भारतीय भेषज संहिता आयोग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
सैक्टर - २३, राज नगर,
गाजियाबाद - २०१ ००२, उत्तर प्रदेश, भारत

सत्यमेव जयते
IPC

INDIAN PHARMACOPOEIA COMMISSION
Ministry of Health & Family Welfare, Government of India
Sector - 23, Raj Nagar
Ghaziabad-201 002 (U.P.), INDIA

डॉ.राजीव सिंह रघुवंशी
सचिव-सह-वैज्ञानिक निदेशक

Dr. Rajeev Singh Raghuvanshi
Secretary-cum-Scientific Director

F. No. T.11015/01/2020-AR&D

Date: January 13, 2023

Subject: Amendment List 02 to IP 2022

The 9th Edition of Indian Pharmacopoeia (IP) 2022 has become effective from 1st December, 2022. Based on scientific inputs, some IP monographs of IP 2022 need amendments for their implementation. Accordingly, Amendment List 02 to IP 2022 is being issued containing such amendments and this will become effective with immediate effect except for amendments in Soft Gelatin Capsules and Vildagliptin & Metformin Tablets for which effective date is mentioned along with the amendments made.

All concerned are requested to bring it to the notice of all authorities under their control for compliance with the IP 2022.

(Dr. Rajeev Singh Raghuvanshi)

Encl. Amendment List 02 to IP 2022

To,

1. The Drugs Controller General (India)
2. CDSCO Zonal Offices
3. All State Drug Controllers
4. Members of the Scientific Body of IPC
5. Directors of the Drugs Testing Laboratories
6. IDMA/OPPI/BDMA/FOPE/FSSAI/Small Scale Industry Associations

2.2.9. Microbial Contamination in Nonsterile Products. Page 40

Enumeration of aerobic microorganisms present in the product

Pour-plate method. Line 13

Change **from**: 25 colonies for fungi.

to: 50 colonies for total fungal count.

2.4.1. Appearance of Solution. Page 211

Clarity of Solution

Method. Line 4 and 5

Change **from**: Into another matched test-tube add the same volume of the freshly prepared *opalescence standard*.

to: Into another matched test-tube add the same volume of *water* or the solvent used for preparing the solution being examined or the freshly prepared *opalescence standard*.

2.4.14. Liquid Chromatography. Page 235

System suitability, para 4, line 3

Change **from**: the symmetry factor is 0.8 to 1.5,

to: the symmetry factor is 0.8 to 1.8,

2.4.22. Optical Rotation and Specific Optical Rotation. Page 257

Method. For liquids, line 2

Change **from**: 25º

to: 25º ± 0.5º

2.4.26. Solubility. Page 264

Insert before **Galantamine Hydrobromide**

Gabapentin. Sparingly soluble in *water*, slightly soluble in *ethanol (95 per cent)*, practically insoluble in *dichloromethane*. It dissolves in dilute acids and dilute solutions of alkali hydroxides.

2.5.2. Dissolution Test. Page 354

Methods.

For Apparatus 1 and Apparatus 2

Conventional and prolonged-release solid dosage forms. Para 1

Insert at the end

"(Applicable for Modified-release dosage forms also)"

4.2 General Reagents

Insert before ***D*-Galactose**. Page. 1093

Gastric Juice, Artificial (without enzyme). Dissolve 2.0 g of *sodium chloride* in *water*, add 80 ml of *1M hydrochloric acid* and dilute to 1000 ml with *water*.

Insert before **Perchloric Acid x M**. Page 1108

Perchloric Acid Solution. Dilute 8.5 ml of *perchloric acid* to 100.0 ml with *water*.

1,10-Phenanthroline. Page 1109

Change **to**: **Phenanthroline Hydrochloride**; 1,10-Phenanthroline Hydrochloride Monohydrate: $C_{12}H_9ClN_2,H_2O$ = 234.7

Analytical reagent grade of commerce.

A white or almost white crystalline powder; mp. about 215º with decomposition.

Phenanthroline Solution. Delete the requirement.

Page 1131

Insert before **Tris Buffered Saline (TBS)**

Tris Buffer xM. Dissolve 121.14 g of *tris* in *water* and dilute to 1000 ml with *water*.

4.3. Indicators and Indicator Test Papers

Ferroin Solution. Page 1137

Change **to**: **Ferroin Solution;** Ferroin Sulphate Solution; Ferroin: Dissolve 0.7 g of *ferrous sulphate* and 1.76 g of *phenanthroline hydrochloride* in 70 ml of *water* and dilute to 100 ml with same solvent.

Complies the following test.

SENSITIVITY — To 50 ml of *dilute sulphuric acid*, add 0.1 ml of *ferroin solution*. After the addition of 0.1 ml of *0.1 M ceric ammonium nitrate* the colour changes from red to light blue.

4.5. Volumetric Reagents and Solutions

Primary Standards. Page 1144

Insert before **Potassium Bromate**

Ferrous Ethylenediammonium Sulphate: Ethylenediammonium iron(II) disulphate tetrahydrate; Ethylenediammonium tetra aquabis(sulphato)iron(II); $Fe(C_2H_{10}N_2)(SO_4)_2,4H_2O$ = 382.1.

Page 1145

Insert before **Cupric Sulphate, 0.02M**

Cerium Sulphate, 0.1M: Dissolve 40.4 g of *cerium sulphate* in a mixture of 500 ml of *water* and 50 ml of *sulphuric acid*. Allow to cool and dilute to 1000.0 ml with *water*. Standardise the solution in following manner.

Dissolve 0.300 g of *ferrous ethylenediammonium sulphate* in 50 ml of *0.5M sulphuric acid* and titrate with 0.1 M cerium sulphate, determine the end-point potentiometrically (2.4.25) or using 0.1 ml of *ferroin solution* as indicator.

1 ml of 0.1 M cerium sulphate is equivalent to 38.21 mg of $Fe(C_2H_{10}N_2)(SO_4)_2,4H_2O$.

