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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-007

Dated: 28-09-2015

#### 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/FSSAI/Small Scale Industry Associations

### **ERRATA** - 007 for IP 2014

As you are aware that the  $7^{th}$  edition of Indian Pharmacopoeia has become official from  $1^{st}$  April, 2014. Based on scientific inputs, some monographs, appendices needed corrections, accordingly an Errata – 007 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

(Dr. G. N/ Singh)

Secretary-cum-Scientific Director

Encl:

ERRATA - 007 for IP 2014

# **Errata 007 to IP-2014**

## **Allopurinol Tablets.** Page 1013

Related substances. Under chromatographic System

Change from:

Time	Mobile phase A	Mobile phase B
(in min)	(per cent v/v)	(per cent v/v)
0	100	100
30	0	100
40	0	100
42	100	0
to:		

to:

Time	Mobile phase A	Mobile phase B
(in min)	(per cent v/v)	(per cent v/v)
0	100	0
30	0	100
40	0	100
42	100	0

## Benzyl Alcohol. Page 1159.

Description.

Change from: A colourless liquid; almost odourless; taste, sharp and burning.

to: Clear, colourless, oily liquid.

# Brimonidine Tartrate Eye Drops. Page 3813

nH.

Change **from:** 5.7 to 6.7 **to:** 5.7 to 8.0

#### **Dexamethasone Tablets.** Page 1523

#### Identification B.

Change **to:** In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

#### Uniformity of Content. Test solution.

Change **from:** Finely crush one tablet, add sufficient quantity of a 0.002 per cent w/v solution of *hydrocortisone* in *methanol* (50 per cent) to produce a solution containing 0.0025 per cent w/v solution of Dexamethasone, shake for 10 minutes and filter through a glass-fiber filter paper (such as Whatman GF/C).

**to:** To one tablet, add sufficient *methanol* (50 per cent) to produce a solution containing 0.0025 per cent w/v of Dexamethasone, shake for 10 minutes and filter through glass-fibre filter.

Reference Solution.

Change **from:** A solution containing 0.0025 per cent w/v of *dexamethasone RS* and 0.002 per cent w/v of *hydrocortisone* (internal standard) in *methanol* (50 per cent).

to: A solution containing 0.0025 per cent w/v of dexamethasone RS in methanol (50 per cent).

#### Assay.

#### **Delete test solution (b)**

Change **from:** Test solution(a)

to: Test solution.

Reference Solution.

Change to: A solution containing 0.0125 per cent w/v of dexamethasone RS in methanol (50 per cent).

After chromatographic system.

Change **from:** Calculate the content of C22H29FO5 in the tablets.

to: Inject the reference solution and the test solution.

Calculate the content of C22H29FO5 in the tablets.

#### Diloxanide Furoate. Page 1580

#### Loss on drying.

Change **from**: (2.3.19)

**to**: (2.4.19)

### Doxofylline. Page 1625

**Assay.** After chromatographic system. line 1.

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

to: Inject reference solution.

Para 2, line 1.

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

to: Inject reference solution.

#### Ethacrynic Acid. Page 1693

Loss on drying.

Change **from**: (2.3.19)

**to**: (2.4.19)

## Fosinopril Sodium. Page 1826

Water.

Change **from**: (2.4.19)

**to**: (2.3.43)

## Frusemide Tablets . Page 1835

Identification B.

Change from: 4-dimethylaminobenzaldehyde solution.

to: 4-dimethylaminobenzaldehyde Regent.

### Gemcitabine Hydrochloride. Page 1849

**Related Substances**. Test solution (b).

Change to: Dilute 1.0 ml of test solution (a) to 20.0 ml with water.

## **Hyoscine Butylbromide**. Page 1926

Apo-compounds. Delete the test.

### **Hyoscine Hydrobromide**. Page 1929

**Apohyoscine**. Delete the test.

### Levodropropizine. Page 2084

**Impurity C**. Last Paragraph Line 3.

Delete. 0.5 times.

### Mebendazole. Page 2154

Identification B. Delete the test

C. Change to: B

### Mebendazole Tablets. Page 2154

Identification B. Delete the test

Delete the word A.

### Mesalazine Prolonged-release Tablets. Page 2183

Related substances. Last paragraph, line 10.

Delete: "0.5 times"

#### Metformin Tablets. Page 2187

**Identification. B**. Line 5.

Change **from**: dilute sodium hypochlorite solution

**to**: sodium hypochlorite solution (3 per cent Cl)

#### **Metolazone Tablets**. Page 3900

Uniformity of content. Test solution.

Change **from:** Disperse 1 tablets in 3 ml of *water* and 100 ml of *methanol* with the aid of ultrasound for 30 minutes. If disintegration is not complete, sonicate for an additional 30 minutes. Shake by mechanical means for 30 minutes and dilute to 200.0 ml with *methanol*. Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v of metolazone in *methanol*.

**to:** Disperse 1 tablets in 0.5 ml of *water* and 10.0 ml of *methanol* with the aid of ultrasound for 30 minutes. If disintegration is not complete, sonicate for an additional 30 minutes. Shake by mechanical means for 30 minutes and dilute to 20.0 ml with *methanol*. Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v of metolazone in the mobile phase.

Reference solution

Change **from:** A 0.0005 per cent w/v solution of *metolazone RS* in *methanol*.

**to:** A 0.025 per cent w/v solution of *metolazone RS* in *methanol*. Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v solution of *metolazone RS* in mobile phase.

Assay. Test solution. Lines 4,5 and 6.

Change **from**: Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v of metolazone in *methanol*.

**to**: Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v of metolazone in mobile phase.

Reference solution.

Change **to**: A 0.025 per cent w/v solution of *metolazone RS* in *methanol*. Dilute a volume of this solution to obtain a solution containing 0.0005 per cent w/v solution of *metolazone RS* in mobile phase.

### Myristic Acid. Page 2270

Lead. Last line

Change from: Calculate the content of lead, in the substance under examination.

to: Calculate the content of lead, in the substance under examination. (2 ppm)

Assay. Last line

Change **from:** Calculate the content  $C_{14}H_{28}O_2$ .

**to:** Calculate the content  $C_{14}H_{28}O_2$  by area normalization method.

#### **Orphenadrine Citrate.** Page 2387

Loss on drying.

Change **from**: (2.3.19) **to**: (2.4.19)

### **Orphenadrine Hydrochloride.** Page 2388

Loss on drying.

Change **from**: (2.3.19) **to**: (2.4.19)

## Piperazine Citrate. Page 2504

Water.

Change **from**: (2.4.19) **to**: (2.3.43)

#### **Teicoplanin**. Page 2828

**Heavy metals.** Line 1. Change **from:** 0.5 g **to:** 1.0 g

## Theophylline Injection Page 2852

**Assay.** Line 3

Change **from**: 0.008 percent **to**: 0.0008 percent

# Triethyl Citrate. Page 2915

Water.

Change **from**: (2.4.19) **to**: (2.3.43)

# **VETERINARY MONOGRAPHS**

# Spectinomycin Hydrochloride. Page 3566

**Assay.** After chromatographic system. Para 1, line 4. Change **from**: test solution (a). **to**: test solution (b).

# **Spectinomycin Injection**. Page 3568

**Assay.** After chromatographic system. Para 1, line 4. Change **from**: test solution (a). **to**: test solution (b).

$$\label{eq:Last line.} \begin{split} \text{Last line.} \quad & \text{Change from: } C_{14}H_{24}N_2O_7, 2HCl \\ & \text{to: } C_{14}H_{24}N_2O_7. \end{split}$$