DRAFT AMENDMENTS

Updated on: 25.01.2019

2.3.51. 2-Ethylhexanoic Acid. Page 168

After Chromatographic system, line 6
Change **from**: Calculate the content
to: Calculate the percent content

4.2 General Reagents. Page 890

Page 934,
Potassium Antimonate Solution: Lines 3 and 4
Change **from:** 5 ml of *1 M sodium hydroxide*
to: 1 ml of *2 M sodium hydroxide*

Beclomethasone Dipropionate. Page 1328

Loss on drying (2.4.19).
Change **to:** Not more than 0.5 per cent for anhydrous from, 2.8 per cent to 3.8 percent for monohydrate from, determined on 1.0 g by drying in an oven at 105° for 3 hours.

Benzhexol Tablets. Page 1344

Identification A. Line 1
Change **from:** Shake a quantity of powdered tablets
to: Shake a quantity of powdered tablets containing 20 mg of benzhexol hydrochloride

Insert before **Uniformity of content**
"Tests"

Uniformity of content.
Change **to:** *Test solution*. Disperse well one tablet in few ml of *water* with the aid of ultrasound and dilute with the mobile phase to obtain a solution containing 0.008 per cent w/v of benzhexol hydrochloride.

Assay. After chromatographic system
Add the following.
Inject the reference solution. The test is not valid unless the resolution between the two principal peaks is not less than 4.0.

Betahistine Mesylate. Page 1362

Identification. C, lines 3 and 4
Change **from**: To a further 0.1 of *anhydrous sodium carbonate*
to: To a further 0.1 g, add 0.5 g of *anhydrous sodium carbonate*

Cefpirome Injection. Page 1532

Related substances. Chromatographic system, gradient programme, line 4
Delete " 10 80 20"

Cetyl Palmitate. Page 1565

Assay.
Change **from:** Determine by gas chromatography (2.4.13).
to: Determine by gas chromatography (2.4.13), using normalization method.

Citalopram Hydrobromide. Page 1635

Specific optical rotation
Change **from: Specific optical rotation**
to: Optical rotation

Cloxacillin Sodium. Page 1681

Assay. After Chromatographic system, line 5
Change **from**: Calculate the content of $C_{19}H_{18}ClN_3O_5S$.
to: Calculate the content of $C_{19}H_{17}ClN_3NaO_5S$.

Codeine Tablets. Page 1689

Assay
Change **from**: Weigh and powder 20 tablets. Weigh accurately a quantity of powder containing 0.3 g of Codeine Phosphate.....
to: Weigh accurately a quantity of powdered tablets containing 0.3 g of Codeine Phosphate.....

Cycloserine Capsules. Page 1725

Usual strengths.
Delete "125 mg;"

Identification, A. Line 2
Change **from:** *1 M sodium hydroxide*
to: *0.1 M sodium hydroxide*

Dextromethorphan Hydrobromide. Page 1792

Identification
Delete the following
Test A may be omitted if tests B, C and D are carried out. Tests B and C may be omitted if tests A and D are carried out.
C. Delete the requirement.

Change **from**: D.
to: C.

Dimethicone. Page 1846

Loss on heating. Line 3
Change **from**: cool to room temperature, Tare the vessel, transfer to it about…….
to: cool to room temperature and weigh. Transfer to it about……

Dipyridamole. Page 1856

Related substances. After chromatographic system, table, column 1, line 4
Change **from:** Flavoxate
to: Dipyridamole

Disopyramide. Page 1859

Assay. Para 1,
Insert the following at the end
"Carry out a blank titration."

Flumazenil Injection. Page 2079

Related substances. Line 6, column 3
Change **from**: 0.9
to: 1.1

Iron and Folic Acid Syrup. Page 2315

Add the following before **Other tests**
Free ferric compounds. Mix a quantity of syrup containing 0.4 g of ferrous sulphate in a mixture of 100 ml of water and 3 ml of *hydrochloric acid* by rapidly heating to the boiling point. Boil for 15 seconds and cool rapidly, add 1 g of *potassium iodide*, allow to stand in dark for 15 minutes and titrate the liberated iodine with *0.1 M sodium thiosulphate* using starch as indicator. Carry out a blank titration.

