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: June 30, 2023

Subject: Amendment List 04 to IP 2022

The 9th Edition of Indian Pharmacopoeia (IP) 2022 has become effective from 1st December, 2022. Based on scientific inputs, some monographs of IP 2022 need amendments for their effective implementation. Accordingly, Amendment List 04 to IP 2022 is being issued containing such amendments and this shall become effective with immediate effect.

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 04 to IP 2022

To,

1. The Drugs Controller General (India)
2. All State Drug Controllers
3. CDSCO Zonal Offices
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

2.4.26. Solubility

Page 274

Diethanolamine

Change **to**: **Diethanolamine**. Soluble in *water*, *ethanol*, *acetone*, *chloroform*, and *glycerin*. Slightly soluble to insoluble in *benzene*, *ether*, and *petroleum ether*.

2.5.6. Contents of Packaged Dosage Forms. Page 365

After para 1

Ointments, Creams, Pastes, Gels, Lotions and Powders

Change **to**: **Ointments, Creams, Pastes, Gels, Lotions, Granules and Powders for oral liquids**

Acceptance Criteria. Para 1, line 1 and 2

Change **from**: weight

to: weight or volume

Para 2, line 1, 2 and 4

Change **from**: weight

to: weight or volume

Line 8

Change **from**: weights

to: weights or volumes

Liquids, Suspensions, Granules and Powders for oral liquids

Change **to**: **Liquids and Suspensions**

4.2 General Reagents

Page 1098

Insert before **Iron Salicylate Solution**

Iron Powder. Fe = 55.85

Use a suitable grade with a content of not less than 99.9 per cent.

Page 1099

Insert before **Lead Acetate**

Lanthanum Oxide; Lanthanum trioxide: La_2O_3 = 325.8

Atomic Absorption Spectroscopy grade.

An almost white, amorphous powder, practically insoluble in *water*. It dissolves in dilute solutions of mineral acids and absorbs atmospheric carbon dioxide.

Amoxycillin and Potassium Clavulanate Oral Suspension. Page 1470

Assay. Chromatographic system

Insert before line 3

– sample temperature: 10º,

Brivaracetam Tablets. Page 1665

Insert before **Assay**

Other tests. Comply with the tests stated under Tablets.

Budesonide. Page 1674

Insert before **Loss on drying**

Epimer A. The content of epimer A (second peak) is 40.0 per cent to 51.0 per cent of the sum of areas of two epimer peaks of budesonide.

Determine by liquid chromatography (2.4.14), as described under Assay using the test solution.

Assay

Insert at the end

"from the sum of the areas of two budesonide epimer peaks."

Chlorambucil. Page 1827

Assay. Para 1

Insert at the end

Carry out a blank titration.

Deferasirox. Page 2028

4-Hydrazino benzoic acid. Line 3

Change **to**: *NOTE — Protect the solutions from light. Add solvent mixture very slowly with stirring.*

Test solution. Line 2

Change **from**: 2.0 ml

to: 1.0 ml

Reference solution (d). Line 3

Change **from**: 2.0 ml

to: 1.0 ml

Diethanolamine. Page 2099

Insert before **Identification**

Description. A white or clear, colorless crystals, deliquescing in moist air; or colorless liquid.

Diltiazem Tablets. Page 2120

Insert at the end

Labelling. The label states whether the product is modified-release tablets or conventional release tablets.

Dorzolamide and Timolol Eye Drops. Page 2175

Identification. A. Line 4

Change **from**: the reference solution.

to: reference solution (a).

B. Line 4

Change **from**: the reference solution.

to: reference solution (a).

Doxofylline. Page 2184

Identification. B, line 1

Change **from**: 200 nm to 400 nm

to: 230 nm to 350 nm

Ergotamine Injection. Page 2258

Bacterial endotoxins

Change **from**: Not more than 357.0 Endotoxin Units per mg of ergotamine.

to: Not more than 357.0 Endotoxin Units pe mg of ergotamine tartrate.

Etodolac Capsules. Page 2312

Identification. B, line 3

Change **from**: the reference solution.

to: reference solution (a).

Assay. After chromatographic system, para 1

Change **to**: Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to etodolac and etodolac 1-methyl analogue is not less than 1.5 in the chromatogram obtained with reference solution (b), the tailing factor is not more than 2.0 and relative standard deviation for replicate injection is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Etodolac Prolonged-release Tablets. Page 2314

Identification. Line 3

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

to: the reference solution.

