INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA
SECTOR-23, RAJ NAGAR, GHAZIABAD- 201 002.
Tel No: 0120- 2783392, 2783400, 2783401; Fax: 2783311
E-Mail: ipclab@vsnl.net, Web: www.ipc.gov.in

No. T.11013/02/2018-AR&D **Dated:25. May, 2018**

To,

1. **Drugs Controller General (India)/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 Drugs Testing Laboratories**
7. **IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations**

Errata– 001 to IP-2018

As you are aware that 8th edition of Indian Pharmacopoeia has been effective from 1st January, 2018. Further, the effective date has been relaxed/ extended till 30th June, 2018 for the stakeholders who could not upgrade/ changed their products for compliance of IP- 2018.

Based on Scientific inputs, some monographs needed up-gradation; accordingly an Errata- 001 is issued containing such amendments.

This is for notice and compliance with IP-2018.

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

Encl:- Errata– 001 to IP-2018

Errata-001 to IP-2018

2.3.27. Hydroxyl Value. Page 143

Method A. Line 10

Change **from**: replace

to: reflux

2.4.26. Solubility. Page 220

Calcium Folinate. Page 224

Change **to**: Sparingly soluble in *water*; practically insoluble in *ethanol* and in *ethanol (95 per cent)*.

Carboxymethylcellulose Sodium. Page 225

Change **to**: Insoluble in *ethanol*, in *ether* and in most organic solvents. Easily dispersed in *water* to form colloidal solution.

Darifenacin Hydrobromide. Page 228, Line 2

Change **from**: *methane*

to: *methanol*

Paracetamol. Page 242

Change **to**: Freely soluble in *ethanol*; sparingly soluble in *water*; very slightly soluble in *dichloromethane*.

Sodium Carboxymethyl Cellulose. Page 247

Delete the requirement.

2.4.29. Weight Per Millilitre and Relative Density (Specific Gravity). Page 256

Method B. Para 3, line 1.

Change **from**: Introduction of two constants $A = c/(4^2 \times V)$ and $B = (M/V)$,

to: Introduction of two constants $A = c/(4\ \pi^2 \times V)$ and $B = (M/V)$,

2.5.2 Dissolution Test. Page 302

Under **Methods, For Apparatus 1 and Apparatus 2**

Change **from*: Modified-release dosage forms.*** Use method A or Method B.

to: ***Modified-release dosage forms***

Gastro-resistant dosage forms. Use method A or Method B.

For Apparatus 3

Change **from***: **Modified-release dosage forms***

to: ***Modified-release dosage forms***

Gastro-resistant dosage forms

For Apparatus 4

Change **from***: **Modified-release dosage forms***

to: ***Modified-release dosage forms***

Gastro-resistant dosage forms

4.2 General Reagents. Page 890

2-Ethylhexanoic Acid. Page 913
Related substances. Para 1, line 1
Change **from**: 1 ml
to: 1µl

Tris(hydroxymethyl)aminomethane solution.
Change **from**: **Tris (hydroxymethyl) aminomethane solution**: Transfer 40 mg of *tris (hydroxymethyl) aminomethane* in 200.0 ml volumetric flask and dilute with *dimethylsulphoxide*.
to: **Tris (hydroxymethyl) aminomethane reagent**: Weigh accurately 1.5g of *tris (hydroxymethyl) aminomethane* in 100 ml volumetric flask, dissolve and dilute to volume with *water* and mix. Transfer 40 ml of this solution to a 200 ml volumetric flask and dilute to volume with *dimethyl sulphoxide*. Use this reagent within 4 hours.

4.5. Volumetric Reagents and Solutions. Page 967
Cerric Ammonium Nitrate, 0.1M;
Para 2. Delete the requirement.

Acarbose. Page 1139
Assay. *Test solution*
Change **from**: Dissolve 10 mg of the substance under examination in *water* and dilute to 50.0 ml of *water.* Dilute 5.0 ml of this solution to 50.0 ml with *water.*
to: Dissolve 10 mg of the substance under examination in *water* and dilute to 50.0 ml with *water.*

Reference solution. Line 1
Change **from**: 0.002
to: 0.02

Acarbose Tablets. Page 1141
Dissolution.
Test solution. Line 2
Change **from**: 0.002
to: 0.01
Reference solution. Line 1
Change **from**: 0.002
to: 0.01