Capsules. Page 1297 *(Effective from 12/07/2023)*

Soft Gelatin Capsules

Disintegration. Line 5

Change **from**: 60 minutes

to: 30 minutes

NOTE — This change shall not be applicable for capsules containing any three or more components of vitamins, minerals, amino acids, fatty acids, trace elements etc. for which amendment will be issued by IPC in forthcoming IP Addendum 2024.

Adrenaline Tartrate. Page 1388

Identification. C, line 1

Change **from**: reaction (C)

to: reaction (B)

Aluminium, Magnesium and Simethicone Oral Suspension. Page 1410

Identification. A

Change **from**: Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *polydimethylsiloxane IPRS* or with the reference spectrum of polydimethylsiloxane.

to: Determine by infrared absorption spectrophotometry (2.4.6), using the test solution prepared in the Assay of polydimethylsiloxane. Compare the spectrum with that obtained with the reference solution in the Assay of polydimethylsiloxane.

Aluminium, Magnesium and Simethicone Chewable Tablets. Page 1412

Identification. A

Change **from**: Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *polydimethylsiloxane IPRS* or with the reference spectrum of polydimethylsiloxane.

to: Determine by infrared absorption spectrophotometry (2.4.6), using the test solution prepared in the Assay of polydimethylsiloxane. Compare the spectrum with that obtained with the reference solution in the Assay of polydimethylsiloxane.

Amiodarone Tablets. Page 1440

Identification

A. Para 2, line 4

Change **from**: amiodarone hydrochloride

to: amiodarone

Amlodipine and Atenolol Tablets. Page 1448

Related substances.

Test solution. Line 2

Change **from**: 100 mg of Atenolol

to: 10 mg of Amlodipine

Assay.

Test solution, line 2

Change **from**: 50 mg of Atenolol

to: 10 mg of Amlodipine

Aspirin Tablets. Page 1516

Dissolution. Para 2, line 4

Change **from**: maximum

to: isosbestic point of aspirin and salicylic acid

Aspirin Gastro-resistant Tablets. Page 1518

Identification

Change **to**: Disperse a quantity of powdered tablets containing 0.5 g of Aspirin with 20 ml of *ethanol* and filter. Evaporate the filtrate and dry the residue at 60º for 1 hour. The residues comply with the following test.

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *aspirin IPRS* or with the reference spectrum of aspirin.

Dissolution.

A. Line 7

Change **from**: maximum

to: isosbestic point of aspirin and salicylic acid

B. Line 7

Change **from**: maximum

to: isosbestic point of aspirin and salicylic acid

Salicylic acid.

Insert before *Test solution*

NOTE — Prepare the solutions immediately before use.

Assay.

Insert before *Test solution*

NOTE — Prepare the solutions immediately before use.

Aspirin Gastro-resistant and Atorvastatin Capsules. Page 1519

Related substances.

For Aspirin —

Insert before *Test solution*

NOTE — Prepare the solutions immediately before use.

Aspirin Gastro-resistant and Rosuvastatin Capsules. Page 1522

Related substances.

For Aspirin —

Insert before *Test solution*

NOTE — Prepare the solutions immediately before use.

Assay.

For Aspirin —

Insert before *Test solution*

NOTE — Prepare the solutions immediately before use.

Atropine Methonitrate. Page 1544

Specific optical rotation. Line 1

Change **from**: **Specific optical rotation**

to: **Optical rotation**

Atropine Sulphate. Page 1545

Specific optical rotation. Line 1

Change **from**: **Specific optical rotation**

to: **Optical rotation**

Barium Sulphate Oral Suspension. Page 1579

Microbial contamination. Line 4

Insert before *Staphylococcus aureus*

"Escherichia coli,"

Compound Benzoic Acid Ointment. Page 1600

Para 1, last line

Change **from**: the ratio of about 2 to 1.

to: the ratio of 2 to 1.

Para 2

Change **to**: Compound Benzoic Acid Ointment contains not less than 95.0 per cent and not more than 105.0 per cent of benzoic acid, $C_7H_6O_2$, and salicylic acid, $C_7H_6O_3$.

Betaxolol Hydrochloride. Page 1631

Assay. Change **to**:

Assay. Dissolve 0.3 g in 10.0 ml of *0.01 M hydrochloric acid* and add 50 ml of *ethanol (95 per cent)*. Titrate with *0.1 M sodium hydroxide*, determining the end-point potentiometrically (2.4.25). Read the volume added between the 2 points of inflexion.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.03439 g of $C_{18}H_{30}ClNO_3$.

Bicalutamide. Page 1636

Assay. *Test solution*, line 2, 3 and 4

Change **from**: mobile phase

to: solvent mixture

Reference solution. Line 2

Change **from**: mobile phase

to: solvent mixture

Cefoperazone Sodium. Page 1785

Acetone. Delete the requirement.

Ceftriaxone and Sulbactam for Injection. Page 1802

Assay. Chromatographic system, insert after line 2

– sample temperature: 10º,

Chlorcyclizine Hydrochloride. Page 1838

Assay. Change **to**:

Assay. Weigh accurately about 0.2 g, dissolve in 1 ml of *0.1 M hydrochloric acid* and add 50 ml of *methanol*. Titrate with *0.1M sodium hydroxide*, determining the end-point potentiometrically (2.4.25). Read the volume added between the 2 points of inflexion.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.03373 g of $C_{18}H_{21}ClN_2$,HCl.

Chloroquine Phosphate Suspension. Page 1849

Assay.

Insert at the end

Determine the weight per ml (2.4.29) of the suspension and calculate the content of $C_{18}H_{26}ClN_3$ weight in volume.

Storage. Store protected from light.

Labelling. The label states the strength in terms of the equivalent amount of chloroquine.

Chlorpromazine Hydrochloride. Page 1859

Identification. B, lines 3 and 4

Change **from**: absorption maxima at about 254 nm and 306 nm; 0.45 to 0.48 (2.4.7).

to: absorption maxima at about 254 nm and 306 nm; absorbance at about 254 nm, 0.45 to 0.48 (2.4.7).

Chlorpromazine Injection. Page 1860

Identification. B, lines 5 and 6

Change **from**: ...absorption maxima at about 254 nm and 306 nm; 0.45 to 0.48 (2.4.7).

to: ...absorption maxima at about 254 nm and 306 nm; absorbance at about 254 nm, 0.45 to 0.48 (2.4.7).

