Phone No. : 2783400, 2783401 2783392
Fax No. : 2783311
E-Mail : ipclab@vsnl.net
Website : www.ipc.gov.in

INDIAN PHARMACOPOEIA COMMISSION
MIN. OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA
SECTOR -23, RAJ NAGAR, GHAZIABAD - 201002

No. IPC/7035/IP-2014/ER-001 **Dated**: 01-10-2014

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/FFSAI/Small Scale Industry Associations**

ERRATA – 001 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 – 001 is issued containing such minor corrections which are already taken care and appear in IP Addendum – 2015 to IP - 2014. This is for notice and immediate compliance.

Yours faithfully,

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

Encl:
ERRATA – 001 for IP 2014

ERRATA - 001 to IP - 2014

Acesulphame Potassium. Page 984

Related substances. After chromatographic system, para 1, line 1
Change **from**: reference solution (b)
to: reference solution (c)

Alprazolam. Page 1015

Identification B, line 1
Change **from**: *water*
to: *methanol*

Arterolane Maleate. Page 1084

Para 1
Change **to**: Arterolane Maleate is [(*N*-(2-amino-2-methylpropyl)-2-*cis*-dispiro(adamantane-2,3'-[1,2,4]trioxolane-5',1''-cyclohexane)-4''- yl]acetamide maleate.

Maleic Acid. Insert in the beginning
22.0 per cent to 24.5 per cent w/w, calculated on anhydrous basis

Assay.
Solvent mixture. Delete the requirement

Test solution. Lines 2 and 3
Change **from** : solvent mixture
to: mobile phase

Reference solution. Line 2
Change **from** : solvent mixture
to: mobile phase

After chromatographic system, para 1, line 2
Change **from** : 3000
to: 600

Line 3
Change **from** : 2.0
to: 3.0

Azithromycin. Page 1117

Specific optical rotation
Change **to**: **Specific optical rotation** (2.4.22). – 45.0º to – 49.0º, determined in solution A, at 20º.

Bambuterol Tablets. Page 1135

Related substances. Change **to**:

Related substances. Determine by liquid chromatography (2.4.14), as described in the Assay with the following modifications.
Test solution. Disperse a quantity of powdered tablets containing 50 mg of Bambuterol Hydrochloride in 20 ml of the mobile phase, with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with the mobile phase, filter. Dilute 5.0 ml of this solution to 10.0 ml with the mobile phase.

Inject the test solution. The area of any secondary peak is not more than 0.5 per cent and the sum of the areas of all the secondary peaks is not more than 1.0 per cent, calculated by area normalization method.

Betaxolol Eye Drops. Page 1184

Para 2, line 3
Change **from**: $C_{18}H_{29}O_{3.}$
to: $C_{18}H_{29}NO_{3.}$

Assay. Last line
Change **from**: $C_{18}H_{29}O_{3.}$
to: $C_{18}H_{29}NO_{3.}$

Bortezomib. Page 1200

Para 2, last line
Change **from**: anhydrous basis.
to: dried basis.

Specific Optical Rotation.
Change **to**: **Specific Optical Rotation** (2.4.22). -50.0° to -55.0°, calculated on dried basis and determined in a 1.0 per cent w/v solution in *methanol.*

Water. Change **to**:
Loss on drying (2.4.19). Not more than 5.0 per cent, determined on 0.5 g by drying over *phosphorus pentoxide* at room temperature, under vacuum at a pressure of 1.5kPa to 2.5kPa for 3 hours.

Bromocriptine Capsules. Page 1205

Identification. B. Line 2
Change **from**: test solution (b)
to: test solution

Line 3
Change **from**: reference solution (d)
to: reference solution (e)

Related substances. *Reference solution (e)*. Line 1
Change **from**: 0.023 per cent
to: 0.23 per cent

Bromocriptine Tablets. Page 1207

Identification. C. Line 2
Change **from**: test solution (b)
to: test solution

Line 3

Change **from**: reference solution (d)
to: reference solution (e)

Related substances. *Reference solution (e)*. Line 1
Change **from**: 0.055per cent
to: 0.55 per cent

Calamine Ointment. Page 1240

Lines 6 and 7.
Change **from**: Calamine Ointment contains not less than 7.8 per cent and not more than 9.4 per cent w/w of Zn.
to: Calamine Ointment contains not less than 13.5 per cent and not more than 16.5 per cent w/w of ZnO.

Assay. Last line
Delete: 1g of the residue is equivalent to 0.8034 g of Zn.

Chloramphenicol Capsules. Page 1349

Identification. Line 8
Change **from**: extracts
to: extracts and evaporate to dryness.

Cholecalciferol Injection. Page 1384

Lines 2 and 3
Change **from**: Cholecalciferol Injection is a sterile solution containing 0.75 per cent w/v of Cholecalciferol in Ethyl Oleate
to: Cholecalciferol Injection is a sterile solution of Cholecalciferol in Ethyl Oleate.

Lines 4 and 5
Change **from**: Cholecalciferol Injection contains not less than 0.67 per cent and not more than 0.83 per cent of cholecalciferol, $C_{27}H_{44}O$
to: Cholecalciferol Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of cholecalciferol, $C_{27}H_{44}O$.

Description.
Change **to**: A clear, colourless to pale yellow liquid.

Clindamycin Injection. Page 1420

Para 2, line 2
Change **from**: 105.0 per cent
to: 120.0 per cent

Clobetasol Propionate. Page 1423

Related substances. After chromatographic system, para 2, lines 1 and 3
Change **from**: test solution
to: test solution (a)

Clonidine Tablets. Page 1438

Uniformity of content. Para 2, line 1
Change **from**: 200 ml
to: 20 ml

Para 2, line 8
Change **from**: supernatant liquid
to: chloroform layer

Assay. Line 2
Change **from**: 100 µg
to: 150 µg

Clotrimazole Cream. Page 1443

2-Chlorotritanol. *Test solution***,** line 7
Change **from**: extraction with further quantities
to: extractions with two further quantities

Line 9
Change **from**: *0.02 M phosphoric acid*.
to: *methanol*.