Acesulphame Potassium.Page 1146
Identification. Para 1
Change **from**: *Tests B and C may be omitted if tests A and C are carried out. Tests A and C may be omitted if tests B and C are carried out.*
to: *Test B may be omitted if tests A and C and carried out and tests A may be omitted if tests B and C are carried out.*

Ampicillin Sodium. Page 1241
Assay. After chromatographic system, para 4.
Change **from**: Calculate the content of $C_{16}H_{19}N_3O_4S$.
to: Calculate the content of $C_{16}H_{19}N_3NaO_4S$ by multiplying the content of $C_{16}H_{19}N_3O_4S$ by 1.063.

Analgin. Page 1247
Identification, Insert the following 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.
Tests
Other tests. Delete the requirements.

Atenolol and Chlorthalidone Tablets. Page 1283

Identification B. Lines 3 & 4

Change **from**: the chromatograms obtained with reference solution solutions (a) and reference solution (b).

to: the chromatograms obtained with reference solution (c).

Bosentan Tablets. Page 1401

Dissolution (2.5.2).

Medium.

Change **from**: 900 ml of 0.5 per cent w/v solution of *sodium lauryl sulphate*, adjusted to pH 6.8 with *0.01M hydrochloric acid* or *0.01 M sodium hydroxide*.

to: 900 ml of a buffer solution prepared by dissolving 6.8 g *sodium dihydrogen orthophosphate* in 1000 ml of *water* and mix. Adjust the pH to 6.8 with 10 per cent w/v solution of *sodium hydroxide*. To this solution add 5 g of *sodium lauryl sulphate*.

Clarithromycin Tablets. Page1645

Related substances.

Reference solution (c). lines 2 and 3

Change **from**: *3″-N-demethy1-6-O-methylerythromycin A RS (clarithromycin impurity A RS)*

to: *3″-N-demethy1-6-O-methylerythromycin A RS (clarithromycin impurity D RS)*

Clomifene Citrate.Page1664

Identification Para 1

Change **to**: *Tests B and C may be omitted if test A is carried out. Test A may be omitted if tests B and C are carried out.*

Cyclobenzaprine Hydrochloride.Page 1715

Assay. Under chromatographic system

- mobile phase:

Change **from**: dissolve 2.0 g of *ammonium acetate* in 350 ml of *water* and adjusted to pH 8.9 with 25 per cent w/v solution of *ammonium hydroxide,*

to: a mixture of 65 volumes of *methanol* and 35 volumes of a buffer solution prepared by dissolving 2.0 g of *ammonium acetate* in 1000 ml of *water* and adjusted to pH 8.9 with 25 per cent w/v solution of *ammonium hydroxide,*

Cyproheptadine Hydrochloride. Page 1729

Para 2, line 3

Change **from**: calculated on the dried basis.

to: calculated on anhydrous basis.

Dexamethasone. Page 1777

Identification. Para 1

Change **from**: Test A may be *om3mes* of *chloroform* and 1 volume of *methanol*.

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

Insert the following before *Test solution*.

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *dexamethasone RS* or with the reference spectrum of dexamethasone.

B. Determine by thin-layer chromatography (2.4.17), coating the plate with a suitable silica gel containing a fluorescent indicator with an optimal intensity at about 254 nm.

Solvent mixture. A mixture of 9 volumes of *chloroform* and 1 volume of *methanol*.

Mobile phase. A mixture of 85 volumes of *ether*, 10 volumes of *toluene* and 5 volumes of *1-butanol* saturated with *water*.

Diclofenac Diethylamine. Page 1805

Loss on drying (2.4.19).

Change **from**: Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105°.

to: Not more than 0.5 per cent, determined on 1.0 g by drying at a pressure not exceeding 1 kpa for 24 hours.

Dicloxacillin Sodium. Page 1812

Identification, Para 1.

Change **to:** *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.*

Diphenoxylate Hydrochloride and Atropine Sulphate Tablets. Page 1852

Assay. Under chromatographic system

- mobile phase:

Change **from**: a mixture of 66 volumes of a buffer solution A and 34 volumes of buffer solution B.

to: a mixture of 34 volumes of buffer solution A and 66 volumes of buffer solution B.

