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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/AL-003 **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**

AMENDMENT LIST – 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 upgradation, accordingly an Amendment list – 003 is issued containing amendment and upgradation. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
Amendment List – 003 for IP 2014

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

Amendment List-003 to IP-2014

4.2 General Reagents. Page 766

Add before Ammonium Molybdate Solution.

Ammonium Molybdate Reagent. Mix 10 ml of a 6.0 per cent w/v solution of *disodium arsenate*, 50 ml of *ammonium molybdate solution*, 90 ml of 1M *sulphuric acid* and add sufficient *water* to produce 200 ml. Condition the mixture at 37° for 24 hours and keep in amber flasks.

Page 776

Insert before Cyclohexane

β-Cyclodextrin. $C_{42}H_{70}O_{35} \cdot x\ H_2O = 1134.98$

Analytical reagent grade of commerce.

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Page 781

Add before Disodium Edetate

Disodium Arsenate. Disodium hydrogen arsenate heptahydrate, dibasic sodium arsenate, sodium arsenate heptahydrate; $Na_2HAsO_4,7H_2O = 312.0$

Crystals, efflorescent in warm air, freely soluble in water, soluble in glycerol, slightly soluble in *ethanol (95 per cent)*. The aqueous solution is alkaline to litmus.

$d^{20}/_{20}$, about 1.87.

mp, about 57°, when rapidly heated.

Adrenaline. Page 999.

Related Substances. Last Para.

Change to: Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak at relative retention time of about 0.2, 0.8 and 1.3 with reference to the principal peak (retention time of Adrenaline is about 4 min) is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent), the area of any peak at relative retention times of about 3.3 multiplied by a correction factor of 0.7 and about 3.7 multiplied by a correction factor of 0.6 with reference to the principal peak is not more than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent), the area of any other secondary peak is not more than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.1 per cent). The sum of areas of all the secondary peaks is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.5 per cent). Ignore any peak with an area less than 0.05 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Gliclazide. Page 1862, 4200

Related substances. Add after first line.

NOTE — Prepare the solutions immediately before use.

Gliclazide Tablets . Page 1863

Related substances. Add after first line.

NOTE — Prepare the solutions immediately before use.

Medroxyprogesterone Injection. Page 2159

Impurity F. *Reference solution.* Line 1.
Change **from**: 0.5 per cent w/v
to: 0.01 per cent w/v

Mesalazine. Page 2180

Line 3.
Change **from**: 101.0
to: 101.5

Methylprednisolone. Page 2205

Related substances, Under chromatographic system. 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	100	100
40	0	100
41	100	0
46	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

Ondansetron Hydrochloride. Page 2376

Identification. Test B, line 1.
Change **from**: 2.3.12
to: 2.3.1
Related substances. Para 1

Change **from**: Use the chromatographic system, the test solution and reference solution (b) described in the Assay.

to: Use the chromatographic system, as described under assay using the test solution, reference solution (b), reference solution (c) and system suitability criteria for resolution.

Ondansetron Orally Disintegrating Tablets. Page. 2377

Assay. *Test solution.*

Change to: Weigh and powder 20 tablets. Disperse a quantity of powder containing about 40 mg of ondansetron with about 60 ml of 0.01 *M hydrochloric acid* with the aid of ultrasound for about 10 minutes and dilute to 100.0 ml. Filter through polypropylene membrane of 0.45 µm pore size. Discard first few ml of the filtrate. Dilute 1.0 ml of the solution to 10.0 ml with *0.01 M hydrochloric acid*.

Valproic Acid. Page 2949

Appearance of solution.

Change **from**: A 20.0 per cent w/v solution in *dilute sodium hydroxide* is clear (2.4.1) and not more intensely coloured than reference solution YS5 (2.4.1).

to: A 20.0 per cent w/v solution of valproic acid in 8.5 percent w/v sodium hydroxide solution is clear (2.4.1) and not more intensely colored than reference solution YS5 (2.4.1).

Methocarbamol. Page 4217

Related substances.

Add after reference solution (b).

Reference solution (c). Dilute 1.0 ml of test solution to 50.0 ml with the mobile phase.

After chromatographic system. Para 3. Line 1 and 5.

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

to: reference solution (c).

Pemetrexed Injection. Page 4234

Para 1

Change **from**: Pemetrexed Injection is a sterile solution of pemetrexed in Water for Injections.

to: Pemetrexed Injection is a sterile material consisting of pemetrexed Disodium heptahydrate with or without buffering agents and other excipients. It is filled in a sealed container.

The injection is constituted by dissolving the contents of the sealed container in the requisite amount of sterile Water for Injections or with suitable diluents immediately before use.

The constituted solution complies with the requirements for Clarity of solution and Particulate matter stated under Parenteral Preparations (Injections).

Related substances. After chromatographic system. Insert before gradient programme.

The relative retention time with reference to pemetrexed for pemetrexed R- dimer and pemetrexed S- dimer peaks are about 0.67 and 0.71 respectively.

Herbs and Herbal Products

Senna Leaf. Page 3261.

Para 2. lines 1 and 2.