Reference solution (a). Line 3
Change **from**: *0.02 M phosphoric acid*.
to: *methanol*.

Reference solution (b). Line 2
Change **from**: the same solvent mixture.
to: *methanol*.

Assay. Change **to**:
Assay. Determine by liquid chromatography (2.4.14).
Test solution. Extract a quantity of the cream containing 25 mg of Clotrimazole by warming with 25 ml of *methanol* in a water-bath at 50° for 5 minutes, shaking occasionally. Remove from the water-bath, shake the mixture vigorously while cooling to room temperature, cool in ice for 15 minutes, centrifuge for 5 minutes and decant the supernatant liquid. Repeat the extraction with 20 ml, of *methanol*. Dilute the combined methanol extracts to 50.0 ml with methanol.

Reference solution (a). A 0.05 per cent w/v solution of *clotrimazole RS* in *methanol*

Reference solution (b). A solution containing 0.01 per cent w/v solution each of *clotrimazole RS* and *2-chlorotritanol RS* in *methanol*

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 75 volume

s of *acetonitrile* and 25 volumes of a buffer solution prepared by dissolving 4.35 g of *dibasic potassium phosphate* in 1000 ml of *water*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 25 µl.

The relative retention time with reference to clotrimazole for 2-chlorotritanol is about 1.2.

Inject reference solution (b). The test is not valid unless the resolution between clotrimazole and 2-chlorotritanol peaks is not less than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{22}H_{17}ClN_2$ in the cream.

Colistimethate Sodium. Page 1456

Identification. D.
Change **from**: reaction (a)
to: reaction (b)

Colistimethate Injection. Page 1457

Identification. D.
Change **from**: reaction (a)
to: reaction (b)

Activated Dimethicone. Page 1585

Identification. A; lines 4 and 5
Change **from**: 5 ml of the lower layer
to: 5 ml of the upper layer

Assay. *For polydimethylsiloxane*, line 6
Change **from**: 5 ml of the lower layer
to: 5 ml of the upper layer

Disodium Edetate. Page 1594

Assay. Line 5.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.

Disodium Edetate Injection. Page 1595

Assay. Lines 6 and 7.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.

Disodium Edetate. Page 1594

Assay. Line 5.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.

Disodium Edetate Injection. Page 1595

Assay. Lines 6 and 7.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.

Domperidone Suspension. Page 1614

Assay. Chromatographic system, line 4
Change **from**: 0.5 per cent w/v of *ammonium acetate solution*
to: 45 volumes of 0.5 per cent w/v of *ammonium acetate solution,*

Drotaverine Tablets. Page 1632

Para 2, line 3
Change **from**: drotaverine, $C_{24}H_{31}NO_4$
to: drotaverine hydrochloride, $C_{24}H_{31}NO_4$.HCl.

Disintegration. Delete the requirement

Assay. Chromatographic system,
mobile phase Change **to:** mobile phase: a mixture of 25 volumes of buffer solution prepared by dissolving 3.12 g of *sodium dihydrogen orthophosphate* in *water* and dilute to 1000 ml with *water*, adjusting the pH to 6.5 with *sodium hydroxide solution* ,40 volumes of *methanol and 35* volumes of *acetonitrile,*

Last line
Change **from**: $C_{24}H_{31}NO_4$
to: $C_{24}H_{31}NO_4$.HCl.

Enoxaparin Sodium. Page 1657

Identification
A. After chromatographic system, para 1, line 2
Change **from**: 10000 theoretical plates
to: 6000 theoretical plates

Eplerenone. Page 1668

Assay. Chromatographic system, line 1
Change **from**: a stainless steel column 5 cm x 2.1 mm
to: a stainless steel column 15 cm x 4.6 mm

Escitalopram Tablets. Page. 1686

Dissolution. line 2,
Change **from**: Medium. 900 ml of *water*
to: Medium. 900 ml of *0.1 M hydrochloric acid*

Ethambutol Hydrochloride. Page 1695

Meso ethambutol (RS isomer)
Method B. Chromatographic system, gradient programme
Change **to**:

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	71	29
30	71	29
35	0	100
37	0	100
38	71	29

Flavoxate Hydrochloride. Page 1763

Related substances. *Reference solution (c)*. line 2
Change **from**: 0.00015 per cent
to: 0.003 per cent

Flurbiprofen Eye Drops. Page 1808

Para 2, line 3

Change **from**: flurbiprofen sodium, $C_{15}H_{12}FNaO_2$
to: flurbiprofen sodium dihydrate, $C_{15}H_{12}FNaO_2.2H_2O$

Assay. Last line
Change **from**: $C_{15}H_{12}FNaO_2$
to: $C_{15}H_{12}FNaO_2.2H_2O$

Fluticasone Propionate. Page 1811

Water (2.3.43). Lines 2 and 3
Change **from**: using as solvent a mixture of equal volumes of *chloroform* and *methanol*
to: using *methanol* as solvent.

Fluvoxamine Tablets. Page 1820

Related substances. Change **to**:

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of powdered tablets containing 0.25 g of Fluvoxamine Maleate with 125 ml of the mobile phase for 10 minutes and dilute to 250.0 ml with the mobile phase. Centrifuge and use the supernatant liquid.

Reference solution (a). Dilute 1.0 ml of the test solution to 100.0 ml with the mobile phase.

Reference solution (b). Add 1.0 ml of *1 M hydrochloric acid* to 10.0 ml of the test solution and heat on a water-bath for 10 minutes.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with endcapped octylsilane bonded to porous silica (5 µm),
- column temeperature: 35°,
- mobile phase: a mixture of 40 volumes of a solution containing 1.25 per cent w/v of *diammonium hydrogen orthophosphate* and 0.275 per cent w/v of *sodium heptanesulphonate monohydrate* and 60 volumes of *methanol*, adjusting the pH to 3.5 with *orthophosphoric acid*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

Inject reference solution (b). The relative retention time with reference to fluvoxamine maleate (retention time: about 7 to 9 minutes) for addition product is about 0.65.