Etodolac Tablets. Page 2314

Identification. B, line 3

Change **from**: the reference solution.

to: reference solution (a).

Assay. After chromatographic system, para 1

Change **to**: Inject reference solution (a) and (b). The test is not valid unless the resolution between the peaks due to etodolac and etodolac 1-methyl analogue is not less than 1.5 in the chromatogram obtained with reference solution (b), the tailing factor is not more than 2.0 and relative standard deviation for replicate injection is not more than 2.0 per cent in the chromatogram obtained with reference solution (a).

Fentanyl Citrate. Page 2347

Related substances. Last para, lines 8 to 10

Change **from**: Ignore any peak with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

to: Ignore any peak due to citric acid and with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Fentanyl Injection. Page 2347

Related substances. Last para, lines 15 to 18

Change **from**: Ignore any peak with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

to: Ignore any peak due to citric acid and with an area less than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Gabapentin Tablets. Page 2447

Assay. *Reference solution*, line 2

Change **from**: buffer solution.

to: diluent.

Glucosamine Sulphate Sodium Chloride. Page 2484

Assay. Line 3 and 4

Change **from**: Carry out a blank titration.

to: Read the volume added between the 2 points of inflection.

Glycerin. Page 2485

Ethylene glycol, diethylene glycol and related substances

Reference solution (a).

Change **to**: *Reference solution (a).* A solution containing 0.005 per cent w/v, each of, *ethylene glycol IPRS*, *diethylene glycol IPRS* and *glycerin IPRS* in *methanol*.

After chromatographic system, para 3, line 6 and 7

Change **from**: and the area of any other secondary peak is not more than 0.1 per cent, calculated by area normalisation.

to: and the area of any other secondary peak is not more than the area of the principal peak in the chromatogram obtained with reference solution (a) (0.10 per cent).

Hydralazine Injection. Page 2525

Bacterial endotoxins

Change **from**: Not more than 1.45 Endotoxin Units per mg of hydralazine.

to: Not more than 1.45 Endotoxin Units per mg of hydralazine hydrochloride.

Hyoscyamine Oral Solution. Page 2564

Assay. Last line

Change **from**: Calculate the content of $C_{17}H_{23}NO_3)_2$, H_2SO_4, $2H_2O$ in the oral solution

to: Determine the weight per ml of the oral solution (2.4.29) and calculate the content of $(C_{17}H_{23}NO_3)_2$, H_2SO_4, $2H_2O$ weight in volume.

Irbesartan Tablets. Page 2622

Identification. A, line 1

Change **from**: Transfer one tablet into a suitable vial, add 10 ml of *methanol*,

to: Disperse a quantity of powdered tablets containing 0.3 g of Irbesartan with 10 ml of *methanol*,

B, last line

Change **from**: the reference solution.

to: reference solution (a).

Isoxsuprine Hydrochloride. Page 2649

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.

Levetiracetam. Page 2729

Levetiracetam impurity B. After chromatographic system, para 2

Change **to**: Inject reference solution (b). The test is not valid unless the tailing factor is not more than 2.0. and the relative standard deviation for the replicate injections is not more than 2.0 per cent.

Levocetirizine Hydrochloride. Page 2734

Related substances

Insert at the end

Ignore any peak with an area less than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent).

Lorazepam. Page 2787

Related substances. *Test solution*, line 1

Change **from**: 32 mg

to: 0.32 g

Mannitol Injection. Page 2825

Identification. B, last para, line 4 and 5

Change **from**: *4,4'-methylenebis-N,N-dimethylanaline*

to: *4,4'-methylenebis-N,N-dimethylaniline*

Meclizine Tablets. Page 2831

Insert before **Assay**

Other tests. Comply with the tests stated under Tablets.

Methadone Hydrochloride. Page 2879

Related substances. Last para, line 4

Change **from**: the area of any secondary peak

to: the area of any peak corresponding to methadone impurity A, B, C, D, E and any other secondary peak, each of,

Methadone Linctus. Page 2880

Labelling. Delete the requirement.

Methyl Salicylate Ointment. Page 2907

Assay. Chromatographic system, insert at the end

– injection volume: 1 µl.