Chlorpromazine Tablets. Page 1860

Identification. B, line 8

Change **from**: maxima at about 254 nm and 306 nm; 0.45 to 0.48 (2.4.7).

to: maxima at about 254 nm and 306 nm; absorbance at about 254 nm, 0.45 to 0.48 (2.4.7).

Dextropropoxyphene Capsules. Page 2066

Identification. A, line 4

Change **from**: *dextropropoxyphene napsilate IPRS*

to: *dextropropoxyphene hydrochloride IPRS*

Line 5

Change **from**: dextropropoxyphene napsilate.

to: dextropropoxyphene hydrochloride.

C. Delete the requirement.

Dithranol. Page 2142

Dihydroxyanthracene. Delete the requirement.

Dihydroxyanthraquinone. Delete the requirement.

Ephedrine Nasal Drops. Page 2243

Identification

B. Line 3

Change **from**: peak

to: spot

Assay.

Insert after Chromatographic system

Inject the reference solution. The test not valid unless 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.

Ephedrine Oral Solution. Page 2244

Identification

Change **from**: peak

to: spot

Assay.

Insert after Chromatographic system

Inject the reference solution. The test not valid unless 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.

Ethylcellulose. Page 2299

Apparent viscosity. Change to:

Apparent viscosity. 80.0 to 120.0 per cent of that stated on the label for viscosity types of more than 6 mPa s; 75.0 to 140.0 per cent of that stated on the label for viscosity types of not more than 6 mPa s, determined by the following method.

Weigh accurately 5.0 g of dried substance under examination and dissolve in 95 g of a mixture of 80 g of *toluene* and 20 g of *ethanol (95 per cent)*. Determine the viscosity at 25° by Method A (2.4.28).

Felodipine. Page 2338

Assay. Line 2

Change **from**: *1M perchloric acid*.

to: *perchloric acid solution*.

Fusidic Acid. Page 2439

Identification. B,

Reference solution. Change **to**:

Reference solution. A 0.2 per cent w/v solution of *fusidic acid IPRS* in *ethanol (95 per cent)*.

Fusidic Acid Cream. Page 2440

Identification. A

Reference solution (a). Change **to**:

Reference solution (a). A 0.5 per cent w/v solution of *fusidic acid IPRS* in *ethanol (95 per cent)*.

Assay.

Reference solution. Change **to**:

Reference solution. A 0.03 per cent w/v solution of *fusidic acid IPRS* in the mobile phase.

Glycerin. Page 2485

Ethylene glycol, diethylene glycol and related substances.

Test solution. Line 1

Change **from**: 5.88 g

to: 5 g

Reference solution (a). Line 4

Change **from**: 5.88 g

to: 5 g

Granisetron Injection. Page 2499

Related substances. Last para, line 2

Change **from**: twice

to: 3 times

Labetalol Hydrochloride. Page 2681

Diasterioisomer ratio. Chromatographic system, line 2 and 3

Delete "(Such as DB-17)"

Levamisole Hydrochloride. Page 2727

Assay. Change **to**:

Assay. Dissolve 0.2 g in 30 ml of *ethanol (95 per cent)*, add 5.0 ml of *0.01 M hydrochloric acid*. Titrate with *0.1 M sodium hydroxide*, determining the end-point potentiometrically (2.4.25). Read the volume added between the 2 points of inflection.

1 ml of *0.1 M sodium hydroxide* is equivalent to 0.02408 g of $C_{11}H_{12}N_2S,HCl$.

Levetiracetam. Page 2729

Levetiracetam impurity B. *Reference solution (a)*, line 2

Change **from**: *levetiracetam impurity B IPRS*

to: *levetiracetam impurity B IPRS ((S)-2-aminobutanamide hydrochloride)*

Lignocaine. Page 2757

Identification. B, line 3

Change **from**: the reference solution.

to: reference solution (a).

Assay. After chromatographic system, para1

Change **to**: Inject reference solution (a) and (c). The test is not valid unless the resolution between the peaks due to lignocaine and methylparaben is not less than 3.0 in the chromatogram obtained with reference solution (c) and the relative standard deviation for replicate injections is not more than 1.5 per cent in the chromatogram obtained with reference solution (a).

Para 2

Change **from**: Inject reference solution (b) and the test solution.

to: Inject reference solution (a) and the test solution.

Mebeverine Hydrochloride. Page 2829

Identification. C, line 2

Change **from**: reactions

to: reaction A

Mefenamic Acid and Dicyclomine Hydrochloride Tablets. Page 2839

Dissolution. *For Mefenamic acid —*

Test solution. Change **to**:

Test solution. Dilute a suitable volume of the filtrate with the dissolution medium to obtain a solution having expected concentration similar to the reference solution.

For Dicyclomine hydrochloride —

Test solution. Change **to**:

Test solution. Dilute a suitable volume of the filtrate with the mobile phase to obtain a solution having expected concentration similar to the reference solution.

Microcrystalline Cellulose. Page 2937

Insert before **Assay**

Microbial contamination (2.2.9). The total aerobic viable count is not more than 1000 cfu per g and total fungal count is not more than 100 cfu per g. 1 g is free from *Escherichia coli, Staphylococcus aureus* and *Pseudomonas aeruginosa* and 10 g is free from *Salmonella* and *Shigella*.

Mometasone Aqueous Nasal Spray. Page 2956

Insert before **Assay**

Other tests. Comply with the tests stated under Nasal Preparations.

Montelukast Sodium. Page 2959

Related substances.

Insert before Chromatographic system

Reference solution (c). A solution containing 0.1 per cent w/v of *montelukast sodium IPRS*, 0.0003 per cent w/v, each of, *montelukast sulphoxide IPRS* and *montelukast styrene IPRS* in the solvent mixture.

After chromatographic system, para 1

Change **to**:

Name	Relative retention time
Montelukast sulphoxide isomer	0.66 and 0.69
Montelukast	1.0
Montelukast styrene	1.38

Inject reference solution (c) to identify the peaks due to montelukast sulphoxide and montelukast styrene.