Inject reference solution (a). The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak due to 'addition product' is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). The area of any other secondary peak 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 the peak due to maleic acid which elutes immediately after the solvent front and 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).

Fusidic Acid. Page 1838

Identification. B; line 2
Change **from**: *silica gel G*
to: *silica gel* G_{254}

Last para, line 3

Change **from**: 365 nm
to: 254 nm

Gemcitabine Hydrochloride. Page 1849

Para 2, line 3
Change **from**: on the dried basis
to: on as is basis

Related substances. *Test solution (b).* Line 1
Change **from**: 10.0 ml
to: 1.0 ml

Hydrochlorothiazide. Page 1900

Assay. Lines 1 and 2
Change **from**: *anhydrous pyridine*
to: *dimethyl sulphoxide*

Hydroxychloroquine Sulphate. Page 1915

Related substances. 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

Chlorides. Line 1
Change **from**: 1.4 g.
to: 0.7 g.

Lamivudine Tablets. Page 2056

Related substances. *Test solution*.
Change **to**: *Test solution*. Disperse a quantity of the powdered tablets containing 600 mg of lamivudine in 20 ml of *water*, with the aid of ultrasound. Add 20 ml of *acetonitrile*, mix with the aid of ultrasound for 10 minutes and dilute to 100.0 ml with *water* and filter.

Assay. *Solvent mixture.*
Change **from**: *Solvent mixture.* 50 volumes of *water* and 50 volumes of *acetonitrile*
to: *Solvent mixture.* 80 volumes of *water* and 20 volumes of *acetonitrile.*

Lansoprazole. Page 2067

Related substances. Last para, line 3
Change **from**: 0.4 per cent
to: 0.4 times

Line 5
Change **from**: reference solution (b)
to: reference solution (b) (0.4 per cent)

Lines 7 and 9
Change **from**: 0.1 per cent
to: 0.1 times

Lines 8 and 11
Change **from**: reference solution (b)
to: reference solution (b) (0.1 per cent)

Levonorgestrel and Ethinyloestradiol Tablets. Page 2091

Identification

Reference solution. Line 3.
Change **from**: *water*.
to: *dichloromethane.*

Reference solution (a). Line 2
Change **from**: *norgestrel RS*
to: *levonorgestrel RS*

Levosalbutamol Sulphate. Page 2095

Enantiomeric Purity. After chromatographic system, para 1, lines 3 to 5
Change **from**: The first peak is due to levosalbutamol and the second peak is due to dextrosalbutamol.
to: The first peak is due to dextrosalbutamol and the second peak is due to levosalbutamol.

Lignocaine Gel. Page 2098

Identification. A. Last line.
Change **from**: reference spectrum of lignocaine hydrochloride.
to: reference spectrum of lignocaine.

2,6-Dimethylaniline. Last line
Change **from**: (20 ppm).
to: (400 ppm).

Menthol. Page 2173

Related substances. Last para, last line.
Change **from**: (0.5 per cent).
to: (0.05 per cent).

Meropenem Injection. Page 2179

Sodium Carbonate. Title
Change **to**: **Content of Sodium**

Line 2
Change **from**: sodium carmbonate
to: sodium

Labelling. Line 1
Change **from**: meropenem
to: meropenem and sodium

Methotrexate Tablets. Page 2194

Related substances. Last para, line 8
Change **from**: 1.5 times
to: 2.5 times

Lines 9 and 10
Change **from**: reference solution (a) (0.3 per cent)
to: reference solution (a) (0.5 per cent)

Methylergometrine Injection. Page 2202

Assay. Para 1, line 10
Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2,
Delete: 1 mg of *methylergometrine maleate RS* is equivalent to 1.032 mg of $C_{20}H_{25}N_3O_2$, $C_4H_4O_4$.

Methylergometrine Tablets. Page 2203

Uniformity of content. Para 2, line 16

Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2,
Delete the requirement.

Assay. Para 1, lines 11
Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2, lines 1 and 2
Delete: 1 mg of *methylergometrine maleate RS* is equivalent to 1.032 mg of $C_{20}H_{25}N_3O_2$, $C_4H_4O_4$.

Mifepristone. Page 2234

Optical rotation. Title
Change **to**: **Specific Optical rotation**

Moxifloxacin Hydrochloride. Page 2254

Molecular formula.
Change **from** : $C_{21}H_{25}ClFNO_3O_4$
to : $C_{21}H_{25}ClFN_3O_4$.

Para 2, line 2
Change **from** : $C_{21}H_{25}ClFNO_3O_4$
to : $C_{21}H_{25}ClFN_3O_4$.

Moxifloxacin Eye Drops. Page 2255

Assay : Chromatographic system: Gradient programme
Change **to** :

Time (in min)	Mobile phase A (per cent w/v)	Mobile phase B (per cent v/v)	Flow rate (ml per minute)
0	69	31	0.5
30	69	31	0.5
31	60	40	0.9
36	60	40	0.9
37	69	31	0.5
42	69	31	0.5

Mupirocin. Page 2265

Para 3, line 2
Change **from**: dried basis
to: anhydrous basis

Ondansetron Tablets. Page 2380

Uniformity of content. Line 4
Change **from**: reference solution (a)
to: the reference solution

Test solution. Line 2
Change **from**: 0.01 per cent
to: 0.005 per cent

Paracetamol Syrup. Page 2433

Title. Change **to**: **Paracetamol Paediatric Syrup**

Line 1.
Change **from**: Paracetamol Oral Solution ; Acetaminophen Syrup
to: Paracetamol Paediatric Oral Solution ; Acetaminophen Paediatric Syrup

Line 2.
Change **from**: Paracetamol Syrup
to: Paracetamol Paediatric Syrup

Line 4.
Change **from**: Paracetamol Syrup
to: Paracetamol Paediatric Syrup

4- Aminophenol. Chromatographic system, line 1.
Change **from**: 20 cm x 4.6 mm
to: 25 cm x 4.6 mm

After chromatographic system, para 1
Change **to**: Inject the reference solution and the test solution. In the chromatogram obtained with the test solution the area of any peak corresponding to 4-aminophenol is not more than the area of the peak in the chromatogram obtained with the reference solution (0.5 per cent). Peaks with a long retention time may occur due to preservatives in the preparations.