Metolazone Tablets. Page 2912

Identification

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

Metoprolol Succinate. Page 2913

Identification. Line 3 and 4

Change **from**: treated in the same manner or with the reference spectrum of metoprolol.

to: or with the reference spectrum of metoprolol succinate.

Mitomycin. Page 2951

Insert before **Identification**

Description. A blue-violet crystalline powder.

Omeprazole. Page 3116

Related substances. *Reference solution (a)*, line 3

Change **from**: (*omeprazole impurity A IPRS*)

to: (*omeprazole impurity D IPRS*)

Paracetamol Paediatric Oral Suspension. Page 3196

Assay. Para 3

Change **to**: Use chromatographic system as described under Related substances with the following modification.

– injection volume: 20 µl.

Pemetrexed Injection. Page 3212

pH

Change **from**: 6.6 to 7.8

to: 6.6 to 7.8, reconstitute solution as directed in the labelling.

Other tests. Delete the requirement

Insert at the end

Labelling. The label states the quantity of Pemetrexed disodium heptahydrate in terms of the equivalent amount of pemetrexed.

Peritoneal Dialysis Solutions. Page 3232

Assay.

For sodium. Change **to**:

For sodium — Dilute suitably with water and determine by Method A for flame photometry (2.4.4), or by Method A for atomic absorption spectrometry (2.4.2), measuring at 589 nm and using *sodium solution FP*, or *sodium solution AAS* respectively, suitably diluted with water for the reference solutions.

NOTE — To counteract potential interferences in atomic absorption spectrometry (2.4.2), add lithium nitrate solution in the preparation of the solutions in the same concentration as stated below.

Lithium nitrate solution (Lithium as ionization suppressant). A 0.104 per cent w/v solution of *lithium nitrate* in *water (NOTE — Store in a tightly closed container)*.

Blank solution. Dilute 98.0 ml of lithium nitrate solution to 100.0 ml with *water*.

Test solution. Dilute the Peritoneal Dialysis Solution to obtain a solution containing 30 ppm of sodium (Na). Dilute 5.0 ml of the solution to 250.0 ml with lithium nitrate solution (Note- This solution contains 0.6 ppm of sodium (Na)).

Reference solutions. Pipette out appropriate volume of the *sodium solution AAS* and dilute to make reference solutions of 10, 20, 30, 40 and 50 ppm. Dilute 5.0 ml of each solution to 250.0 ml, individually with the lithium nitrate solution.

For calcium. Change **to**:

For calcium — Dilute suitably with water and determine by Method A for atomic absorption spectrometry (2.4.2) measuring at 422.7 nm using *calcium solution AAS*, suitably diluted with water for the reference solutions.

NOTE — To counteract potential interferences in atomic absorption spectrometry (2.4.2), add lanthanum chloride solution in the preparation of the solutions in the same concentration as stated below.

Lanthanum chloride solution (Lanthanum as ionization suppressant): To 58.65 g of *lanthanum trioxide*, slowly add 100 ml of *hydrochloric acid*. Heat to boiling. Allow to cool and dilute to 1000 ml with *water (NOTE — Store in a tightly closed container)*.

Blank solution. Dilute 20.0 ml of lanthanum chloride solution to 100.0 ml with *water*.

Test solution. Dilute the Peritoneal Dialysis Solution to obtain a solution containing 5 ppm of calcium (Ca). Add a suitable volume of lanthanum chloride solution in the final dilution so as to contain 20 per cent of the final volume.

Reference solutions. Pipette out appropriate volume of the *calcium solution AAS* and dilute to make reference solutions of 3, 4, 5, 6 and 7 ppm. Add a suitable volume of lanthanum chloride solution in the final dilutions so as to contain 20 per cent of the final volume.

For magnesium. Change **to**:

For magnesium — Dilute suitably with water and determine by Method A for atomic absorption spectrometry (2.4.2), measure at 285.2 nm and using *magnesium solution AAS*, suitably diluted with water for the reference solution.

NOTE — To counteract potential interferences in atomic absorption spectrometry (2.4.2), add lanthanum chloride solution in the preparation of the solutions in the same concentration as stated below.

Lanthanum chloride solution (Lanthanum as ionization suppressant): To 58.65 g of *lanthanum trioxide*, slowly add 100 ml of *hydrochloric acid*. Heat to boiling. Allow to cool and dilute to 1000 ml with *water (NOTE — Store in a tightly closed container)*.