Enalapril Maleate and Hydrochlorothiazide Tablets. Page 1941

Related substances. *Buffer solution*. Line 1

Change **from**: 136 g

to: 136 mg

Assay. *For Hydrochlorothiazide-*

Buffer solution. Line 1

Change **from**: 136 g

to: 136 mg

Ethyl Vanillin. Page 2006

Assay. Line 1

Change **from**: Dissolve 0.3 g, previously dried in 50 ml of….

to: Dissolve 0.3 g, in 50 ml of….

Etophylline and Theophylline Prolonged-release Tablets. Page 2017

Assay. Under Chromatographic system

– mobile phase:

Change **from**: a mixture of 70 volumes of *acetonitrile* and 30 volumes of buffer solution prepared by dissolving 2.72 g of *sodium acetate dihydrate* in 200 ml of *water*, add 10 ml of *glacial acetic acid* and dilute to 2000 ml with *water*,

to: a mixture of 10 volumes of *acetonitrile* and 90 volumes of a buffer solution prepared by dissolving 2.72 g of *sodium acetate trihydrate* in 200 ml of *water*, add 10 ml of *glacial acetic acid* and dilute to 2000 ml with *water*,

Gabapentin. Page 2145

Solubility. Delete the requirement.

Glibenclamide and Metformin Tablets. Page 2172

Related substances. *For Glibenclamide-*

Last para, lines 10 and 11

Change **from**: reference solution (b) (0.5 per cent).

to: reference solution (b) (0.5 per cent) excluding peak due to glibenclamide related compound A.

Lactulose.Page 2372

Appearance of solution. Line 2.

Change **from**: BY_5

to: BYS_5

Latanoprost and Timolol Ophthalmic Solution. Page 2398

Related substances, *For Timolol -*

After chromatographic system,

Para 3, Insert at the end,

Ignore the peak due to maleic acid at relative retention time of about 0.22.

Assay. *For Timolol*- Under chromatographic system
- mobile phase:

Line 4
Change **from**: *0.05 M orthophosphoric acid*
to: *orthophosphoric acid*

Letrozole. Page 2403

Related substances. Last para, line 11
Insert the following before ignore any peak……..
The sum of the areas of all the secondary peak is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (0.5 per cent).

Levonorgestrel and Ethinyloestradiol Tablets. Page 2429

Uniformity of Content, Delete the requirements.
Reference solution (a) and Reference solution (b)

Assay, after chromatographic system.
Para 1, line 1
Change **from**: reference solution
to: reference solution (c)

Para 2, line 1
Change **from**: reference solution
to: reference solution (c)

Lopinavir and Ritonavir Tablets. Page 2459

Related substances.
For Lopinavir. Under Chromatographic system, line 2
Change **from**: (5 mm)
to: (5µm)

For Ritonavir. Under Chromatographic system, line 3
Change **from**: (3 mm)
to: (3 µm)

Assay. Under chromatographic system, line 2
Change **from**: (5 mm)
to: (5µm)

Lorcaserin Hydrochloride Hemihydrate. Page 2464

Chloride content. Line 1
Add the following after title.
Between 14.5 to 17.5 per cent on anhydrous basis.

Magaldrate and Simethicone Oral Suspension. Page 2483

Magnesium Hydroxide. Para 2, line 2
Change **from**: *0.01M hydrochloric acid*
to: *dilute hydrochloric acid* (1 in 10)

Memantine Hydrochloride Page 2520

Related substances.
Reference solution (a). Line 1
Change **from**: 0.25 per cent w/v

to: 0.025 per cent w/v

Reference solution (b). Line 2
Change **from**: 0.050 g
to: 0.5 g

Reference solution (c). Line 2
Change **from**: 100.0 ml
to: 10.0 ml

Reference solution (d). Lines 1 & 2
Change **from**: Dilute 1.0 ml of reference solution (b) to 100 ml with *n-hexane*.
to: Dilute 1.0 ml of reference solution (b) to 10.0 ml with *n-hexane*. Further dilute 1.0 ml of this solution and 10.0 ml of reference solution (a) to 100.0 ml with *n-hexane*.