Paroxetine Hydrochloride. Page 2439

Related substances. Chromatographic system, mobile phase A, line 1
Change **from**: 5 volumes of trifluoroacetic acid
to: 0.5 volumes of trifluoroacetic acid

mobile phase B, line 1
Change **from**: 5 volumes of trifluoroacetic acid
to: 0.5 volumes of trifluoroacetic acid

Gradient programme
Change **to**:

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	80	20
30	80	20
50	20	80
55	20	80
60	80	20
65	80	20

Plaster of Paris. Page 2511

Para 1, line 2.
Change **from**: Plaster of Paris is prepared by heating powdered gypsum, $CaSO_4,½H_2O$,
to: Plaster of Paris is prepared by heating powdered gypsum, $CaSO_4,2H_2O$,

Procainamide Hydrochloride. Page 2555

Assay. Line 2, insert after *hydrochloric acid*
", add 3 g of *potassium bromide*, cool in ice"

Procainamide Injection. Page 2555

Assay. Lines 2 and 3, insert after boil for 1 minute
", add 3 g of *potassium bromide*, cool in ice"

Procainamide Tablets. Page 2556

Assay. Line 4, insert after boil for 1 minute
", add 3 g of *potassium bromide*, cool in ice"

Proguanil Hydrochloride. Page 2567

4-Chloroaniline.
Insert after **4-Chloroaniline.**
“Not more than 250 ppm.”

Line 10.
Change **from**: 1.25 µg
to: 1.25 µg per ml

Proguanil Tablets. Page 2568

Insert after **4-Chloroaniline.**
“Not more than 250 ppm.”

Line 14
Change **from**: 1.25 µg
to: 1.25 µg per ml

Propofol Injection. Page 2578

Assay. Para 3
Change **from**: reference solution (b)
to: reference solution (a)

Protriptyline Tablets. Page 2592

Insert before **Other tests.**
Uniformity of content. *(For tablets containing 10 mg or less)*
Disperse one tablet in 50 ml of a solution prepared by mixing 1 volume of *1 M hydrochloric acid* and 9 volumes of *methanol* and dilute to 100.0 ml with the same solution. Shake well and filter, discard the first few ml of filtrate and dilute a volume of the filtrate containing 1 mg of protriptyline hydrochloride to 100 ml with the same solution and measure the absorbance at the maximum at 292 nm (2.4.7). Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the specific absorbance at 292 nm.

Assay. Line 8.
Change **from**: Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the absorbance
to: Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the specific absorbance at 292 nm.

Racecadotril Capsules. Page 2634

Assay. Chromatographic system, line 2
Change **from**: porous silica
to: porous silica (5 µm)

Sertraline Tablets. Page 2722

Para 1, lines 2 and 3
Change **from**: sertraline hydrochloride, $C_{17}H_{17}Cl_2N$,HCl.
to: sertraline, $C_{17}H_{17}Cl_2N$.

Dissolution. After chromatographic system, line 1
Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$
Last line

Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$

Related substances. After chromatographic system, para 2, last line
Change **from**: reference solution (c)
to: reference solution (d)

Assay. Last line
Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$

Sodium Chloride Injection. Page 2744

Assay. Change **to**:
Assay. Titrate a measured volume containing about 0.2 g of sodium chloride with *0.1 M silver nitrate* using *potassium chromate solution* as indicator.
1 ml of *0.1 M silver nitrate* is equivalent to 0.005844 g of NaCl.

Sucralose. Page 2801

Related substances. Line 2
Change **from**: coating the plate with *silica gel*.
to: coating the plate with *octadecylsilanized silica gel*.

Assay. Change **to**:

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 250 mg of the substance under examination in the mobile phase and dilute to 25.0 ml with the mobile phase.

Reference solution. A 1.0 per cent w/v solution of *sucralose RS* in the mobile phase.

Chromatographic system
- a stainless steel column 10 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 85 volumes of *water* and 15 volumes of *acetonitrile*,
- flow rate: 1.5 ml per minute,
- refractive index detector
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{12}H_{19}Cl_3O_8$.

Tobramycin Injection. Page 2881

Related substances.
Reference solution. Line 1
Change **from**: 0.008 per cent w/v.
to: 0.02 per cent w/v.

Tranexamic Acid. Page 2901

Related substances.
Reference Solution (c).
Change **from**: 0.000006 per cent w/v

to: 0.00006 per cent w/v

Triclofos Oral Solution. Page 2914

Assay. Line 1
Change **from**: 0.13 g
to: 16 mg

Tropicamide Eye Drops. Page 2929

Related substances.
Reference solution (a). Line 2
Change **from**: *chloroform*
to: *water*
*Reference solution (b).*Line 2
Change **from**: *chloroform*
to: *water*

Voglibose Dispersible Tablets. Page 2980

Assay. *Reference solution*. Line 2
Change **from**: solvent mixture
to: mobile phase

After chromatographic system, insert before para 1
Equilibrate the column for at least 5 hours.

Storage. Change **to**:
Storage. Store protected from moisture at a temperature not exceeding 30º.

Zinc Chloride Injection. Page 3010

Assay.
Reference solution, line 5
Change **from**: Transfer 2.0, 3.0 and 4.0 ml
to: Transfer 3.0, 4.0 and 5.0 ml

Lines 9 and 10

Change **from**: 0.50, 0.75, and 1.0 µg of Zinc per ml.
to: 0.75, 1.0, and 1.25 µg of Zinc per ml.