Montelukast Granules. Page 2960

Dissolution. After chromatographic system, line 4 and 5,

Delete the following requirement

'1 mg of $C_{47}H_{59}ClN_2O_3S$ is equivalent to 0.7637 mg of $C_{35}H_{36}ClNO_3S$.'

Uniformity of content. Last line

Delete the following requirement

'1 mg of $C_{47}H_{59}ClN_2O_3S$ is equivalent to 0.7637 mg of $C_{35}H_{36}ClNO_3S$.'

Assay. Last line

Delete the following requirement

'1 mg of $C_{47}H_{59}ClN_2O_3S$ is equivalent to 0.7637 mg of $C_{35}H_{36}ClNO_3S$.'

Montelukast Tablets. Page 2962

Related substances.

Reference solution (a). Change **to**:

Reference solution (a). Dissolve a suitable quantity of *montelukast sodium IPRS* in the solvent mixture and dilute with the same solvent to obtain a solution containing 0.0025 per cent w/v of *montelukast*.

Insert before Chromatographic system

Reference solution (c). A solution containing 0.5 per cent w/v of *montelukast sodium IPRS*, 0.0025 per cent w/v of *montelukast sulphoxide IPRS* and 0.005 per cent w/v of *montelukast styrene IPRS* in a mixture of 80 volumes of *methanol* and 20 volumes of *water*. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

After chromatographic system. Para 1 and 2

Change **to**

Name	Relative retention time
Montelukast sulphoxide isomer	0.64 and 0.66
Montelukast	1.0
Montelukast styrene	1.37

Inject reference solution (c) to identify the peaks due to montelukast sulphoxide and montelukast styrene.

Inject reference solution (b). The test is not valid unless the relative standard deviation for replicate injections is not more than 5.0 per cent.

Inject reference solution (b) and the test solution. In the chromatogram obtained with the test solution, the sum of areas of the peaks due to montelukast sulphoxide isomers is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent), the area of any peak corresponding to montelukast styrene is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent), the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent) and the sum of areas of all the secondary peaks is not more than 4 times the area of the principal peak in the chromatogram obtained with reference solution (b) (2.0 per cent). Ignore any peak with an area less than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.05 per cent).

Montelukast and Levocetirizine Tablets. Page 2963

Assay. *Test solution*, line 2

Change **from**: Montelukast Sodium

to: montelukast

Reference solution (a). Change **to**:

Reference solution (a). A solution of *montelukast sodium IPRS* containing 0.25 per cent w/v of *montelukast* in the solvent mixture.

Naloxone Hydrochloride. Page 3020

Related substances. Last para, line 4

Change **from**: A, B, C, E, F multiplied with correction factor 0.5

to: A, B, C, E, F

Nystatin Pessaries. Page 3095

Identification

Change **to**: **Identification**

Para 2- Delete the requirement

Ornidazole Injection. Page 3131

Appearance of solution. Change **to**:

Appearance of solution. The solution is clear (2.4.1) and not more than intensely coloured than YS5 (2.4.1).

Orphenadrine Citrate. Page 3133

Identification. A

Insert at the end

"or with the reference spectrum of orphenadrine citrate."

Oseltamivir Oral Suspension. Page 3138

Insert after para 3

When stored at the temperature and for the period stated on the label during which the constituted suspension may be

expected to be satisfactory for use, it contains not less than 80.0 per cent of the stated amount of oseltamivir, $C_{16}H_{28}N_2O_4$.

Assay. Last line

Change **from**: Calculate the content of $C_{16}H_{28}N_2O_4$.

to: Determine the weight per ml of the suspension (2.4.29) and calculate the content of $C_{16}H_{28}N_2O_4$, weight in volume.

Paracetamol Infusion. Page 3194

Related substances. Last para, lines 1 to 6

Change **to**: Inject reference solution (a), (b), (c) and the test solution. Run the chromatogram 12 times the retention time of the principal peak. The area of any peak corresponding to 4-aminophenol is not more than 0.5 times the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.1 per cent).

Phenylephrine Injection. Page 3257

Bacterial endotoxins. Line 2

Change **from**: phenylephrine.

to: phenylephrine hydrochloride.

Piperacillin and Tazobactam Injection. Page 3286

Related substances. *Reference solution (d)*. Change **to**:

Reference solution (d). Dilute reference solution (a) and (b) with the mobile phase to obtain a solution containing 0.0025 per cent w/v of tazobactam and 0.02 per cent w/v of piperacillin.

Polyethylene Glycol 4000. Page 3303

Viscosity. Line 1

Change **from**: determined at 100º

to: determined between 98.6º to 99.2º

Prednisone. Page 3340

Identification

Change **from**: *Tests A and B may be omitted if tests C and D are carried out. Tests C and D may be omitted if tests A and B are carried out.*

to: *Tests A and C may be omitted if tests B and D are carried out. Tests B and D may be omitted if tests A and C are carried out.*

Pyrantel Pamoate Oral Suspension. Page 3398

Identification. A. Line 2

Change **from**: *silica gel H*.

to: *silica gel GF 254*.

Assay. *Test solution*. Line 2

Change **from**: 60 mg

to: 70 mg

Pyridostigmine Tablets. Page 3401

Assay. *Reference solution*, line 1

Change **from**: 0.25 per cent

to: 0.025 per cent

Rabeprazole Gastro-resistant Tablets. Page 3441

Dissolution. Change **to**:

Dissolution (2.5.2).

A. Apparatus No. 2 (Paddle),
Medium. 700 ml of *0.1 M hydrochloric acid*,
Speed and time. 100 rpm and 2 hours.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 80 volumes of *methanol*, 20 volumes of *water* and 0.1 volume of *diethylamine*.

Test solution. Withdraw the medium completely and disperse the intact tablet in *0.1M sodium hydroxide* (20 volume of the total volume), with the aid of ultrasound and dilute to volume with the solvent mixture to obtain a solution containing 0.02 per cent w/v of Rabeprazole Sodium and filter.