Mesalazine Prolonged-release Tablets. Page 2538

Impurity K. under chromatographic system, after line 3
Insert the following
- column temperature: 40°,

Metadoxine. Page 2543

Related substances. Last para, insert at the end.
Ignore the peak due to pyroglutamic acid at the relative retention time of about 0.24.

Metformin Hydrochloride Prolonged-release Tablets. Page 2546

Assay. Lines 3 & 4.
Change **from**: with 70 ml of *water* for 15 minutes, dilute to 100 ml with *water* and filter.
to: with 70 ml of *water* until complete dispersion, dilute to 100 ml with *water* and filter.

Methylcobalamin.Page 2561

Assay. Under chromatographic system.
Insert the following after line 2.
- Column temperature 40°,

Methylprednisolone Acetate. Page 2575

Related substances. Last para, lines 4 to 6
Change **from**: ……, the sum of the areas of all the secondary peaks is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent).
to: ……, the sum of areas of all the secondary peaks is not more than 0.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.0 per cent).

Metoclopramide Syrup. Page 2580

Related substances.
Reference solution. Line 1
Change **from**:100.0 ml
to: 200.0 ml

Metoprolol Succinate Prolonged-release and Amlodipine Tablets. Page 2585

Related substances. Last para, lines 7 and 14.
Change **from**: amlodipine
to: metoprolol
Change **from**: peak in the chromatogram…
to: peak of metoprolol in the chromatogram….

Metronidazole Injection. Page 2595

Related substances. After chromatographic system, para 1

Change **from**: Inject reference solution (b). Adjust the sensitivity so that the height of the peak due to *2- methyl-5-nitroimidazole* is about 50 per cent of full scale deflection. Measure the height (a) of the peak due to *2-methyl-5-nitroimidazole* and the height (b) of the lowest part of the curve separating this peak from the principal peak. The test is not valid unless *a* is not more than 10b.

to: Inject reference solution (b). The test is not valid unless the resolution between the peak due to metronidazole and *2-methyl-5-nitroimidazole* is not less than 2.

Metronidazole Sterile Suspension. Page 2597

Related substances. After chromatographic system, para 1

Change **from**: Inject reference solution (b). Adjust the sensitivity so that the height of the peak due to *2- methyl-5-nitroimidazole* is about 50 per cent of full scale deflection. Measure the height (a) of the peak due to *2-methyl-5-nitroimidazole* and the height (b) of the lowest part of the curve separating this peak from the principal peak. The test is not valid unless a is not more than 10 times b.

to: Inject reference solution (b). The test is not valid unless the resolution between the peak due to metronidazole and *2-methyl-5-nitroimidazole* is not less than 2.

Metronidazole Tablets. Page 2598

Related substances. After chromatographic system, para 1

Change **from**: Inject reference solution (b). Adjust the sensitivity so that the height of the peak due to *2- methyl-5-nitroimidazole* is about 50 per cent of full scale deflection. Measure the height (a) of the peak due to *2-methyl-5-nitroimidazole* and the height (b) of the lowest part of the curve separating this peak from the principal peak. The test is not valid unless a is not more than 10 times b.

to: Inject reference solution (b). The test is not valid unless the resolution between the peak due to metronidazole and *2-methyl-5-nitroimidazole* is not less than 2.

Montelukast Sodium and Levocetirizine Hydrochloride Tablets. Page 2633

Uniformity of content. Para 1

Change **from**: Determine by liquid chromatography (2.4.14), using the chromatographic system as described under Assay.

to: Determine by liquid chromatography (2.4.14), using the chromatographic system, reference solution (c) as described under Assay.

Reference solution. Delete the requirements.

Mycophenolate Mofetil Capsules. Page 2654

Identification B. Line 2

Change **from**: 0.05 per cent w/v solution

to: 0.0025 per cent w/v solution

Mycophenolate Mofetil Tablets. Page 2656

Related substances. After Chromatographic system, line 4

Change **from**:

Name	Relative retention time	Correction factor
Any single unspecified impurity	1.0	---

to:

Name	Relative retention time	Correction factor
Any single unspecified impurity	---	1.0

Naloxone Hydrochloride. Page 2686

Related substances. After chromatographic system, para 3, line 6

Insert the following after (0.2 per cent).
Multiply the area of the peak corresponding to naloxone impurity E with correction factor 0.5.