Blank solution. Dilute 20.0 ml of lanthanum chloride solution to 100.0 ml with *water*.

Test solution. Dilute the Peritoneal Dialysis Solution to obtain a solution containing 0.5 ppm magnesium (Mg). Add a suitable volume of lanthanum chloride solution in the final dilution so as to contain 20 per cent of the final volume.

Reference solutions. Pipette out appropriate volume of the *magnesium solution AAS* and dilute to make reference solutions of 0.3, 0.4, 0.5, 0.6 and 0.7 ppm. Add a suitable volume of lanthanum chloride solution in the final dilutions so as to contain 20 per cent of the final volume.

Pregabalin Capsules. Page 3344

Assay. Chromatographic system, line 7

Insert at the end

"and dilute to 1000 ml with *water*,"

Propylene Glycol. Page 3381

Diethylene glycol and Ethylene glycol. Last para, last line

Change **from**:(0.1 per cent).

to:(0.10 per cent).

Rabeprazole Gastro-resistant Tablets.

Page 3441 and Amendment List- 02, page 8

Dissolution. A, *Test solution*. Line 2

Change **from**:*0.1M sodium hydroxide*

to:*0.5M sodium hydroxide*

Reference solution. Line 2

Change **from**:*0.1M sodium hydroxide*

to:*0.5M sodium hydroxide*

Change **from**:Use chromatographic system as described under Assay

to:Use chromatographic system as described under Assay with following modification.

– sample temperature: 10º,

B. *Test solution*. Line 3

Change **from**:*0.1M sodium hydroxide*

to:*0.5M sodium hydroxide*

Reference solution. Line 2 and 5

Change **from**:*0.1M sodium hydroxide*

to:*0.5M sodium hydroxide*

Change **from**:Use chromatographic system as described under Assay

to:Use chromatographic system as described under Assay with following modification.

– sample temperature: 10º,

Rocuronium Injection. Page 3517

Related substances. Last para

Change **to**:

Inject reference solution (a) and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to rocuronium impurity C is not more than 2.5 times the area of the principal peak in the chromatogram obtained with reference solution (a) (2.5 per cent), the area of any peak corresponding to rocuronium impurity A, B, F, G, H, each of, 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), the area of any other secondary peak is not more than 0.2 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.2 per cent) and the sum of the areas of all the secondary peaks is not more than 3 times the area of the principal peak in the chromatogram obtained with reference solution (a) (3.0 per cent). Ignore any peak eluting before impurity A and 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).

Ropivacaine Injection. Page 3527

Limit of Ropivacaine related compound A

Test solution. Line 2

Change **from**: 0.2 per cent

to: 0.25 per cent

Last para

Change **to**: Inject the reference solution and the test solution. In the chromatogram obtained with test solution, the area of the peak corresponding to ropivacaine impurity A is not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.01 per cent).

Rosuvastatin and Ezetimibe Tablets. Page 3530

Assay.

Test solution. Change **to**:

Test solution. Weigh and powder 20 tablets. Disperse a quantity of the powder containing 50 mg of Rosuvastatin with 70 ml of the solvent mixture, with the aid of ultrasound for 10 minutes and dilute to 100.0 ml with the solvent mixture, mix and filter. Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

Sodium Starch Glycolate (Type A). Page 3625

Sodium glycolate

Test solution. Line 1

Change **from**: *glacial acetic acid,*

to: *acetic acid,*

Sodium Starch Glycolate (Type B). Page 3626

Sodium glycolate

Test solution. Line 1

Change **from**: *glacial acetic acid,*

to: *acetic acid,*

Sorbitol Solution (70 Per cent) (Crystallising). Page 3649

Identification. Change **to**:

Identification

A. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).

B. Diethylene glycol and Ethylene glycol (see Tests).

C. Dissolve 4 g of sorbitol solution in 75 ml of *water*. Transfer 3 ml of the solution to a test tube, add 3 ml of freshly prepared solution of *catechol* (1 in 10) and mix. Add 6 ml of *sulphuric acid*, mix again and gently heat the tube in a flame for 30 seconds. Deep pink or wine-red colour produced.

Insert before **Reducing sugars**

Diethylene glycol and Ethylene glycol. Determine by gas chromatography (2.4.13).

Solvent mixture. 96 volumes of *acetone* and 4 volumes of *water*.