Reference solution. Dissolve 20 mg of *rabeprazole sodium IPRS* in 20 ml of *0.1M sodium hydroxide* and dilute to 100.0 ml with the solvent mixture.

Use chromatographic system as described under Assay.

Inject the reference solution and the test solution.

Calculate the content of $C_{18}H_{20}N_3O_3S$,Na released in the acid medium by subtracting the content of $C_{18}H_{20}N_3O_3S$,Na in the

test solution from the total content of Rabeprazole Sodium $C_{18}H_{20}N_3O_3S$,Na determined in the Assay.

Complies with the acceptance criteria given under acid stage.

B. Apparatus No. 2 (Paddle),
Medium. 900 ml of a mixture containing 70 volumes of *0.1 M hydrochloric acid* and 30 volumes of *0.6 M tris buffer*, adjusted to pH 8.0 with *2 M hydrochloric acid* or *2 M sodium hydroxide*,
Speed and time. 100 rpm and 45 minutes.

Transfer another 6 tablets and run the apparatus for 2 hours in *0.1 M hydrochloric acid*. Decant the medium without losing the tablets, add dissolution medium and run the apparatus for 45 minutes. Withdraw a suitable volume of the medium and filter.Determine by liquid chromatography (2.4.14).

Test solution. Dilute the filtrate, if necessary, with the dissolution medium. To 5.0 ml of the solution, add immediately 1.0 ml of *0.1M sodium hydroxide*

Reference solution. A 0.055 per cent w/v solution of *rabeprazole sodium IPRS* in *0.1M sodium hydroxide*. Dilute 2.0 ml of the solution to 100.0 ml with the dissolution medium. To 5.0 ml of the solution, add immediately 1.0 ml of *0.1M sodium hydroxide*.

Use chromatographic system as described under Assay.

Inject the reference solution and the test solution.

Calculate the content of $C_{18}H_{20}N_3O_3S$,Na in the medium.

Q. Not less than 70 per cent of the stated amount of $C_{18}H_{20}N_3O_3S$,Na.

Related substances.

Insert after Para 5

Reference solution (c). Dissolve 2.5 mg, each of, *rabeprazole sulphide IPRS* and *rabeprazole sulphone IPRS* in 2.5 ml *methanol* and dilute to 50.0 ml with the solvent mixture.

Reference solution (d). Dissolve 25 mg of *rabeprazole sodium IPRS* in 30 ml of *water*, add 5.0 ml of reference solution (c) and dilute to 50.0 ml with the solvent mixture.

Para 7

Change **from**: 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.

to: Inject reference solution (d) to identify the peaks due to rabeprazole sulphide and rabeprazole sulphone.

Inject reference solution (b) and (d). The test is not valid unless the resolution between the peaks due to rabeprazole sodium and rabeprazole sulphone is not less than 1.5 in the chromatogram obtained with reference solution (d), 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 5.0 per cent in the chromatogram obtained with reference solution (b).

Last para, line 2

Change **from**: three times

to: four times

Silver Sulphadiazine. Page 3581

Related substances. Last para, line 9

Change **from**: and the sum of areas of all peak

to:, the area of any other secondary peak

Sisomicin Sulphate. Page 3586

Identification. A, *Reference solution (a)*

Change **from**: *sisomicin IPRS*

to: *sisomicin sulphate IPRS*

Sisomicin Sulphate Injection. Page 3586

Identification. *Reference solution (a)*

Change **from**: *sisomicin IPRS*

to: *sisomicin sulphate IPRS*

Sodium Aminosalicylate Tablets. Page 3595

3-aminophenol. *Reference solution (a)*. Change **to**:

Reference solution (a). A 0.025 per cent w/v solution of *m-aminophenol IPRS* in the mobile phase. Dilute 1.0 ml of the solution to 50.0 ml with the mobile phase.

Monobasic Sodium Phosphate. Page 3622

Line 1

Change **to**: Sodium Dihydrogen Phosphate; Sodium Acid Phosphate

Sodium Starch Glycolate (Type A). Page 3625

Para 2, line 3

Change **from**: Ethanol (95 per cent)

to: Ethanol (80 per cent)

Iron. Change **to**:

Iron (2.3.14). 10.0 ml of solution A complies with the limit test for iron (20 ppm), using 1.0 ml of *iron standard solution (10 ppm)*.

Sodium glycolate. *Reference solution*, line 6 and 7

Delete the following

"Add 50 ml of *acetic acid* and allow to stand for 30 minutes."

Assay

Line 3 and 4

Change **from**: *silver nitrate solution*.

to: *dilute silver nitrate solution*.

Sodium Starch Glycolate (Type B). Page 3626

Iron. Change **to**:

Iron (2.3.14). 10.0 ml of solution A complies with the limit test for iron (20 ppm), using 1.0 ml of *iron standard solution (10 ppm)*.

Assay

Line 3 and 4

Change **from**: *silver nitrate solution*.

to: *dilute silver nitrate solution*.

Sodium Valproate Gastro-resistant Tablets. Page 3634

Related substances. Last para, line 5 and 6

Change **from**: and the sum of areas of all peak

to:, the area of any other secondary peak

Sofosbuvir Tablets. Page 3637

Related substances. After chromatographic system, impurity table

Change **to**:

Name	Relative retention time	Correction factor
Fluoro uridine phosphate impurity[1]	0.21	0.93
Fluoro uridine impurity[2]	0.39	0.5
Uridine alanine phosphate impurity[3]	0.45	1.61
Uridine phenyl phosphate impurity[4]	0.61	1.11
Uridine isopropyl alanine phosphate impurity[5]	0.65	0.9
Phenol impurity[6]	0.72	2.17
Ethyl analog[7*]	0.93	---
Sofosbuvir Rp isomer[8*]	0.98	---
Sofosbuvir (Retention time: about 16.5 minutes)	1.0	---
Chloro analog impurity[9*]	1.05	---
Penta fluoro phenyl impurity[10*]	1.13	---
Phosphoramidate sofosbuvir impurity[11*]	1.41	---
Phosphoramidate intermediate impurity[12*]	1.57	---

*Process impurity include for identification only and not included in the calculation of total degradation products.