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Acesulphame Potassium. Page 984

Related substances. After chromatographic system, para 1, line 1
Change **from**: reference solution (b)
to: reference solution (c)

Alprazolam. Page 1015

Identification B, line 1
Change **from**: *water*
to: *methanol*

Arterolane Maleate. Page 1084

Para 1
Change **to**: Arterolane Maleate is [(*N*-(2-amino-2-methylpropyl)-2-*cis*-dispiro(adamantane-2,3'-[1,2,4]trioxolane-5',1''-cyclohexane)-4''- yl]acetamide maleate.

Maleic Acid. Insert in the beginning
22.0 per cent to 24.5 per cent w/w, calculated on anhydrous basis

Assay.
Solvent mixture. Delete the requirement

Test solution. Lines 2 and 3
Change **from** : solvent mixture
to: mobile phase

Reference solution. Line 2
Change **from** : solvent mixture
to: mobile phase

After chromatographic system, para 1, line 2
Change **from** : 3000
to: 600

Line 3
Change **from** : 2.0
to: 3.0

Azithromycin. Page 1117

Specific optical rotation
Change **to**: **Specific optical rotation** (2.4.22). – 45.0º to – 49.0º, determined in solution A, at 20º.

Bambuterol Tablets. Page 1135

Related substances. Change **to**:
Related substances. Determine by liquid chromatography (2.4.14), as described in the Assay with the following modifications.

Test solution. Disperse a quantity of powdered tablets containing 50 mg of Bambuterol Hydrochloride in 20 ml of the mobile phase, with the aid of ultrasound for 15 minutes and dilute to 100.0 ml with the mobile phase, filter. Dilute 5.0 ml of this solution to 10.0 ml with the mobile phase.

Inject the test solution. The area of any secondary peak is not more than 0.5 per cent and the sum of the areas of all the secondary peaks is not more than 1.0 per cent, calculated by area normalization method.

Betaxolol Eye Drops. Page 1184

Para 2, line 3
Change **from**: $C_{18}H_{29}O_{3.}$
to: $C_{18}H_{29}NO_{3.}$

Assay. Last line
Change **from**: $C_{18}H_{29}O_{3.}$
to: $C_{18}H_{29}NO_{3.}$

Bortezomib. Page 1200

Para 2, last line
Change **from**: anhydrous basis.
to: dried basis.

Specific Optical Rotation.
Change **to**: **Specific Optical Rotation** (2.4.22). -50.0° to -55.0°, calculated on dried basis and determined in a 1.0 per cent w/v solution in *methanol.*

Water. Change **to**:
Loss on drying (2.4.19). Not more than 5.0 per cent, determined on 0.5 g by drying over *phosphorus pentoxide* at room temperature, under vacuum at a pressure of 1.5kPa to 2.5kPa for 3 hours.

Bromocriptine Capsules. Page 1205

Identification. B. Line 2
Change **from**: test solution (b)
to: test solution

Line 3
Change **from**: reference solution (d)
to: reference solution (e)

Related substances. *Reference solution (e).* Line 1
Change **from**: 0.023 per cent
to: 0.23 per cent

Bromocriptine Tablets. Page 1207

Identification. C. Line 2
Change **from**: test solution (b)
to: test solution

Line 3
Change **from**: reference solution (d)
to: reference solution (e)

Related substances. *Reference solution (e)*. Line 1
Change **from**: 0.055per cent
to: 0.55 per cent

Calamine Ointment. Page 1240

Lines 6 and 7.
Change **from**: Calamine Ointment contains not less than 7.8 per cent and not more than 9.4 per cent w/w of Zn.
to: Calamine Ointment contains not less than 13.5 per cent and not more than 16.5 per cent w/w of ZnO.

Assay. Last line
Delete: 1g of the residue is equivalent to 0.8034 g of Zn.

Chloramphenicol Capsules. Page 1349

Identification. Line 8
Change **from**: extracts
to: extracts and evaporate to dryness.

Cholecalciferol Injection. Page 1384

Lines 2 and 3
Change **from**: Cholecalciferol Injection is a sterile solution containing 0.75 per cent w/v of Cholecalciferol in Ethyl Oleate
to: Cholecalciferol Injection is a sterile solution of Cholecalciferol in Ethyl Oleate.

Lines 4 and 5
Change **from**: Cholecalciferol Injection contains not less than 0.67 per cent and not more than 0.83 per cent of cholecalciferol, $C_{27}H_{44}O$
to: Cholecalciferol Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of cholecalciferol, $C_{27}H_{44}O$.

Description.
Change **to**: A clear, colourless to pale yellow liquid.

Clindamycin Injection. Page 1420

Para 2, line 2
Change **from**: 105.0 per cent
to: 120.0 per cent

Clobetasol Propionate. Page 1423

Related substances. After chromatographic system, para 2, lines 1 and 3
Change **from**: test solution
to: test solution (a)

Clonidine Tablets. Page 1438

Uniformity of content. Para 2, line 1
Change **from**: 200 ml
to: 20 ml

Para 2, line 8
Change **from**: supernatant liquid
to: chloroform layer

Assay. Line 2
Change **from**: 100 µg
to: 150 µg

Clotrimazole Cream. Page 1443

2-Chlorotritanol. *Test solution***,** line 7
Change **from**: extraction with further quantities
to: extractions with two further quantities

Line 9
Change **from**: *0.02 M phosphoric acid*.
to: *methanol*.

Reference solution (a). Line 3
Change **from**: *0.02 M phosphoric acid*.
to: *methanol*.

Reference solution (b). Line 2
Change **from**: the same solvent mixture.
to: *methanol*.

Assay. Change **to**:
Assay. Determine by liquid chromatography (2.4.14).
Test solution. Extract a quantity of the cream containing 25 mg of Clotrimazole by warming with 25 ml of *methanol* in a water-bath at 50° for 5 minutes, shaking occasionally. Remove from the water-bath, shake the mixture vigorously while cooling to room temperature, cool in ice for 15 minutes, centrifuge for 5 minutes and decant the supernatant liquid. Repeat the extraction with 20 ml, of *methanol*. Dilute the combined methanol extracts to 50.0 ml with methanol.