Nicotinamide. Page 2724

Identification. Para 1

Change **to**: *Test A may be omitted if tests B and C are carried out. Tests B and C may be omitted if test A is carried out.*
D. Delete the requirements.

Nicotinamide Tablets. Page 2725

Identification. After Para 1

Insert the following.
Test A may be omitted if tests B and C are carried out. Tests B and C may be omitted if test A is carried out.
C. Delete the requirement.
Change **from**: D
to: C

Nicotinic Acid. Page 2726

Identification Para 1

Change **to**: *Test A may be omitted if tests B and C are carried out. Tests B and C may be omitted if test A is carried out.*
D. Delete the requirements.

Nicotinic Acid Tablets. Page 2727

Identification B. Delete the requirements.
Change **from**: C
to: B

Norfloxacin. Page 2748

Dose.
Change **from**: g
to: mg

Ofloxacin and Ornidazole Tablets. Page 2770

Storage.

Change **from**: Store at a temperature not exceeding 30^{O}, protected from moisture.
to: Store protected from light and moisture.

Olmesartan Medoxomil and Hydrochlorothiazide Tablets. Page 2777

Related substances, *For Olmesartan Medoxomil-*
Line 9
Change **from**: olmesartan
to: olmesartan impurity A

Omeprazole and Domperidone Capsules. Page 2785

Dissolution (2.5.2).

Omeprazole-

A. line 7
Change **from**: 340 nm (2.4.7)
to: 308 nm (2.4.7)

Oxaliplatin. Page 2807

Related substances. B. Under Chromatographic system.

- a gradient programme using the condition given below. Delete the requirement.

After Chromatographic system
Change **from**:

Name	Relative retention time	Correction factor
oxaliplatin related compound C[1]	0.8	---
oxaliplatin	1.0	---
(*SP*-4-2)-Diaqua[(1R,2R)-cyclohexane-1,2-diamine-*N,N'*] platinum	2.7	0.4
Diaquodiaminocyclohexaneplatinum dimer	6.0	---

to:

Name	Relative retention time	Correction factor
oxaliplatin related compound C[1]	0.8	---
oxaliplatin	1.0	---
(*SP*-4-2)-Diaqua[(1R,2R)-cyclohexane-1,2-diamine-*N,N'*] platinum	2.7	---
Diaquodiaminocyclohexaneplatinum dimer	6.0	0.4

C. Line 1
Change **from**: *Oxaliplatin Related Compound C*
to: *Oxaliplatin Related Compound D*

Oxaliplatin Injection.Page 2810

Assay. Under chromatographic system
- mobile phase:

Change **from**: 30 volumes of *acetonitrile*, and 70 volumes of *acidified water,*
to: 1 volume of *acetonitrile* and 99 volumes of *acidified water,*

Paliperidone. Page 2845

Related substances.
Reference solution (a). Line 1
Change **from**: 0.5 per cent
to: 0.05 per cent

Pantoprazole Gastro-resistant and Domperidone Prolonged–release Capsules. Page 2850

Synonym.
Change **from**: Pantoprazole Sodium Gastro-resistant and Domperidone Maleate Prolonged–release Capsules
to: Pantoprazole Sodium Gastro-resistant and Domperidone Prolonged–release Capsules

Para 2
Change **from**: Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of pantoprazole, $C_{16}H_{15}F_2N_3O_4S$ and of domperidone, $C_{22}H_{24}ClN_5O_2$.

to: Pantoprazole Gastro-resistant and Domperidone Prolonged-release Capsules contains an amount of pantoprazole sodium equivalent to pantoprazole and domperidone not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of pantoprazole, $C_{16}H_{15}F_2N_3O_4S$ and of domperidone, $C_{22}H_{24}ClN_5O_2$.