[1]2'-deoxy-2'-fluoro-2'-methyluridine 5'-(dihydrogen phosphate),

[2]2' -deoxy-2' -fluoro-2' -methyluridine,

[3](2*S*)-2{[{[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2*H*)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2yl]methoxy}(hydroxy) phosphoryl]amino}propanoic acid,

[4]2'-deoxy-2'-fluoro-5-O-[hydroxyl(phenoxy)phosphoryl]-2'-methyl-uridine,

[5]propan-2-yl(2S)-2-{[{[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydro-pyrimidin-1(2*H*)-yl)-4-fluro-3hydroxy-4-methyltetrahydrofuran-2-yl] methoxy}(hydroxy)phosphoyl]amino}propanoate,

[6]phenol or hydroxy benzene,

[7](*S*)-2-[(S)-[[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydro-2*H*-pyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyltetrahydro-2-furanyl] methoxy] (phenoxy) phosphorylamino]propanoic acid-1-ethyl ester,

[8]propan-2-yl-(2*S*)-2-{[(*R*)-{[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydropyrimidin-1-(2*H*)-yl)-4-fluoro-3-hydroxy-4-methyltetra-hydrofuran-2-yl]methoxy}(phenoxy)phosphoryl]amino} propanoate,

[9]propan-2-yl-(2*S*)-2-{[(*S*)-{[(2*R*,3*R*,4*R*,5*R*)-4-chloro-5-(2,4-dioxo-3,4-dihydropyrimidin-1-(2*H*)-yl)-3-hydroxy-4-methyltetrahydrofuran-2-yl] methoxy}(phenoxy)phosphoryl]amino} propanoate ,

[10]2,3,4,5,6-pentafluoro phenol,

[11]propan-2-yl (2*S*)-2-{[(*R*)-{[(2*R*,3*R*,4*R*,5*R*)-2-[(3*S*,5*S*)-5,8-dimethyl-3-oxido-6-oxo-3-phenoxy-2,7-dioxa-4-aza-315-phosphanon-1-yl]-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2*H*)-yl)-4-fluoro-4-methyltetrahydrofuran-3-yl]oxy}(phenoxy)phosphoryl]amino}propanoate,

[12]*N*-[(*S*)-(2,3,4,5,6-pentafluoro phenoxy) phenoxyphos-phinyl]-*L*-Alanine-1- methyl ethyl ester.

Last para, line 8 and 9

Change **from**: sum of areas of all peak

to: area of any other secondary peak

Assay.

Reference solution. Change **to**:

Reference solution. A 0.048 per cent w/v solution of *sofosbuvir IPRS* in the solvent mixture.

Sofosbuvir and Daclatasvir Tablets. Page 3639

Related substances. *For Daclatasvir —*

After chromatographic system, impurity table

Change **to**:

Name	Relative retention time
Coupled amine hydrochloride impurity[1*]	0.49
Mono impurity[2*]	0.85
Acetyl impurity[3*]	0.87
Daclatasvir (Retention time: about 41 minutes)	1.0
SSSR-Diastermer[4*]	1.08
RSSR-Diasteromer[5*]	1.14
Oxazolidine impurity[6*]	1.48

*Process impurity include for identification only and not included in the calculation of total degradation products.

[1]5,5'-biphenyl-4,4'-diylbis{2-[(2S)-pyrrolidin-2-yl]-1*H*-imidazole} tetrahydrochloride,

[2]methyl(1*S*)-1-(((2*S*)-2-(5-(4'-(2-((2*S*)-1-((2S)-2-((methoxy carbonyl) amino)-3-methylbutanoyl)-2-pyrrolidinyl)-1*H*-imidazol-5-yl)-4-biphenylyl)-1*H* imidazol-2-yl)-1-pyrrolidinyl) carbonyl)-2-methylpropyl) carbamate,

[3]methyl [(2*S*)-1-{(2*S*)-2-[5-(4'-{*2*-[(2S)-1-acetylpyrrolidin-2-yl]-1*H*-imidazol-5-yl}biphenyl -4-yl)-1*H*-imidazol-2-yl]pyrrolidin-1-yl}-3-methyl -1-oxobutan-2-yl]carbamate,

[4]methyl [(2*S*)-1-{(2*S*)-2-[5-(4'-{2-[(2*S*)-1-{(2*R*)-2- [(methoxy carbonyl) amino]-3-methyl butanoyl}pyrrolidin-2-yl]-1*H* imidazol-5-yl} biphenyl-4-yl)-1*H*-imidazol-2-yl]pyrrolidin-1-yl}-3-methyl-1-oxobutan-2-yl] carbamate,

[5]methyl [(2*R*)-1-{(2*S*)-2-[5-(4'-{2-[(2*S*)-1-{(2*R*)-2-[(methoxy carbonyl) amino]-3-methyl butanoyl}pyrrolidin-2-yl]-1*H* imidazol-5-yl} biphenyl-4-yl)-1*H*-imidazol-2-yl] pyrrolidin-1-yl}-3-methyl-1-oxobutan-2-yl] carbamate,

[6]methyl [(2*S*)-1-{(2*S*)-2-[5-(4'-{2-[(2S)-1-{(2*S*)-2-[(methoxycarbonyl) amino]-3-methylbutanoyl}pyrrolidin-2-yl]-1,3-oxazol-5-yl} biphenyl-4-yl) -1*H*-imidazol-2-yl]pyrrolidin-1-yl}-3-methyl-1-oxobutan-2-yl]carbamate.

For Sofosbuvir —

After chromatographic system, impurity table

Change to:

Name	Relative retention time	Correction factor
Fluoro uridine impurity[1]	0.14	0.49
Ethyl analog impurity[2*]	0.91	---
Sofosbuvir Rp isomer[3*]	0.97	---
Sofosbuvir	1.0	---
Chloro analog impurity[4*]	1.06	---
Penta fluoro phenyl impurity[5*]	1.09	---
Phosphoramidate sofosbuvir impurity[6*]	1.53	---
Phosphoramidate intermediate impurity[7*]	1.73	---

*Process impurity include for identification only and not included in the calculation of total degradation products.