Reference solution (a). A 0.05 per cent w/v solution of *clotrimazole RS* in *methanol*

Reference solution (b). A solution containing 0.01 per cent w/v solution each of *clotrimazole RS* and *2-chlorotritanol RS* in *methanol*

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 75 volume

s of *acetonitrile* and 25 volumes of a buffer solution prepared by dissolving 4.35 g of *dibasic potassium phosphate* in 1000 ml of *water*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 25 µl.

The relative retention time with reference to clotrimazole for 2-chlorotritanol is about 1.2.

Inject reference solution (b). The test is not valid unless the resolution between clotrimazole and 2-chlorotritanol peaks is not less than 2.0 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject reference solution (a) and the test solution.

Calculate the content of $C_{22}H_{17}ClN_2$ in the cream.

Colistimethate Sodium. Page 1456

Identification. D.
Change **from**: reaction (a)
to: reaction (b)

Colistimethate Injection. Page 1457

Identification. D.
Change **from**: reaction (a)
to: reaction (b)

Activated Dimethicone. Page 1585

Identification. A; lines 4 and 5
Change **from**: 5 ml of the lower layer
to: 5 ml of the upper layer

Assay. *For polydimethylsiloxane*, line 6
Change **from**: 5 ml of the lower layer
to: 5 ml of the upper layer

Disodium Edetate. Page 1594

Assay. Line 5.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.

Disodium Edetate Injection. Page 1595

Assay. Lines 6 and 7.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.

Disodium Edetate. Page 1594

Assay. Line 5.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.

Disodium Edetate Injection. Page 1595

Assay. Lines 6 and 7.
Change **from**: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03722 g of $C_{10}H_{14}N_2Na_2O_8,2H_2O$.
to: 1 ml of *0.1 M lead nitrate* is equivalent to 0.03362 g of $C_{10}H_{14}N_2Na_2O_8$.

Domperidone Suspension. Page 1614

Assay. Chromatographic system, line 4
Change **from**: 0.5 per cent w/v of *ammonium acetate solution*
to: 45 volumes of 0.5 per cent w/v of *ammonium acetate solution,*

Drotaverine Tablets. Page 1632

Para 2, line 3
Change **from**: drotaverine, $C_{24}H_{31}NO_4$
to: drotaverine hydrochloride, $C_{24}H_{31}NO_4$.HCl.

Disintegration. Delete the requirement

Assay. Chromatographic system,
mobile phase Change **to:** mobile phase: a mixture of 25 volumes of buffer solution prepared by dissolving 3.12 g of *sodium dihydrogen orthophosphate* in *water* and dilute to 1000 ml with *water*, adjusting the pH to 6.5 with *sodium hydroxide solution* ,40 volumes of *methanol and 35* volumes of *acetonitrile*,

Last line
Change **from**: $C_{24}H_{31}NO_4$
to: $C_{24}H_{31}NO_4$.HCl.

Enoxaparin Sodium. Page 1657

Identification
A. After chromatographic system, para 1, line 2
Change **from**: 10000 theoretical plates
to: 6000 theoretical plates

Eplerenone. Page 1668

Assay. Chromatographic system, line 1
Change **from**: a stainless steel column 5 cm x 2.1 mm
to: a stainless steel column 15 cm x 4.6 mm

Escitalopram Tablets. Page. 1686

Dissolution. line 2,
Change **from**: Medium. 900 ml of *water*
to: Medium. 900 ml of *0.1 M hydrochloric acid*

Ethambutol Hydrochloride. Page 1695

Meso ethambutol (RS isomer)
Method B. Chromatographic system, gradient programme
Change **to**:

Time (in min.)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	71	29
30	71	29
35	0	100
37	0	100
38	71	29

Flavoxate Hydrochloride. Page 1763

Related substances. *Reference solution (c)*. line 2
Change **from**: 0.00015 per cent
to: 0.003 per cent

Flurbiprofen Eye Drops. Page 1808

Para 2, line 3
Change **from**: flurbiprofen sodium, $C_{15}H_{12}FNaO_2$
to: flurbiprofen sodium dihydrate, $C_{15}H_{12}FNaO_2.2H_2O$

Assay. Last line
Change **from**: $C_{15}H_{12}FNaO_2$
to: $C_{15}H_{12}FNaO_2.2H_2O$

Fluticasone Propionate. Page 1811

Water (2.3.43). Lines 2 and 3
Change **from**: using as solvent a mixture of equal volumes of *chloroform* and *methanol*
to: using *methanol* as solvent.

Fluvoxamine Tablets. Page 1820

Related substances. Change **to**:

Related substances. Determine by liquid chromatography (2.4.14).

Test solution. Disperse a quantity of powdered tablets containing 0.25 g of Fluvoxamine Maleate with 125 ml of the mobile phase for 10 minutes and dilute to 250.0 ml with the mobile phase. Centrifuge and use the supernatant liquid.

Reference solution (a). Dilute 1.0 ml of the test solution to 100.0 ml with the mobile phase.

Reference solution (b). Add 1.0 ml of *1 M hydrochloric acid* to 10.0 ml of the test solution and heat on a water-bath for 10 minutes.

Chromatographic system
- a stainless steel column 25 cm x 4.6 mm, packed with endcapped octylsilane bonded to porous silica (5 µm),
- column temeperature: 35°,
- mobile phase: a mixture of 40 volumes of a solution containing 1.25 per cent w/v of *diammonium hydrogen orthophosphate* and 0.275 per cent w/v of *sodium heptanesulphonate monohydrate* and 60 volumes of *methanol*, adjusting the pH to 3.5 with *orthophosphoric acid*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

Inject reference solution (b). The relative retention time with reference to fluvoxamine maleate (retention time: about 7 to 9 minutes) for addition product is about 0.65.

Inject reference solution (a). The test is not valid unless the column efficiency is not less than 2000 theoretical plates and the tailing factor is not more than 2.0.

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak due to 'addition product' is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). The area of any other secondary peak 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 the peak due to maleic acid which elutes immediately after the solvent front and 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).