The difference is not more than 3.6 ml (5 per cent of ferric iron in ferrous sulphate).

Assay. *For ferrous sulphate*

Change **to:** *For ferrous sulphate*- To 10 ml of Syrup, add in a mixture of 100 ml of water and 20 ml of *1 M sulphuric acid* and titrate with *0.05 M ceric ammonium sulphate* using *ferroin solution* as indicator.

1 ml of *0.05 M ceric ammonium sulphate* is equivalent to 0.002792 g of Fe (II).

Iron and Folic Acid Tablets. Page 2316

Uniformity of content. After chromatographic system, line3
Change **from:** *For ferric iron—*
to: Free ferric compounds.

Line 4
Change **from:** 1.625 g of ferrous sulphate
to: 1.5 g of ferrous sulphate

Levetiracetam Tablets. Page 2411

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

Levetiracetam Prolonged-release Tablets. Page 2410

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

Losartan Potassium. Page 2467

Assay. Chromatographic system, line 2
Change **from:** 5 mm
to: 5 µm

Menotropin for Injection. Page 2526

Water.
Change **from**: Not more than 5 per cent, by using 75 IU of follicle stimulating hormone (Method 3).
to: Not more than 5 per cent (Method 3).

Mesna. Page 2541

Related substances. Chromatographic system, line 2
Change **from:** 5 µm
to: 10 µm

Miconazole Cream. Page 2607

Related substances. Last line
Change **from:** (0.5 per cent)
to: (0.5 per cent) and the peak due to nitrate ion.

Naproxen. Page 2695

Assay. Para 1
Insert at the end.
"Carry out a blank titration".

Paracetamol and Caffeine Tablets. Page 2858

Add the following before **Other tests**
Uniformity of content. Complies with the test stated under Tablets.
Determine by liquid chromatography (2.4.14), as described in the Assay for caffeine using following modifications.

Test solution. Disperse one tablet in 60 ml of the mobile phase and dilute to 100.0 ml with the same solvent and filter. Dilute a suitable volume of this solution with the mobile phase, to obtain a solution having concentration similar to the reference solution.

Reference solution. A 0.0025 per cent w/v solution of *caffeine RS* in the mobile phase.

Inject the reference solution and the test solution.

Calculate the content of $C_8H_{10}N_4O_2$ in the tablet.

Pilocarpine Nitrate. Page 2926

Sulphated ash (2.3.18).
Change **from:** Not more than 0.1 per cent, determined on 0.5 g.
to: Not more than 0.1 per cent.

Prazosin Tablets. Page 2978

Related substances. Last para, line 1
Change **from:** Apply to the plate 20 µl of each solution.
to: Apply to the plate 20 µl of each solution. Allow the mobile phase to rise 15 cm. Dry the plate in warm air and examine under ultraviolet light at 254 nm.

Quiniodochlor Cream. Page 3071

Usual strength.
Change **from**: 4 per cent w/v.
to: 4 per cent w/w.

Quiniodochlor Ointment. Page 3072

Usual strength
Change **from**: 4 per cent w/v.
to: 4 per cent w/w.

Rosuvastatin Calcium and Ezetimibe Tablets. Page 3143

Labelling. Line 1
Change **from:** rosuvastatin
to: rosuvastatin calcium

Roxithromycin Tablets. Page 3146

Assay. *Reference solution (b),* line 3
Change **from**: *(roxithromycin impurity A)*
to: *(roxithromycin impurity I)*

After Chromatographic system, para 1, line 3
Change **from**: (impurity A)
to: (impurity I)

Line 6
Change **from**: impurity A
to: impurity I

Saccharin. Page 3157

Line 5
Delete "It may contain a variable quantity of water."