[1]2' -deoxy-2' -fluoro-2' -methyluridine,

[2](*S*)-2-[(*S*)-[[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydro-2*H*-pyrimidin-1-yl)-4-fluoro-3-hydroxy-4-methyltetrahydro-2-furanyl] methoxy](phenoxy) phosphorylamino]propanoic acid-1-ethyl ester,

[3]propan-2-yl-(2*S*)-2-{[(*R*)-{[(2*R*,3*R*,4*R*,5*R*)-5-(2,4-dioxo-3,4-dihydro-pyrimidin-1-(2*H*)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl] methoxy}(phenoxy)phosphoryl]amino} propanoate,

[4]propan-2-yl-(2*S*)-2-{[(*S*)-{[(2*R*,3*R*,4*R*,5*R*)-4-chloro-5-(2,4-dioxo-3,4-dihydropyrimidin-1-(2*H*)-yl)- 3-hydroxy-4-methyltetrahydrofuran-2-yl] methoxy}(phenoxy)phosphoryl]amino} propanoate ,

[5]2,3,4,5,6-pentafluoro phenol,

[6]propan-2-yl (2*S*)-2-{[(*R*)-{[(2*R*,3*R*,4*R*,5*R*)-2-[(3*S*,5*S*)-5,8-dimethyl-3-oxido-6-oxo-3-phenoxy-2,7-dioxa-4-aza-315-phosphanon-1-yl]-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2*H*)-yl)-4-fluoro-4-methyltetrahydrofuran-3-yl]oxy}(phenoxy)phosphoryl]amino}propanoate,

[7]*N*-[(*S*)-(2,3,4,5,6-pentafluoro phenoxy) phenoxyphosphinyl]-*L*-Alanine-1-methyl ethyl ester.

Para 2, line 6

Change **from**: sum of areas of all peak

to: area of any other secondary peak

Sulbactam Sodium. Page 3676

Related substances. *Reference solution (a)*, line 1

Change **from**: 70 mg of *sulbactam IPRS*

to: 77 mg of *sulbactam sodium IPRS*

Last para, line 15

Change **from**: sum of areas of all peak

to: area of any other secondary peak

Assay. Line 5

Delete the following requirement

"1 mg of sulbactam is equivalent to 1.094 mg of $C_8H_{10}NNaO_5S$."

Tamsulosin Hydrochloride Prolonged-release and Dutasteride Capsules. Page 3715

Dissolution. *For tamsulosin hydrochloride* — line 2

Change **from**: Tablets.

to: Capsules.

Teneligliptin and Metformin Hydrochloride Prolonged-release Tablets. Page 3738

Dissolution. *Reference solution*, line 1 and 2

Change **from**: A 0.02 per cent w/v solution of *teneligliptin hydrobromide hydrate IPRS* in the solvent mixture…….

to: A solution of *teneligliptin hydrobromide hydrate IPRS* containing 0.02 per cent w/v of teneligliptin in the solvent mixture….

Related substances. *Reference solution*, lines 1 to 3

Change **from**: A solution containing 0.05 per cent w/v, each of, *teneligliptin impurity A*, *teneligliptin impurity B* and *teneligliptin hydrobromide hydrate IPRS* in the solvent mixture…...

to: A solution containing 0.05 per cent w/v, each of, *teneligliptin impurity A*, *teneligliptin impurity B* and *teneligliptin hydrobromide hydrate IPRS* equivalent to teneligliptin in the solvent mixture…….

Assay. *Reference solution*

Change **from**: A 0.02 per cent w/v solution of *teneligliptin hydrobromide hydrate IPRS* in the solvent mixture.

to: A solution of *teneligliptin hydrobromide hydrate IPRS* containing 0.02 per cent w/v of teneligliptin in the solvent mixture.

Tolvaptan. Page 3832

Heavy metals. Line 2

Change **from**: Method D

to: Method B

Torsemide. Page 3836

Related substances.

Reference solution (a). Change **to**:

Reference solution (a). Dissolve 9.5 mg, each of, *4-[(3-methylphenyl)amino]-3-pyridinesulphonamide (torsemide related compound A) IPRS*, *N-[(n-butylamino) carbonyl]-4-[(3-methylphenyl)amino]-3-pyridinesulphonamide] (torsemide related compound B) IPRS* and *N-[(ethylamino)carbonyl]-4-[(3-methylphenyl) amino]-3-pyridinesulphonamide (torsemide related compound C) IPRS* in 30 ml of *methanol*, with the aid of ultrasound about 10 minutes and add 45 ml of *0.02 M potassium phosphate buffer pH 3.5* and dilute to 100.0 ml with the mobile phase. Dilute 1.0 ml of the solution to 50.0 ml with the mobile phase.

Reference solution (b).Change **to**:

Reference solution (b). Dissolve 3 mg, each of, *torsemide IPRS* and *torsemide related compound A IPRS* in 3 ml of *methanol*, with the aid of ultrasound for 10 minutes and add 4.5 ml of *0.02 M potassium phosphate buffer pH 3.5* and dilute to 10.0 ml with the mobile phase.

Last para

Change **to**: The area of any other secondary peak is not more than 0.1 per cent, the sum of the areas of all the secondary peaks, excluding torsemide related compound A, B and C is not more than 0.2 per cent calculated by area normalization method.

The sum of the areas of all the secondary peaks is not more than 1.0 per cent.

Trifluoperazine Injection. Page 3866

Assay. Change **to**:

Assay. To a measured volume of the injection containing 5 mg of trifluoperazine, add 10 ml of *2 M sulphuric acid* and extract with three quantities, each of 25 ml, of *carbon tetrachloride*. Discard the carbon tetrachloride extract after each extraction. Add 10 ml of *strong ammonia solution* and extract with five quantities, each of 50 ml, of *cyclohexane*. Extract the combined cyclohexane extracts with five quantities, each of 50 m1, of *0.1 M hydrochloric acid* and dilute the combined acid extracts to 500.0 ml with *0.1 M hydrochloric acid*. Measure the absorbance of the resulting solution at the maximum at about 255 nm and 278 nm (2.4.7). Calculate the difference between two absorbance of $C_{21}H_{24}F_3N_3S$ in the resulting solution from the absorbance obtained from the known concentration of *trifluoperazine hydrochloride IPRS* in the same solvent.