Fusidic Acid. Page 1838

Identification. B; line 2
Change **from**: *silica gel G*
to: *silica gel* G_{254}

Last para, line 3
Change **from**: 365 nm
to: 254 nm

Gemcitabine Hydrochloride. Page 1849

Para 2, line 3
Change **from**: on the dried basis
to: on as is basis

Related substances. *Test solution (b)*. Line 1
Change **from**: 10.0 ml
to: 1.0 ml

Hydrochlorothiazide. Page 1900

Assay. Lines 1 and 2
Change **from**: *anhydrous pyridine*
to: *dimethyl sulphoxide*

Hydroxychloroquine Sulphate. Page 1915

Related substances. 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

Chlorides. Line 1
Change **from**: 1.4 g.
to: 0.7 g.

Lamivudine Tablets. Page 2056

Related substances. *Test solution*.
Change **to**: *Test solution*. Disperse a quantity of the powdered tablets containing 600 mg of lamivudine in 20 ml of *water*, with the aid of ultrasound. Add 20 ml of *acetonitrile*, mix with the aid of ultrasound for 10 minutes and dilute to 100.0 ml with *water* and filter.

Assay. *Solvent mixture.*
Change **from**: *Solvent mixture.* 50 volumes of *water* and 50 volumes of *acetonitrile*
to: *Solvent mixture.* 80 volumes of *water* and 20 volumes of *acetonitrile.*

Lansoprazole. Page 2067

Related substances. Last para, line 3
Change **from**: 0.4 per cent
to: 0.4 times

Line 5
Change **from**: reference solution (b)
to: reference solution (b) (0.4 per cent)

Lines 7 and 9
Change **from**: 0.1 per cent
to: 0.1 times

Lines 8 and 11
Change **from**: reference solution (b)
to: reference solution (b) (0.1 per cent)

Levonorgestrel and Ethinyloestradiol Tablets. Page 2091

Identification

Reference solution. Line 3.
Change **from**: *water*.
to: *dichloromethane.*

Reference solution (a). Line 2
Change **from**: *norgestrel RS*
to: *levonorgestrel RS*

Levosalbutamol Sulphate. Page 2095

Enantiomeric Purity. After chromatographic system, para 1, lines 3 to 5
Change **from**: The first peak is due to levosalbutamol and the second peak is due to dextrosalbutamol.
to: The first peak is due to dextrosalbutamol and the second peak is due to levosalbutamol.

Lignocaine Gel. Page 2098

Identification. A. Last line.
Change **from**: reference spectrum of lignocaine hydrochloride.
to: reference spectrum of lignocaine.

2,6-Dimethylaniline. Last line
Change **from**: (20 ppm).
to: (400 ppm).

Menthol. Page 2173

Related substances. Last para, last line.
Change **from**: (0.5 per cent).
to: (0.05 per cent).

Meropenem Injection. Page 2179

Sodium Carbonate. Title
Change **to**: **Content of Sodium**

Line 2
Change **from**: sodium carmbonate
to: sodium

Labelling. Line 1
Change **from**: meropenem
to: meropenem and sodium

Methotrexate Tablets. Page 2194

Related substances. Last para, line 8
Change **from**: 1.5 times
to: 2.5 times

Lines 9 and 10
Change **from**: reference solution (a) (0.3 per cent)
to: reference solution (a) (0.5 per cent)

Methylergometrine Injection. Page 2202

Assay. Para 1, line 10
Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2,
Delete: 1 mg of *methylergometrine maleate RS* is equivalent to 1.032 mg of $C_{20}H_{25}N_3O_2$, $C_4H_4O_4$.

Methylergometrine Tablets. Page 2203

Uniformity of content. Para 2, line 16

Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2,
Delete the requirement.

Assay. Para 1, lines 11
Change **from**: *ergometrine maleate RS*
to: *methylergometrine maleate RS*

Para 2, lines 1 and 2
Delete: 1 mg of *methylergometrine maleate RS* is equivalent to 1.032 mg of $C_{20}H_{25}N_3O_2$, $C_4H_4O_4$.

Mifepristone. Page 2234

Optical rotation. Title
Change **to**: **Specific Optical rotation**

Moxifloxacin Hydrochloride. Page 2254

Molecular formula.
Change **from** : $C_{21}H_{25}ClFNO_3O_4$
to : $C_{21}H_{25}ClFN_3O_4$.

Para 2, line 2
Change **from** : $C_{21}H_{25}ClFNO_3O_4$
to : $C_{21}H_{25}ClFN_3O_4$.

Moxifloxacin Eye Drops. Page 2255

Assay : Chromatographic system: Gradient programme
Change **to** :

Time (in min)	Mobile phase A (per cent w/v)	Mobile phase B (per cent v/v)	Flow rate (ml per minute)
0	69	31	0.5
30	69	31	0.5
31	60	40	0.9
36	60	40	0.9
37	69	31	0.5
42	69	31	0.5

Mupirocin. Page 2265

Para 3, line 2
Change **from**: dried basis
to: anhydrous basis

Ondansetron Tablets. Page 2380

Uniformity of content. Line 4
Change **from**: reference solution (a)
to: the reference solution

Test solution. Line 2
Change **from**: 0.01 per cent
to: 0.005 per cent

Paracetamol Syrup. Page 2433

Title. Change **to**: **Paracetamol Paediatric Syrup**

NOTE: Change in title will be effective from 01-01-2015

Line 1.
Change **from**: Paracetamol Oral Solution ; Acetaminophen Syrup
to: Paracetamol Paediatric Oral Solution ; Acetaminophen Paediatric Syrup

Line 2.
Change **from**: Paracetamol Syrup
to: Paracetamol Paediatric Syrup

Line 4.
Change **from**: Paracetamol Syrup
to: Paracetamol Paediatric Syrup

4- Aminophenol. Chromatographic system, line 1.
Change **from**: 20 cm x 4.6 mm
to: 25 cm x 4.6 mm

After chromatographic system, para 1
Change **to**: Inject the reference solution and the test solution. In the chromatogram obtained with the test solution the area of any peak corresponding to 4-aminophenol is not more than the area of the peak in the chromatogram obtained with the reference solution (0.5 per cent). Peaks with a long retention time may occur due to preservatives in the preparations.