Related substances. *Solvent mixture*.
Change **from**: A mixture of equal volume of *1 M sodium hydroxide* and *acetonitrile*.
to: A mixture of equal volume of *0.001M sodium hydroxide* and *acetonitrile.*

Reference solution. Line 2
Change **from**: *pantoprazole RS*
to: *pantoprazole sodium RS*

After chromatographic conditions. Para 2, line 3
Change **from**: twice
to: five times
Line 5
Change **from**: (0.2 per cent),
to: (0.5 per cent),

Paracetamol and Caffeine Tablets. Page 2858

Related substances. Determine by liquid chromatography (2.4.14).
After chromatographic system
Para 2 line 8
Change **from**: (0.0001 per cent).
to: (0.001 per cent).

Pheniramine Maleate. Page 2896

Identification C. Delete the requirement.

Pheniramine Tablets. Page 2898

Identification C. Delete the requirement.

Phenylephrine Hydrochloride and Chlorpheniramine Maleate Drops. Page 2912

Assay, *Test solution*.
Change **to**: Transfer a volume of oral drops containing 25 mg of Phenylephrine Hydrochloride to a 250-ml volumetric flask and dilute to volume with the mobile phase and filter.

Pralidoxime Chloride. Page 2972

Identification B. Line 4
Change **from**: 332 nm.
to: 336 nm.

Pralidoxime Chloride Injection. Page 2972

Identification B. Line 4
Change **from**: 332 nm.
to: 336 nm.

Procarbazine Hydrochloride Capsules. Page 3004

Assay.
Under Chromatographic system, mobile phase:
Change **to**: mobile phase: a mixture of 14 volumes of *acetonitrile*, 14 volumes of *methanol* and 72 volumes of buffer solution prepared by dissolving 2.0 g of *sodium hexanesulphonate* and 4 ml of *triethylamine* in 1000 ml of *water*, adjusted to pH 3.5 with *orthophosphoric acid.*

Progesterone Injectable Suspension. Page 3010

Assay. *Reference solution*, line 3
Change **from**: 2.0 ml
to: 5.0 ml

Racecadotril Capsules. Page 3083

Related substances, under chromatographic system.
Change **from**:-spectrophotometer set at 254 nm,
to: spectrophotometer set at 231 nm,

Racecadotril Sachet. Page 3084

Related Substances, under chromatographic system.

Change **from**: spectrophotometer set at 254 nm,

to: spectrophotometer set at 231 nm,

Rosuvastatin Calcium and Ezetimibe Tablets. Page 3143

Dissolution (2.5.2). Line 1

Change **from**: Apparatus No. 2

to: Apparatus No. 1

Reference solution, line 2

Change **from**: *rosuvastatin calcium RS*

to: *rosuvastatin calcium RS* and *ezetimibe RS*

Sodium Ascorbate. Page 3206

Loss on drying (2.4.19).

Change **from**: Not more than 0.25 per cent, determined on 1.0 g by drying over *phosphorus pentoxide* at a pressure not exceeding 0.7 kPa for 24 hours.

to: Not more than 0.25 per cent, determined on 1.0 g by drying in an oven at 105°.

Sodium Valproate Injection. Page 3239

Assay. After chromatographic system, para 2, line 1

Change **from**: reference solution (a)

to: reference solution (b)

Sorafenib Tosylate. Page 3242

Related substances.

Under Chromatographic system, line 2

Change **from**: porous silica (3 µm) (Such as YMC Basic),

to: octadecylsilane bonded to porous silica (3 µm) (Such as YMC Basic),

Sorafenib Tablets. Page 3244

Related substances.

Under Chromatographic system, line 2

Change **from**: porous silica (3 µm) (Such as YMC Basic),

to: octadecylsilane bonded to porous silica (3 µm) (Such as YMC Basic),

Assay.

Under Chromatographic system, line 2

Change **from**: porous silica (3 µm) (Such as YMC Basic),

to: octadecylsilane bonded to porous silica (3 µm) (Such as YMC Basic),

Line 4

Change **from**: 53 volumes

to: 530 volumes

Sucralfate. Page 3270

Assay. Under chromatographic system, lines 1& 2

Change **from**: a stainless steel column 30 cm x 3.9 mm, packed with octylsilane bonded to porous silica (5µm),

to: a stainless steel column 30 cm x 3.9 mm, packed with aminopropylsilane chemically bounded to totally porous silica (5µm),

Sucralfate Tablets. Page 3272

Assay. Under chromatographic system, lines 1 & 2

Change **from**: a stainless steel column 30 cm x 3.9 mm, packed with octylsilane bonded to porous silica (5µm),

to: a stainless steel column 30 cm x 3.9 mm, packed with aminopropylsilane chemically bounded to totally porous silica (5µm),

Tamsulosin Hydrochloride Prolonged-release and Dutasteride Capsules. Page 3309

Related substances.