Test solution. Weigh and transfer 2.0 g of sorbitol solution in 25-ml volumetric flask, add 1.0 ml of the *solvent mixture* and mix on a vortex mixer for 3 minutes. Add the remaining *solvent mixture* to the flask up to the mark in three equal portions. Mix on a vortex mixer for about 3 minutes after each addition of the *solvent mixture*. Filter the supernatant layer through a 0.45-µm nylon filter. *[NOTE — Acetone is used to precipitate sorbitol].*

Reference solution. A solution containing 0.008 per cent w/v, each of, *diethylene glycol IPRS* and *ethylene glycol IPRS* in the solvent mixture.

Chromatographic system
- a fused silica capillary column 15 m x 0.32 mm, packed with 14 per cent cyanopropylphenyl and 86 per cent dimethylpolysiloxane (film thickness 0.25 µm) (Such as DB-1701),
- temperature:
  column. 70° for 2 minutes, 70° to 300° @ 50° per minute and hold at 300° for 5 minutes,
  inlet port 240° and detector 300°,
- split ratio: 10:1,
- flame ionization detector,
- flow rate: 3.0 ml per minute, using nitrogen as the carrier gas,
- injection volume: 1 µl.

The elution order of the peaks is ethylene glycol and diethylene glycol.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to ethylene glycol and diethylene glycol is not less than 30.0.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to diethylene glycol and ethylene glycol, each of, is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.10 per cent).

Sorbitol Solution (70 Per cent) (Non-Crystallising). Page 3650

Identification. Change **to**:

Identification

A. In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with reference solution (a).

B. Diethylene glycol and Ethylene glycol (see Tests).

C. Dissolve 4 g of sorbitol solution in 75 ml of *water*. Transfer 3 ml of the solution to a test tube, add 3 ml of freshly prepared solution of *catechol* (1 in 10) and mix. Add 6 ml of *sulphuric acid*, mix again and gently heat the tube in a flame for 30 seconds. Deep pink or wine-red colour produced.

Insert before **Reducing sugars**

Diethylene glycol and Ethylene glycol. Determine by gas chromatography (2.4.13).

Solvent mixture. 96 volumes of *acetone* and 4 volumes of *water*.

Test solution. Weigh and transfer 2.0 g of sorbitol solution in 25-ml volumetric flask, add 1.0 ml of the *solvent mixture*and mix on a vortex mixer for 3 minutes. Add the remaining *solvent mixture* to the flask up to the mark in three equal portions. Mix on a vortex mixer for about 3 minutes after each addition of the *solvent mixture*. Filter the supernatant layer through a 0.45-µm nylon filter. *[NOTE —Acetone is used to precipitate sorbitol].*

Reference solution. A solution containing 0.008 per cent w/v, each of, *diethylene glycol IPRS* and *ethylene glycol IPRS* in the solvent mixture.

Chromatographic system
- a fused silica capillary column 15 m x 0.32 mm, packed with 14 per cent cyanopropylphenyl and 86 per cent dimethylpolysiloxane (film thickness 0.25 µm) (Such as DB-1701),
- temperature:
  column. 70° for 2 minutes, 70° to 300° @ 50° per minute and hold at 300° for 5 minutes,
  inlet port 240° and detector 300°,
- split ratio: 10:1,
- flame ionization detector,
- flow rate: 3.0 ml per minute, using nitrogen as the carrier gas,
- injection volume: 1 µl.

The elution order of the peaks is ethylene glycol and diethylene glycol.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to ethylene glycol and diethylene glycol is not less than 30.0.

Inject the reference solution and the test solution. In the chromatogram obtained with the test solution, the area of any peak corresponding to diethylene glycol and ethylene glycol, each of, is not more than the area of the principal peak in the chromatogram obtained with the reference solution (0.10 per cent).

Teicoplanin Injection. Page 3724

Water. Delete the requirement.

Telmisartan and Hydrochlorothiazide Tablets. Page 3730

Related substances. Last para, line 4

Change **from**: 6.4 times

to: twice

Thyroxine Tablets. Page 3788

Assay

Test solution. Change **to**:

Test solution. Transfer 20 intact tablets into a suitable volumetric flask, disperse in the solvent mixture with the aid of ultrasound, cool and dilute to volume with the solvent mixture to obtain a solution containing 0.001 per cent w/v of Thyroxine Sodium and filter.