Change from: Senna leaf contains not less than 1.0 per cent w/w of *sennosides A* and *B*, calculated on the dried basis.

to: Senna leaf contains not less than 1.0 per cent w/w of total *sennosides* calculated as *sennoside B*, on the dried basis**.**

Assay. *Test solution***.** lines 2 and 3.
Change **from:** add about 10 ml of 1.0 per cent v/v *acetic acid* and 25 ml of *methanol.*
to: add about 10 ml of 1.0 per cent v/v *glacial acetic acid* and 25 ml of *methanol.*
Reference solution. line 1.
Change **from:** A 0.004 per cent w/v solution of *sennosides RS* in *methanol.*
to: Dissolve an accurately weighed quantity of *calcium sennosides RS* containing about 10 mg of *sennosides* in 50 ml of the mixture of 10 ml of 1.0 per cent v/v *glacial acetic acid* and 40 ml of *methanol.*

After chromatographic system, line 5.
Change **from**: Calculate the content of *sennoside A* and *B.*
to: Calculate the total *sennosides* from the peak area of *sennoside A* and *B* using the content of total *sennosides* in *calcium sennoside RS*.
1 mg of *calcium sennoside* contain 0.9579 mg *sennoside*.

Senna Pods. Page 3262.

Para 2. lines 1 and 2.
Change **from**: Senna Pods contains not less than 1.0 per cent w/w of *sennosides A* and *B,* calculated on the dried basis.
to: Senna Pods contains not less than 1.0 per cent w/w of total *sennosides* calculated as *sennoside B,* on the dried basis.

Assay.*Test solution*. lines 2 and 3.
Change **from**: add about 10 ml of 1.0 percent v/v *acetic acid* and 25 ml of *methanol.*
to: add about 10 ml of 1.0 percent v/v *glacial acetic acid* and 25 ml of *methanol.*

Reference solution. line 1.
Change **from**: A 0.004 per cent w/v solution of *sennosides RS* in *methanol.*

to: Dissolve an accurately weighed quantity of *calcium sennosides RS* containing about 10 mg of *sennosides* in 50 ml of the mixture of 10 ml of 1.0 per cent v/v *glacial acetic acid* and 40 ml of *methanol*.

After chromatographic system, line 5.
Change **from:** Calculate the content of *sennoside A* and *B.*
to: Calculate the total *sennosides* from the peak area of *sennoside A* and *B* using content of total *sennosides in calcium sennoside RS.*
1 mg *calcium sennoside* contains 0.9579 mg *sennosides*.

Senna Dry Extract. Page 3263.

Para 2, line 1**.**
Change **from:** Senna dry extract contains not less than 90.0 per cent w/w and not more than 110.0 per cent w/w of the stated amount of *sennosides A* and *sennosides B,* calculated on the dried basis.
to: Senna dry extract contains not less than 85.0 per cent w/w and not more than 115.0 per cent w/w of the stated amount of total *sennosides*, calculated as *sennoside B*, as calcium salt on dried basis.
1 mg of *sennoside* is equivalent to 1.044 mg of *calcium sennoside*.

Identification. *Reference solution.* line 1**.**

Change **from**: Dissolve 10 mg of *senna dry extract RS* in 1 ml of a mixture of equal volumes of *methanol* and *water*.

to: Dissolve 10 mg of *calcium sennosides RS* in 1 ml of a mixture of equal volumes of *methanol* and *water*.

Assay. *Test solution*,
Change **from:** Dissolve an accurately weighed quantity of substance under examination containing about 10 mg of *sennosides* in 50.0 ml of the solvent mixture.

to: Dissolve an accurately weighed quantity of substance under examination containing about 10 mg of *calcium sennosides* in 50.0 ml of the solvent mixture.
Reference solution
Change **from:**. Dissolve an accurately weighed quantity of *calcium sennosides RS* containing about 10 mg of *sennosides* in 50.0 ml of the solvent mixture.

to: *Reference solution*: Dissolve an accurately weighed quantity of *calcium sennoside RS* containing about 10 mg of *calcium sennosides* in 50.0 ml of the solvent mixture.

After Chromatographic conditions, last line.
Change **from:** Calculate the content of *sennosides A* and *B*.

to: Calculate the total *sennosides* from the peak area of *sennoside A* and *B* using the declared content of total *sennosides* in *calcium sennosides RS.*

Senna Tablets. Page 3264.

Para 1. line 1.
Change **from:** Senna tablets contain not less than 85.0 per cent w/w and not more than 115.0 per cent w/w of the stated amount of *sennosides A* and *B*, calculated as *Sennoside B.*

to: Senna tablets contains not less than 85.0 per cent w/w and not more than 115.0 per cent w/w of the stated amount of total *sennosides*, calculated as *sennoside B*, as calcium salt .

1 mg of *sennoside* is equivalent to 1.044 mg of *calcium sennoside*.

Assay. ***Test solution***

Change **from:** Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing about 10 mg of *sennosides*, dissolve about 40 ml of solvent mixture and mix with the aid of ultrasound for 15 minutes. Dilute to 50 ml with the solvent mixture and filter.

to: Weigh and powder 20 tablets. Weigh accurately a quantity of the powder containing about 10 mg of *calcium sennosides*, dissolve about 40 ml of solvent mixture and mix with the aid of ultrasound for 15 minutes. Dilute to 50 ml with the solvent mixture and filter.

After Chromatographic system, Last line.
Change **from**: Calculate the content of *sennosides A* and *B*.

to: Calculate the total sennosides from the peak area of *sennoside A* and *B* using the declared content of total sennosides in *calcium sennosides RS*.

Labelling

Change **from**: The quantity of active ingredient is stated in terms of total *sennosides A* and *B*, expressed as the equivalent content of *sennoside B*.

to: Labelling. The quantity of active ingredient is stated in terms of total *sennosides* as calcium salt.