For Dutasteride dihydro impurity-

Under Chromatographic system, lines 1 & 2.

Change **to**: a stainless steel column 25 cm x 4.6 mm, packed with porous silica (5 µm) (Such as kromasil 100 silica),

Terbinafine Hydrochloride. Page 3335

Related substances. Under Chromatographic system, line 2

Change **from**: (5 mm)

to: (5µm)

Terbutaline Sulphate. Page 3339

Assay. Para 2, line 1

Change **from**: 0.05486 g

to: 0.05487 g

Verapamil Tablets. Page 3489

Dissolution. Para 1, lines 3 and 4.

Change **from**: Measure the absorbance of the resulting solution at the maximum at about 278 nm (2.4.7).

to: Measure the absorbance of the resulting solution at the maximum at about 278 nm and 300 nm (2.4.7).

Zoledronic Acid Injection. Page 3548

Usual Strength.

Change **from**: 4 mg per ml.

to: 4 mg per vial.

VACCINES AND IMMUNOSERA FOR HUMAN USE

Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed). Page No. 3666

FINAL LOT

Total saccharide content.

Change **from:** The total saccharide protein content of the final vaccine should be determined by means of an appropriate validated assay and comply with limits for the particular product.

to: The total saccharide content of the final vaccine should be determined by means of an appropriate validated assay and comply with limits for the particular product.

Typhoid Vi Conjugate Vaccine. Page 3708

FINAL LOT

O-Acetyl content (2.7.1). Line 1

Change **from:** 0.085 (± 25 per cent) µmol per dose.

to: 0.0034 (± 25 per cent) µmole per µg of polysaccharide [0.085 (± 25 per cent) µmole per dose for vaccine having label claim of 25 µg of polysaccharide per dose and 0.017 (± 25 per cent) µmole per dose for vaccine having 5 µg of polysaccharide per dose].

BIOTECHNOLOGY DERIVED THERAPEUTIC PRODUCTS

Filgrastim Injection. Page 3981

Identification.

B. Determine by Size-exclusion chromatography (2.4.16).

Change **from:** In the test for impurities of molecular masses higher than that of filgrastim, the retention time, of the principal peak obtained with the test solution is similar to that of the principal peak obtained with the reference solution.

to: In the test for dimers and related substances of higher molecular mass, the retention time of the principal peak obtained with the test solution is similar to that of the principal peak obtained with the reference solution.

C. Determine by Polyacrylamide gel electrophoresis under both reducing and non-reducing conditions (2.4.12).

Change **from:** In the test for dimers and related substances of higher molecular mass, the retention time of the principal peak obtained with the test solution is similar to that of the principal peak obtained with the reference solution.

to: In the test for impurities with molecular masses differing from that of filgrastim under both reducing and non-reducing conditions, the principal band in the electropherogram obtained with test solution (a) is similar in position to the principal band in the electropherogram obtained with reference solution (b).

VETERINARY DRUG MONOGRAPHS

Veterinary Vaccines: General Requirements, Page 4170

Bacterial Seed Lots, Propagation, Line 5

Change **from** : titre
to : cfu

Test for purity for the live bacterial vaccines, Lines 5 to 8

Delete the following.

Other tests include examination for motility of the organisms, fermentation reactions and agglutination test and dye-inhibitor tests in case of Brucella vaccine.

Viral Vaccine

General standards. d)

Change **form** : d) Purity tests for living bacterial vaccine
to : d) Virus titre

Buparvaquone. Page 4199, Para 2

Change **from** : Buparvaquone contains not less than 90.0 per cent and not more than 110 per cent of stated amount.
to : Buparvaquone contains not less than 98.0 per cent and not more than 101.0 per cent of the stated amount.