Tolnaftate Cream. Page 3827

Assay. Line 3, 4 and 5

Change **from**: Wash the chloroform solution successively with two 25 ml portions of *0.1 M hydrochloric acid* and 25 ml of *water.*

to: Wash the chloroform solution successively with two 25 ml portions of *0.1 M sodium hydroxide*, two 25 ml portions of *0.1 M hydrochloric acid* and 25 ml of *water.*

Tolnaftate Gel. Page 3828

Assay. Line 3, 4 and 5

Change **from**: Wash the chloroform solution successively with two 25 ml portions of *0.1 M hydrochloric acid* and 25 ml of *water.*

to: Wash the chloroform solution successively with two 25 ml portions of *0.1 M sodium hydroxide*, two 25 ml portions of *0.1 M hydrochloric acid* and 25 ml of *water.*

Vecuronium Bromide. Page 3928 and Amendment List-02, page 12

Assay. Line 1

Delete 'add 10 ml of *mercuric acetate solution*'

Vildagliptin Tablets. Page 3941

Related substances. Last para, last line

Change **from**: 1.0 per cent

to: 0.1 per cent

Zolpidem Tartrate. Page 4003

Identification. B. Line 1

Change **from**: reaction (c)

to: reaction (b)

VITAMINS, MINERALS, AMINO ACIDS, FATTY ACIDS ETC.

Glutamic Acid. Page 4084

Loss on drying. Line 1

Change **from**: 0.1 per cent

to: 0.5 per cent

Herbs and herbal Products

Shellac. Page 4301

Identification. B. *Test solution*, lines 3 to 5

Change **from**: Cool and add 5 ml of *dilute acetic acid*. Shake and filter the upper layer through *anhydrous sodium sulphate*.

to: Cool, add 5 ml of *ethyl acetate* and slowly, with stirring, 2 ml of *dilute acetic acid*. Shake and filter the upper layer through *anhydrous sodium sulphate*.

Last para, line 2

Change **from**: 8 cm

to: 15 cm

Tests

Acid value

Change **to**: **Acid value** (2.3.23). Weigh accurately 1.0 g and dissolve with the aid of gentle heat, in 50 ml of *ethanol (95 per cent)* previously neutralized to *ethanolic thymol blue solution*. Titrate with *0.1 M ethanolic potassium hydroxide* using *ethanolic thymol blue solution* as an indicator. Calculate the acid value from the expression

$$5.61 \times a/w$$

where, a = number of ml of *0.1 M ethanolic potassium hydroxide* and,

w = weight, in g, of the sample

Acceptance criteria:

Orange Shellac: 68 to 76

Refined Orange Shellac: 68 to 79

Regular Bleached Shellac: 73 to 89

Refined Bleached Shellac: 75 to 91

Vaccines and Immunosera for Human Use

Antisera. Page 4329

Para 3, line 7

Change **from**: CPCSEA guideline

to: CCSEA guidelines

Test for Pyrogens

Change **from**: **Test for Pyrogens**. Unless otherwise justified and authorized, it complies with the test for Pyrogens. Inject 1 ml/kg body weight of the rabbit.

to: **Test for Pyrogens**. Unless otherwise justified and authorized, it complies with the test for pyrogens. Inject 1ml/kg body weight or a validated test for Bacterial endotoxins (2.2.3) may be used and should be within the limits approved by the National Regulatory authority.

Diphtheria Vaccine (Adsorbed). Page 4386

FINAL BULK VACCINE

Specific toxicity

Insert at the end

NOTE — Specific toxicity test on the final bulk could be omitted for routine lot release once consistency of production has been established to the satisfaction of the National Regulatory Authority.

Inactivated Influenza Vaccine (Split Virion). Page 4406

PROPAGATION AND HARVEST

Mycoplasma

Insert at the end

When vaccine is produced on egg and if the inactivation process is shown to be capable of inactivating Mycoplasma, testing for Mycoplasma at stage propagation and harvest is not required.

Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human). Page 4419

FINAL LOT

Insert before **Identification**

NOTE — If the assay has been carried out with satisfactory results on the final bulk vaccine, same may be omitted on the final lot.

VETERINARY PRODUCTS

Ivermectin. Page 4886

Heavy metals. Line 2

Change **from**: Method C (20 ppm).

to: Method B (20 ppm).