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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-012 **Dated:** 16-12-2016

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 – 012 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 012 is issued containing minor corrections. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 012 for IP 2014

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

Errata-012 to IP-2014

2.3.45. Ethanol. Page 116.

Method I, under chromatographic system.

Change **from: -** nitrogen as carrier gas**.**

to: – flow rate. 30 ml per minute, using nitrogen as carrier gas

After chromatographic system, para 1.

Change **from:** Calculate the percentage content of ethanol from the area of the peaks due to ethanol in the chromatogram obtained with test solution (b) and reference solution

to: Calculate the percentage content of ethanol from the ratio of the area of the peaks due to ethanol and internal standard in the chromatogram obtained with test solution (b) and reference solution**.**

3.1. Infra- red Reference Spectra. Page 556.

Change the title **from**: **Promazine Hydrochloride**

to: **Promazine.**

Amoxycillin Trihydrate. Page 1054

Para2, line 2.

Change **from:** 100.5 per cent

to: 102.0 per cent

***N,N*-Dimethylaniline** (2.3.21).

Change **from:** Not more than 20 ppm, determined by Method A.

to: Not more than 20 ppm, determined by Method A.

NOTE - Test to be performed only if N,N Dimethylaniline is used in the synthesis.

Ampicillin Trihydrate. Page. 1070.

***N,N*-Dimethylaniline** (2.3.21).

Change **from:** Not more than 20 ppm, determined by Method B.

To: Not more than 20 ppm, determined by Method B.

NOTE- Test to be performed only if N,N Dimethylaniline is used in the synthesis

Bambuterol Tablets. Page 1135.

Assay, *Reference solution***.**

Change **from**: A 0.005 per cent w/v solution of *bambuterol RS* in the mobile phase.

To: A 0.005 per cent w/v solution of *bambuterol hydrochloride RS* in the mobile phase.

Betamethasone Cream. Page 1173

Assay. *Test solution*

Change **from:** Shake a quantity of Cream containing about 1 mg of Betamethasone Dipropionate with 50.0 ml of the solvent mixture containing 1.0 ml of internal standard solution. Heat in a water-bath at 60°, shaking intermittently, until the cream melts. Remove from the bath, and shake vigorously until the specimen has resolidified. Repeat the heating and shaking. Freeze in an ice-methanol bath for about 15 minutes, and centrifuge at 2500 rpm for about 5 minutes. Transfer a portion of the supernatant to a suitable vial.

to: Weigh and transfer the cream containing 2.0 mg of of Betamethasone Dipropionate into a capped 50.0 ml centrifuge tube, add 10.0 ml of solvent mixture followed by 5.0 ml of internal standard solution and mix. Heat in a water bath maintained at 60°, shaking intermittently, until the cream melts. Remove from the bath, and shake vigorously until the specimen has solidified. Repeat the heating and shaking. Freeze in an ice-methanol bath for about 15 minutes, and centrifuge to obtain a clear supernatant liquid.

Reference solution

Change **from:** Dissolve 1mg of *betamethasone dipropionate RS* in 50.0 ml of the solvent mixture containing 1.0 ml of internal standard solution.

Transfer 10.0 ml of this solution to a suitable vial, and add 5.0 ml of internal standard solution, to obtain a solution having known concentrations of about 0.133 mg of Betamethasone Dipropionate and about 0.15 mg of Beclomethasone Dipropionate per ml.

to: Add 5.0 ml of internal standard solution to 10.0 ml of a 0.02 percent w/v solution of *betamethasone dipropionate RS* in solvent mixture and mix.

Last para.

Change **from**: Calculate the content of betamethasone, $C_{22}H_{29}FO_5$ in the Cream.

to: Calculate the content of betamethasone, $C_{22}H_{29}FO_5$ in the cream by using the peak area ratio of the betamethasone dipropionate peak and the internal standard peak obtained from the reference solution and the test solution.

Bifonazole Cream. Page 1191

Assay. *Test solution*.
Change **from**: Shake a quantity of the cream containing about 100 mg of Bifonazole --------.

to: Shake a quantity of the cream containing about 10 mg of Bifonazole ---------.

Reference solution.
Change **from**: A 0.2 per cent w/v solution of *bifonazole RS* in *methanol.*

to: A 0.02 per cent w/v solution of *bifonazole RS* in *methanol.*

Clomifene Citrate. Page 1429.

Identification D.

"Delete the test"

Ethanolamine. Page 1701

Related substances. Under Chromatographic system

- flow rate:

Change **to**: Use helium or nitrogen as the carrier gas at 1.0 ml per minute with a flow rate of the make up gas of 20 ml per minute.