Saccharin Sodium. Page 3158

Para 2
Insert the following at the end
"It may anhydrous or contain a variable quantity of water."

Selegiline Tablets. Page 3178

Identification. B, line 3
Change **from:** reference solution
to: reference solution (a)

Uniformity of content
Test solution.
Change **to:** *Test solution*. Disperse 1 tablet in 50 ml of equal volumes of *methanol* and *acetonitrile* and dilute with water to obtain a solution containing 0.005 per cent w/v solution of Selegiline Hydrochloride.

Sodium Citrate. Page 3215

Water.
Change **to: Water** (2.3.43). 11.0 to 13.0 per cent, determined on 0.3 g in a mixture of 20 ml of *methanol*, 30 ml of *formamide* and 5 g of *salicylic acid*.

Sodium Fusidate. Page 3219

Assay. Para 1
Insert the following at the end
"Carry out a blank titration."

Sodium Valproate Oral Solution. Page 3240

Related substances. Chromatographic system
Insert the following at the end
Inlet port at 190° and detector at 250°.

After chromatographic system, para 1
Change **to:** Inject 1 µl of the reference solution, test solution (a) and (b). In the chromatogram obtained with test solution (b), the sum of the areas of all the secondary peaks is not more than the area of peak in the chromatogram obtained with the reference solution (0.4 per cent).

Sodium Valproate Tablets. Page 3242

Related substances. Chromatographic system
Insert the following at the end
Inlet port at 190° and detector at 250°.

After chromatographic system, para 1
Change **to:** Inject 1 µl of the reference solution, test solution (a) and (b). In the chromatogram obtained with test solution (b), the sum of the areas of all the secondary peaks is not more than the area of peak in the chromatogram obtained with the reference solution (0.4 per cent).

Sorbic Acid. Page 3245

Assay. Para 1
Insert the following at the end
"Carry out a blank titration."

Sorbitan Oleate. Page 3246

Heavy metals. Last para
Insert at the end
Prepare the standard using 10.0 ml of *lead standard solution (1 ppm Pb)*.

Sulpiride. Page 3280

Impurity A.
Reference solution (b). Line 1
Change **from**: 0.002
to: 0.0002

Tamoxifen Tablets. Page 3305

Assay. Change **to**:

Assay. Determine by liquid chromatography (2.4.14).

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 20 mg of tamoxifen in 30 ml of the mobile phase in a glass stoppered 50-ml centrifuge tube, with the aid of mechanical shaker for at least 15 minutes and centrifuge at 1000 rpm. Dilute 5.0 ml of the clear supernatant liquid to 25.0 ml with the mobile phase.

Reference solution. Dissolve a quantity of *tamoxifen citrate RS* in the mobile phase to obtained a solution containing 0.02 per cent w/v of tamoxifen.

Chromatographic system

- a stainless steel column 30 cm x 4.0 mm, packed with porous silica with chemically bonded phenyl groups (5 µm),
- mobile phase: a solution prepared by dissolving 1.08 g of *octanesulphonic acid,* in 320 ml of *water* and 2 ml of *glacial acetic acid* and dilute to1000 ml with *methanol*,
- flow rate: 1.5 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 25 µl

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 3.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{26}H_{29}NO$ in the tablets.

Tenofovir Disoproxil Fumarate Tablets. Page 3328

Related substances. *Reference solution (a)*

Change **to**: *Reference solution (a).* A 0.2 per cent w/v solution of *tenofovir disoproxil fumarate RS* in *methanol*.

Tolazamide. Page 3394

Assay. Para 1

Insert the following at the end.

"Carry out a blank titration".

Trimethoprim and Sulphamethoxazole Oral Suspension. Page 3441

Assay. Chromatographic system, line 2

Change **from:** octylsilane

to: octadecylsilane