mg of Zolmitriptan, disperse in 20.0 ml of mobile phase and filter.

After chromatographic system. Para 2.

Change **from**: Inject reference solution (a) and the test solution.

to: Inject reference solution (b) and the test solution.

Herbs and Herbal Products

Castor oil. Page 3201

Storage.

Change **from**: Store protected from light and moisture at a temperature not exceeding 15°.

to: Store protected from moisture.