Related substances. Para 1

Change **from** : Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel G.*
to : Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel GF 254.*

Buparvaquone Injection. Page 4200, Para 1

Change **from** : Buparvaquone injection is a sterile solution of Buparvaquone in Water for Injection and contains suitable pharmaceutical aids.
to : Buparvaquone injection is a sterile solution of Buparvaquone in ethyl oleate or other suitable ester, in a suitable fixed oil or in a mixture of these.

Assay. *Test solution*

Change **from** : Dilute a volume of the injection approximately 0.4 ml Buparvaquone injection to a 100.0 ml with *methanol*. Dilute 10 ml of this solution with *methanol* to100.0 ml.

to : Dilute a volume containing 0.05 g of Buparvaquone to 250.0 ml with *methanol*. Dilute 10.0 ml of this solution with *methanol* to 100.0 ml.

VETERINARY BIOLOGICAL MONOGRAPHS

Blackquarter Vaccine. Page 4314

Manufacturer's tests

Safety and Potency. Para 1, Line 9

Change **from** : 20 viable spores of virulent *C. chauvoei* in …….
to : 20 viable spores or virulent culture of *C. chauvoei* in ……..

Batch tests

Description.

Change **from** : Yellowish-brown liquid containing dead bacteria in suspension.
to : An off-white to yellowish-brown liquid containing dead bacteria in suspension.

Brucella Abortus (Strain 19 Vaccine) Vaccine, Live. Page 4317

Change title **to** : **Brucella Abortus (Strain 19) Vaccine, Live**

Change **from** : Contagious Abortion (Strain 19 Vaccine) Live; Contagious Bovine Vaccine (Strain 19) Live
to : Contagious Abortion (Strain 19) Vaccine, Live; Contagious Brucella Vaccine (Strain 19) Live

Para 1, line 1

Change **from** : Brucella Abortus (Strain 19 Vaccine), Vaccine Live is a…….
to : Brucella Abortus (Strain 19) Vaccine, Live is a ……

Expiry.

Change **from** : Not more than five weeks from the date of manufacture.
to : Not more than 5 weeks from the date of manufacture for liquid vaccine.

Canine Coronavirus Vaccine, Inactivated. Page 4319

Batch tests, Identification, Line 3

Change **from** : molecular techniques…….

to : validated molecular techniques…….

Canine Parvovirus Vaccine, Inactivated. Page 4324

Batch tests, Identification, Line 3

Change **from** : molecular techniques…….

to : validated molecular techniques…….

Classical Swine Fever Vaccine, Live. Page 4327

Tests

Test for extraneous pathogens.

Add the following after title. Use method A or B.
Para 1. Add A. before Para 1
Para 2. Add B. before Para 2

Labelling. Point 1

Change **from** : the minimum dose (PD_{50} or $TCID_{50}$)
to : the minimum dose (PD_{50} or $TCID_{50}$)

Enterotoxaemia Vaccine, Inactivated. Page 4333

Manufacturer's tests

Safety and potency. Para 1, Line 3
Change **from** : 5 ml
to : 10 ml

Para 1, Line 8
Change **from** : 5 ml
to : 10 ml

Para 2, Lines 1 and 2

Change **from** : pooled sheep serum
to : pooled serum

Batch tests

Description.

Change **from** : Yellowish-brown liquid containing dead bacteria in suspension.
to : An off-white yellowish-brown liquid containing dead bacteria in suspension.

Infectious Canine Hepatitis Vaccine, Inactivated. Page 4345

Batch tests, Identification, Line 3

Change **from** : molecular techniques…….

to : validated molecular techniques…….

Peste Des Petits Ruminants Vaccine, Live. Page 4349

Tests

Potency. Page 4349, Line 4

Change **from** : Vaccinate two goats and two sheep subcutaneously with 1/10 dose each.
to : Vaccinate two goat and two sheep subcutaneously with 1/10 dose each and two goat and two sheep subcutaneously with one dose of the vaccine.

Sheep Pox Vaccine, Live Attenuated. Page 4356

Master seed lot, Virus titre.

Change **from** : Not less than $10^{2.5}$ $TCID_{50}$ of the virus per dose, determining the titer of the vaccine in a suitable cell culture using suitable medium**.**
to : Not less than 10^{3} $TCID_{50}$ of the virus titer per dose, determining the titer of the vaccine in a suitable cell culture using suitable medium