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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-2010/AL-3 **Dated:** 11-04-2012

To,

1. **All State Drug Controllers**
2. **Members of Scientific Body of the IPC**
3. **Members of Sub-committee of Scientific Body of the IPC**
4. **Government Analysts**
5. **Director of Drug Laboratories**
6. **IDMA/OPPI/BDMA/FFSAI/Small Scale Industry Associations**

TO
1) Have copy in IP volume for reference
2) Copy to JSO (D) Nodal
3) Also place a copy on website under circular
2/5/12
02/05/2012

AMENDMENT LIST-3 FOR IP 2010

As you are aware that the 6th edition of Indian Pharmacopoeia has become official from 1st December, 2010. Based on scientific inputs, some monographs, appendices needed upgradation, accordingly an Amendment List No. 3 is issued containing such amendments. This is for notice and compliance.

Yours faithfully,

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

Encl:
Amendment List-3 for IP 2010

AMENDMENT LIST-3 TO IP 2010

2.2.10. Microbiological Assay of Antibiotics

Table 3 - Stock solution and test dilution of Standard Preparation. Page 51
Column 4, line 2
Change **from**: DMF[7]
to: DMSO[11]
After Table 3, line 4
Insert at the end
"11. DMSO = Dimethyl sulphoxide"

2.3.21. *N,N*-Dimethyaniline. Page 83

Method B. last para, lines 6 and 7
Change **from**: internal standard solution
to: the reference solution

2.3.27. Hydroxyl Value. Page 85

Method A. Table, line 8, column 1
Change **from**: 01 to 350
to: 301 to 350

Inhalation Preparations. Page 726

Content of active ingredient delivered per actuation.
Para 3, last sentence
Change **from**: assay (A)
to: assay

Paragraphs 4 and 5: Delete the requirement

Microbial contamination. Page 740
Change **from**: **Microbial contamination** (2.2.9). Total viable aerobic bacterial count. Not more than 100 cfu per g of the powder.
E. coli. Absent in 10 g of the powder.
Salmonella. absent in 50 g of the powder.
Staphylococcus aureus. Absent in 10 g of the powder.
Psedomonas aeruginosa. Absent in 10 g of the powder.
to: **Microbial contamination** (2.2.9). Total viable aerobic bacterial count. Not more than 100 cfu per g of the powder.
E. coli. Absent in 1 g of the powder.
Staphylococcus aureus. Absent in 1g of the powder.
Psedomonas aeruginosa. Absent in 1g of the powder.

Adrenaline Injection. Page 779

Identification Para 1, line 3
Change **from**: adrenaline
to: adrenaline tartrate

Ampicillin. Page 2879
Test solution.
Change **to**: *Test solution.* Dissolve 27 mg of the substance under examination in mobile phase A and dilute to 10.0 ml with the same solvent.

Ampicillin Sodium. Page 2880
Test solution. Line 2
Change **from**: 50.0 ml
to: 10.0 ml

Ampicillin Injection. Page 2880
Test solution.
Change **to**: *Test solution.* Dissolve a quantity of the injection containing about 27 mg of the substance under examination in mobile phase A and dilute to 10.0 ml with the same solvent.

Ampicillin Trihydrate. Page 2881
Test solution. Line 2
Change **from**: 50.0 ml
to: 10.0 ml

Bupivacaine Hydrochloride. Page 933
Assay. Lines 3 and 4
Change **from**: *0.01 M ethanolic sodium hydroxide*
to: *0.1 M ethanolic sodium hydroxide*

Line 6
Change **from**: *0.01 M ethanolic sodium hydroxide*
to: *0.1 M ethanolic sodium hydroxide*

Carvedilol Tablets. Page 992
Related substances. After chromatographic system, para 1, line 1
Change **from**: reference solution (a)
to: reference solution (b)

Cinnarizine. Page 1088
Identification B.
Change **to**: In the test for Related substances the principal peak in the chromatogram obtained with the test solution corresponds to the principal peak due to cinnarizine in the chromatogram obtained with reference solution (a).

Dextrose. Page 1190
Sulphite. Line 4
Change **from**: decolorised magenta solution
to: decolorised magenta reagent

Docetaxel Trihydrate. Page 1242
Water. Line 1
Change **from**: 6.0 per cent to 8.0 per cent
to: 5.0 per cent to 7.0 per cent

Doxycycline Hydrochloride. Page 1257

Para 2, line 3
Change **from**: anhydrous basis
to: anhydrous and ethanol free basis.

Specific optical rotation. Line 1
Change **from**: -105° to -120°
to: -105° to -120°, calculated on anhydrous and ethanol free basis.

Light absorption. Line 5
Change **from**: 0.300 to 0.335
to: 0.300 to 0.335, calculated on anhydrous and ethanol free basis.

Light-absorbing impurities. Line 5
Change **from**: not more than 0.07
to: not more than 0.07, calculated on anhydrous and ethanol free basis.

Assay. Last line
Change **from**: $C_{22}H_{24}N_2O_8$
to: $C_{22}H_{25}ClN_2O_8$

Imipenem. Page 1486

Related substances. Last para, line 10
Change **from**: the secondary peaks
to: the secondary peaks, other than the peak corresponding to imipenem impurity A

Miconazole Nitrate. Page 2933

Identification. C, line 1
Change **from**: B
to: C

Neotame. Page 1769

Para 2, line 2
Change **from**: dried
to: anhydrous

Loss on ignition. Line 1
Change **from**: **Loss on ignition** (2.4.20).
to: **Sulphated ash** (2.3.18).