Paroxetine Hydrochloride. Page 2439

Related substances. Chromatographic system, mobile phase A, line 1
Change **from**: 5 volumes of trifluoroacetic acid
to: 0.5 volumes of trifluoroacetic acid

mobile phase B, line 1
Change **from**: 5 volumes of trifluoroacetic acid
to: 0.5 volumes of trifluoroacetic acid

Gradient programme
Change **to**:

Time (in min)	Mobile phase A (per cent v/v)	Mobile phase B (per cent v/v)
0	80	20
30	80	20
50	20	80
55	20	80
60	80	20
65	80	20

Plaster of Paris. Page 2511

Para 1, line 2.
Change **from**: Plaster of Paris is prepared by heating powdered gypsum, $CaSO_4,½H_2O$,
to: Plaster of Paris is prepared by heating powdered gypsum, $CaSO_4,2H_2O$,

Procainamide Hydrochloride. Page 2555

Assay. Line 2, insert after *hydrochloric acid*
", add 3 g of *potassium bromide*, cool in ice"

Procainamide Injection. Page 2555

Assay. Lines 2 and 3, insert after boil for 1 minute
", add 3 g of *potassium bromide*, cool in ice"

Procainamide Tablets. Page 2556

Assay. Line 4, insert after boil for 1 minute
", add 3 g of *potassium bromide*, cool in ice"

Proguanil Hydrochloride. Page 2567

4-Chloroaniline.
Insert after **4-Chloroaniline.**
"Not more than 250 ppm."

Line 10.
Change **from**: 1.25 µg
to: 1.25 µg per ml

Proguanil Tablets. Page 2568

Insert after **4-Chloroaniline.**
"Not more than 250 ppm."

Line 14
Change **from**: 1.25 µg
to: 1.25 µg per ml

Propofol Injection. Page 2578

Assay. Para 3
Change **from**: reference solution (b)
to: reference solution (a)

Protriptyline Tablets. Page 2592

Insert before **Other tests.**
Uniformity of content. *(For tablets containing 10 mg or less)*
Disperse one tablet in 50 ml of a solution prepared by mixing 1 volume of *1 M hydrochloric acid* and 9 volumes of *methanol* and dilute to 100.0 ml with the same solution. Shake well and filter, discard the first few ml of filtrate and dilute a volume of the filtrate containing 1 mg of protriptyline hydrochloride to 100 ml with the same solution and measure the absorbance at the maximum at 292 nm (2.4.7). Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the specific absorbance at 292 nm.

Assay. Line 8.
Change **from**: Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the absorbance
to: Calculate the content of $C_{19}H_{21}N$,HCl taking 465 as the specific absorbance at 292 nm.

Racecadotril Capsules. Page 2634

Assay. Chromatographic system, line 2
Change **from**: porous silica
to: porous silica (5 µm)

Sertraline Tablets. Page 2722

Para 1, lines 2 and 3
Change **from**: sertraline hydrochloride, $C_{17}H_{17}Cl_2N$,HCl.
to: sertraline, $C_{17}H_{17}Cl_2N$.

Dissolution. After chromatographic system, line 1
Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$
Last line
Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$

Related substances. After chromatographic system, para 2, last line
Change **from**: reference solution (c)
to: reference solution (d)

Assay. Last line
Change **from**: $C_{17}H_{17}Cl_2N$,HCl
to: $C_{17}H_{17}Cl_2N$

Sodium Chloride Injection. Page 2744

Assay. Change **to**:
Assay. Titrate a measured volume containing about 0.2 g of sodium chloride with *0.1 M silver nitrate* using *potassium chromate solution* as indicator.
1 ml of *0.1 M silver nitrate* is equivalent to 0.005844 g of NaCl.

Sucralose. Page 2801

Related substances. Line 2
Change **from**: coating the plate with *silica gel*.
to: coating the plate with *octadecylsilanized silica gel*.

Assay. Change **to**:

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Dissolve 250 mg of the substance under examination in the mobile phase and dilute to 25.0 ml with the mobile phase.

Reference solution. A 1.0 per cent w/v solution of *sucralose RS* in the mobile phase.

Chromatographic system
- a stainless steel column 10 cm x 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm),
- mobile phase: a mixture of 85 volumes of *water* and 15 volumes of *acetonitrile*,
- flow rate: 1.5 ml per minute,
- refractive index detector
- injection volume: 20 µl.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{12}H_{19}Cl_3O_8$.

Tobramycin Injection. Page 2881

Related substances.
Reference solution. Line 1
Change **from**: 0.008 per cent w/v.
to: 0.02 per cent w/v.

Tranexamic Acid. Page 2901

Related substances.

Reference Solution (c).

Change **from**: 0.000006 per cent w/v
to: 0.00006 per cent w/v

Triclofos Oral Solution. Page 2914

Assay. Line 1
Change **from**: 0.13 g
to: 16 mg

Tropicamide Eye Drops. Page 2929

Related substances.
Reference solution (a). Line 2
Change **from**: *chloroform*
to: *water*
*Reference solution (b).*Line 2
Change **from**: *chloroform*
to: *water*

Voglibose Dispersible Tablets. Page 2980

Assay. *Reference solution*. Line 2
Change **from**: solvent mixture
to: mobile phase

After chromatographic system, insert before para 1
Equilibrate the column for at least 5 hours.

Storage. Change **to**:
Storage. Store protected from moisture at a temperature not exceeding 30º.

Zinc Chloride Injection. Page 3010

Assay.
Reference solution, line 5
Change **from**: Transfer 2.0, 3.0 and 4.0 ml
to: Transfer 3.0, 4.0 and 5.0 ml

Lines 9 and 10

Change **from**: 0.50, 0.75, and 1.0 µg of Zinc per ml.
to: 0.75, 1.0, and 1.25 µg of Zinc per ml.