Vecuronium Bromide. Page 3928

Assay. Change **to**:

Assay. Dissolve 0.45 g in 50 ml of *glacial acetic acid*, add 10 ml of *mercuric acetate solution*. Titrate with *0.1 M*

perchloric acid, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of *0.1 M perchloric acid* is equivalent to 0.0638 g of $C_{34}H_{57}BrN_2O_4$.

Venlafaxine Prolonged-release Capsules. Page 3931

Identification. Para 2, line 1

Change **from**: Dissolve a quantity of the powdered tablets

to: Disperse a quantity of the mixed contents of capsules

Vildagliptin and Metformin Tablets. Page 3942 *(Effective from 12/04/2023)*

Benzyltrimethylammonium hydroxide. Change **to**:

1-amino-adamantan-3-ol. Not more than 0.4 per cent.

Determine by gas chromatography (2.4.13).

NOTE — Use freshly prepared solutions.

Internal standard solution. A 0.5 per cent v/v solution of *benzyl alcohol* in *acetone*. Dilute 1.0 ml of the solution to 10.0 ml with *acetone*. Dilute 2.0 ml of the solution to 200.0 ml with *acetone*.

Test solution. Disperse a quantity of the powdered tablets containing 62.5 mg of Vildagliptin in the internal standard and vortex for 2 minutes. Then stir the solution for 45 minutes, with the aid of magnetic stirrer, dilute to 50.0 ml with internal standard and centrifuge at 4000 rpm for 30 minutes. Use supernatant liquid.

Reference solution (a). A 0.000625 per cent w/v solution of *1-amino-adamantan-3-ol IPRS* in internal standard solution.

Reference solution (b). Dilute 2.0 ml of reference solution (a) to 10.0 ml with internal standard solution.

Reference solution (c). A 0.125 per cent w/v solution of *vildagliptin IPRS* in reference solution (a).

Chromatographic system

- a fused-silica capillary column, 15 m x 0.25 mm coated with crossbond 5 per cent diphenyl and 95 per cent dimethylpolysiloxane with film thickness of 1.0 µm (Such as Rtx-5 amine),
- temperature:
  column 100° for 4 minutes, 100° to 290° @ 35° per minutes and hold at 290°, for 14 minutes,
- inlet port at 250° and detector at 300°,
- flame ionisation detector,
- split ratio of 5:1,
- flow rate: 1.0 ml per minute using nitrogen as the carrier gas,
- injection volume: 1 µl.

Inject reference solution (a), (b) and (c). The test is not valid unless the resolution between the peaks due to 1-amino-adamantan-3-ol and benzyl alcohol is not less than 2.5 in the chromatogram obtained with reference solution (c), the relative standard deviation of the peak area ratio due to 1-amino-adamantan-3-ol and internal standard for replicate injections is not more than 10.0 per cent in the chromatogram obtained with reference solution (a) and the signal-to-noise ratio is not less than 10 in the chromatogram obtained with reference solution (b).

Inject reference solution (a) and the test solution.

Calculate the content of 1-amino-adamantan-3-ol, using ratio of the peak area of 1-amino-adamantan-3-ol to that of peak area of the internal standard.

Warfarin Tablets. Page 3963

Assay. *Reference solution*, line 2

Change **from**: *warfarin IPRS*

to: *warfarin sodium IPRS*

Xylometazoline Hydrochloride. Page 3974

Identification

Insert before A.

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.

Iron. Line 1

Change **from**: (2.4.14)

to: (2.3.14)

Insert at the end

"using 1.0 ml of *iron standard solution (10 ppm)*."

VITAMINS, MINERALS, AMINO ACIDS, FATTY ACIDS ETC.

Calcium and Vitamin D3 Tablets. Page 4059

Dissolution. Line 6

Change **from**: Transfer 20 ml of the solution in to 250-ml volumetric flask,

to: Transfer 20.0 ml of the solution in to 250-ml conical flask,

Cholecalciferol Tablets. Page 4061

Assay. Test solution, line 2

Change **from**: Calciferol

to: Cholecalciferol

Reference solution (a). Change **to**:

Reference solution (a). Dissolve 10.0 mg of *cholecalciferol IPRS* in 10 ml of *toluene* without heating and dilute to 100.0 ml with the mobile phase. Dilute 1.0 ml of the solution to 10.0 ml with the mobile phase

Reference solution (b). Line 2

Delete " *or ergocalciferol IPRS* as appropriate"

After chromatographic system, para 2, line 2

Delete " or ergocalciferol"

Last para. Line 2

Delete " or ergocalciferol, $C_{28}H_{44}O$"

Potassium Chloride. Page 4107

Sodium. Change **to**:

Sodium. Not more than 0.1 per cent, determine by Method A for flame photometry (2.4.4) or by Method A for atomic absorption spectrophotometry (2.4.2), measuring at 589 nm and using sodium solution FP, or sodium solution AAS respectively, suitably diluted with *water*, for the standard solutions.

HERBS AND HERBAL PRODUCTS

Starch. Page 4303

Microbial contamination

Change **from**: 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella* and *Shigella*.

to: The total aerobic viable count is not more than 1000 cfu per g, the total fungal count is not more than 100 cfu per g, determined by plate count. 1 g is free from *Escherichia coli* and 10 g is free from *Salmonella* and *Shigella*.

VETERINARY PRODUCTS

Dexamethasone Injection. Page 4863

Usual strengths.

Change **from**: The equivalent of 4 mg of dexamethasone per ml in 2 ml, 5 ml and 10 ml vials.

to: The equivalent of 4 mg of dexamethasone phosphate per ml

Monobasic Sodium Phosphate. Page 4921

Line 1

Change **to**: Sodium Dihydrogen Phosphate; Sodium Acid Phosphate

Sodium Acid Phosphate Injection. Page 4921

Add synonym

Monobasic Sodium Phosphate Injection