Ondansetron Oral Solution. Page 1818

Ondansetron Impurity D. *Test solution*. Lines 2 and 3
Change **from**: 0.08 per cent
to: 0.04 per cent

Reference solution (a). Line 1
Change **from**: 0.00005 per cent
to: 0.000025 per cent

Reference solution (b). Line 1
Change **from**: 0.00005 per cent
to: 0.000025 per cent

Line 2
Change **from**: 0.0002 per cent
to: 0.0001 per cent

Chromatographic system, last line
Change **from**: 20 µl
to: 40 µl

Paracetamol Oral Suspention. Page 2940

Lines 4 to 6
Delete the following
The suspension is constituted by dispersing the contents of the sealed container in the specified volume of water just before use.

Phenoxyethanol. Page 2942

Insert after **Identification**
Test A may be omitted if tests B and C are carried out. Tests B and C may be omitted if test A is carried out.

Simvastatin Tablets. Page 2104

Related substances. Last para
Change **to**: Inject the test solution and reference solution (a). In the chromatogram obtained with the test solution the area of any peaks corresponding to lovastatin and epilovastatin is not more than five times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent), the area of any peak corresponding to simvastatin impurity A is not more than 7.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.5 per cent). The area of any other secondary peak is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (0.4 per cent). The sum of the areas of all the secondary peaks other than any peaks corresponding to lovastatin, epilovastatin and simvastatin impurity A, is not more than five times the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent). Ignore any peak with an area less than 0.25 times of the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Streptomycin Sulphate. Page 2161

Para 2,
Change **from**: Streptomycin Sulphate has a potency equivalent to not less than 700 µg and not more than 850 µg of streptomycin per mg. It contains not less than 90.0 per cent of the stated amount of streptomycin, $C_{21}H_{39}N_7O_{12}$, calculated on the dried basis.
to: Streptomycin Sulphate has a potency equivalent to not less than 720 µg of streptomycin per mg.

Sulphadiazine. Page 2169

Related substances.
Change **to**: **Related substances**. Complies with test C for Related substances in Sulphonamides (2.3.7), Method C.

Sulphadiazine Tablets. Page 2170

Related substances. Line 1
Change **from**: Complies with test C,
to: Complies with test C for Related substances in Sulphonamides (2.3.7), Method C,

Telmisartan Tablets. Page 2960

Dissolution. Para 2, last line

Change **from:** 0.011 per cent

to: 0.0011 per cent

Thiopentone Sodium. Page 2216

Related substances. Line 1

Change **from:** Complies with the test,

to: Complies with the test for Related substances in Barbiturates (2.3.4),

Thiopentone Injection. Page 2217

Related substances. Line 1

Change **from:** Complies with the test,

to: Complies with the test for Related substances in Barbiturates (2.3.4),

Travoprost Eye Drops. Page 2251

Related substances.

Change **to:** **Related substances.** Determine by liquid chromatography (2.4.14).

Solvent mixture. Equal volumes of *water* and *acetonitrile.*

Test solution. Dilute the eye drops with the solvent mixture to obtain a solution containing 0.004 per cent w/v of travoprost.

Reference solution (a). A 0.004 per cent w/v solution of *travoprost RS* in the solvent mixture.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 10.0 ml with the solvent mixture.

Chromatographic system

- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Hypersil ODS),
- column temperature: 35°,
- sample temperature: 10°,
- mobile phase
  A: a buffer solution prepared by dissolving 1.5 g of *1-octane sodium sulphonic acid* in 1000 ml of *water*, adjusted to pH 2.5 with *orthophosphosric acid* ,
  B: a mixture of 80 volumes of *acetonitrile* and 20 volumes of mobile phase A,
- a linear gradient programme using the conditions given below,
- flow rate: 1 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 100 µl.

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0 - 50	50-42	50-58
50-52	42-50	58-50
52-60	50	50

Equilibrate the column for at least 60 minutes with the mobile phase at the initial composition.

Inject reference solution (a). The test is not valid unless the resolution obtained between travoprost and 5-trans travoprost is not less than 1.5. The column efficiency is not less than 2000 theoretical plates, the tailing factor is not more than 2.0 and the relative standard deviation for replicate injections is not more

than 2.0 per cent. The relative retention time with respect to travoprost for 5-trans travoprost is 1.05.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution the area of any secondary peak is not more than 0.4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (4.0 per cent) and the sum of areas of all the secondary peaks is not more than 0.6 times the area of the principal peak in the chromatogram obtained with reference solution (b) (6.0 per cent).

Assay.

Change to: **Assay.** Determine by liquid chromatography (2.4.14) as described in the test for Related substances. Inject reference solution (a) and the test solution.

Calculate the content of $C_{26}H_{35}F_3O_6$.

Zoledronic Acid. Page 2339

Loss on drying.

Change to: **Water** (2.3.43). 5.0 to 8.0 per cent, determined on 1.0 g in a mixture of equal volumes of *acetic acid* and *formamide*.