Finasteride. Page.1759, 4189

Related substances, Under chromatographic system

Change **from:**

Name	Relative Retention time (in minutes)	Correction factor
Finasteride impurity A[1]	0.9	2.4
Finasteride (Retention time: about 28 minutes)	1.0	---
Finasteride impurity C[2]	1.3	--

to:

Name	Relative Retention time (in minutes)	Correction factor
Finasteride impurity A[1]	0.9	2.4
Finasteride (Retention time about: 28 minutes)	1.0	---
Finasteride impurity C[2]	1.3	0.72

Hydroxychloroquine Tablets. Page 1916, 4200

Assay. Under chromatographic system, gradient programme.

Change **to**:

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	100	0
2	100	0
10	85	15
18	100	0
25	100	0

Hyoscyamine Sulphate. Page 1932

Related substances. Under chromatographic system, gradient programme,

Change **to**:

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	95	5
2	95	5
20	70	30
20.1	95	5
25	95	5

Glibenclamide Tablets. Page 1861

Assay. *Test solution.*

Change **to**: Weigh and powder 20 tablets. Weigh a quantity of powder containing 5 mg of Glibenclamide and disperse with the aid of ultrasound, with a mixture of 2.0 ml of *water* and 20.0 ml of *methanol.* Shake for further 10 minutes, filter, rejecting the first few ml of filterate.

Reference solution. Lines 2 and 3.
Change **from**: Dilute 1ml of this solution to 4 ml with *methanol*.
to: Dilute 1 volume of this solution to 4 volumes with *methanol*.

Liquid Maltitol. Page 2149

Assay. *Reference solution (a)*.
Change **from:** A 1.0 per cent w/v solution of *maltitol RS* in *water*.
to: A 2.0 per cent w/v solution of *maltitol RS* in *water*.
Reference solution (b).
Change **from:** A 0.16 per cent w/v solution of *sorbitol RS* in *water*.
to: A 0.32 per cent w/v solution of *sorbitol RS* in *water*.
Reference solution (c).
Change **from:** A solution containing 1.0 per cent w/v each of *maltitol RS* and *sorbitol RS* in *water*.
to: An equal mixture of reference solution (a) and reference solution (b).

Metformin Hydrochloride. Page 2186, 3891, lines 5 and 6

Assay. Para 2

Change **from**: 1 ml of *0.1 M perchloric acid* is equivalent to 0.0165 g of C_4H_{12} Cl N_5.

to: 1 ml of *0.1 M perchloric acid* is equivalent to 0.01656 g of C_4H_{12} Cl N_5

Methotrexate Tablets. Page. 2194.

Assay. After chromatographic system.

Change from: Inject reference solution (a). The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (b). The resolution between the peaks due to methotrexate and folic acid is not less than 5.0.

Inject reference solution (a) and the test solution.

to: Inject reference solution (a). The resolution between the peaks due to methotrexate and folic acid is not less than 5.0.

Inject reference solution (b). The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (b) and the test solution.

Methylprednisolone. Page. 2205.

Related substance. Under Chromatographic condition**.**

Change from:

Time (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 (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

Ofloxacin Tablets. Page 2369

Related Substances. Chromatographic system, mobile phase,

Change **from**: a mixture of 8 volumes of *acetonitrile* and 92 volumes of *phosphate buffer pH 2.4* prepared by dissolving 27.2 g of *monobasic potassium phosphate* in 1000 ml of *water*, adjust the pH to 2.4 with *orthophosphoric acid*,

to: a mixture of 8 volumes of *acetonitrile* and 92 volumes of *phosphate buffer* prepared by dissolving 2.72 g of *monobasic potassium phosphate* in 1000 ml of *water*, adjust the pH to 2.4 with *orthophosphoric acid*,

Promazine Tablets.Page 2570

Identification A. Lines 6, 7, 8 and 9
Change **from**: On the residue, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *promazine hydrochloride RS* treated in the same manner.

.

to: On the resulting solution, determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *promazine hydrochloride RS* treated in the same manner or with the reference spectrum of promazine.

Sildenafil Citrate. Page.2725.

Identification B.

"Delete the test"

Tolazamide Tablets. Page. 2885

Assay, Para 1**,** last line.
Change **from**: Using phenolphthalein solution as indicator.
to: Using phenolphthalein solution as indicator.Carry out a blank titration**.**

Tamsulosin Hydrochloride Prolonged-release Capsules. Page. 3936.

Para 2**.**
Change from: Tamsulosin Prolonged release Capsules contain not less than 95.0 per cent and not more than 105.0 per cent of the stated amount of tamsulosin hydrochloride, $C_{20}H_{28}N_2O_5$ S,HCl.

To: Tamsulosin Prolonged release Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of Tamsulosin hydrochloride, $C_{20}H_{28}N_2O_5$ S,HCl.

Abiraterone Acetate. Page 4151

Related substances. After chromatographic system.

Change **from**: Name

	Relative retention time	Correction factor
Abiraterone acetate impurity A[1]	0.22	1.3
Abiraterone acetate impurity B[2]	0.41	1.51
Abiraterone acetate impurity C[3]	0.49	0.49
Abiraterone acetate impurity D[4]	0.58	0.89
Abiraterone	0.67	0.44
Abiraterone acetate (Retention time: about 26 minute)	1.0	---
Reduced impurity	1.07	1.3

1(3β)- 3-hydroxy-androst-5- en-17-one,
2(3β)- 3-acetoxy-androst-5- en-17-one,
317-iodo-androsta-5,16-dien-3-beta-ol,
45,16-pregnadien-3B-acetoxy-20-one.

to: Name

	Relative retention time	Correction factor
Abiraterone acetate impurity A[1]	0.22	1.3
Abiraterone acetate impurity B[2]	0.41	1.51
Abiraterone acetate impurity C[3]	0.49	0.49
Abiraterone acetate impurity D[4]	0.58	0.89
Abiraterone	0.67	0.44
Abiraterone acetate (Retention time: about 26 minute)	1.0	---
Reduced impurity[5]	1.07	1.3

[1](3β)- 3-hydroxy-androsta-5- ene-17-one,
[2](3β)- 3-acetoxy-androsta-5- ene-17-one,
[3]17-iodo-androsta-5,16-diene-3-beta-ol,
[4]5, 16-pregnadien-3B-acetoxy-20-one,
[5](3β)- 17-(pyridine-3-yl)androsta-16- ene-3-ol,

Labetalol Hydrochloride. Page 4206

Change title **to**: **Labetalol Injection.** Page 2048

HERBS AND HERBAL PRODUCTS.

Arjuna Dry Extract. Page 3181

Identification B.

Reference solution, Line 1.

Change **from**: *arjugenin*

to: *arjungenin*.

Daruharidra Roots. Page 3206

Just above the Grid.

Change **from**: *Berberis arisata*.

to: *Berberis aristata*.

Bhibhitaki. Page 3192

Assay. *Reference solution*, line 2.
Change **from**: *ellagic RS*
to: *ellagic acid RS*

Guggul Resin. Page 3219

Para 2, line 2
Change **from**: *gugulsterones*
to: *guggulsterones*

Assay. *Reference solution*. line 2.
Change **from**: gugulsterones
to: guggulsterones

After chromatographic system, lines 2, 3 and 6.
Change **from**: gugulsterones
to: guggulsterones

Gugulipid. Page 3220

Change Title **from**: **Gugulipid.**
to: **Guggulipid.**

Para 2, line 2.
Change **from**: gugulsterones
to: guggulsterones

Identification B
*Reference solution***.** Line 2.
Change **from**: *gugulipid RS*
to: *guggulipid RS*

Assay. Reference solution. Line 2.
Change **from**: *gugulsterones*
to: *guggulsterones*

After chromatographic system, lines 2, 3 and 6
Change **from**: *gugulsterones*
to: *guggulsterones*

Gugulipid tablets. Page 3221

Change Title **from**: **Gugulipid Tablets.**
to: **Guggulipid Tablets.**

Para 1, line 1.
Change **from**: *gugulipid*
to: *guggulipid*
Para 1, line 2.
Change **from**: *gugulsterones*
to: *guggulsterones*

Identification.
Para1,Line 2.
Change **from**: gugulsterones
to: guggulsterones

Identification B.
*Reference solution***.** Line 1.
Change **from**: *gugulipid RS*
to: *guggulipid RS*

Assay. *Test solution*. Line 3
Change **from**: *gugulsterones*
to: *guggulsterones*

Reference solution. line 2
Change **from**: *gugulsterones*
to: *guggulsterones*

After chromatographic system, lines 2, 3 and 6
Change **from**: *gugulsterone*
to: *guggulsterone*

Labelling. Line 2
Change **from**: *gugulsterones*
to: *guggulsterones*

Methi. Page 3246
Identification C.
Reference solution, line 1and 2
Change **from**: *trigonelline hydrochloride*.
to: *trigonelline hydrochloride RS*.

Veterinary Monographs.
Benzathine Penicillin, Page 1145

Under **Tests**

change **from**: **Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared in the following manner. Suspend 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide*, dilute 1 ml to 100 ml and use the supernatant liquid.

to: **Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared by suspending 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide* diluted 1 ml to 100 ml and using the supernatant.

Benzathine Penicillin Injection, Page 1147

Under **Tests**

change **from**:**Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared by suspending 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide*, diluting 1 ml to 100 ml and using the supernatant.

to:**Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared by suspending 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide* diluted 1 ml to 100 ml and using the supernatant.

Fortified Benzathine Penicillin Injection, Page 1148

Under **Tests**

change **from**: **Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared by suspending 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide*, diluting 1 ml to 100 ml and using the supernatant.

to:**Bacterial endotoxin** (2.2.3). Not more than 0.13 Endotoxin Unit per ml of a solution prepared by suspending 20 mg of the substance under examination in 20 ml of *0.1 M sodium hydroxide* diluted 1 ml to 100 ml and using the supernatant.