

# भारतीय भेषज संहिता आयोग

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



## INDIAN PHARMACOPOEIA COMMISSION

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

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सचिव-सह-वैज्ञानिक निदेशक

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

To,

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

### Subject: Errata 01 to IP 2026

The 10<sup>th</sup> Edition of Indian Pharmacopoeia (IP) 2026 shall become effective from 1<sup>st</sup> July, 2026. Based on the scientific inputs, some monographs of the IP 2026 need minor corrections for their effective implementation. Accordingly, Errata 01 to IP 2026 is being issued containing such corrections.

All concerned are requested to bring it to the notice of all authorities under their control for compliance with the IP 2026.

  
(Dr. V. Kalaiselvan)

Encl. Errata 01 to IP 2026

INDIAN PHARMACOPOEIA  
(IP)

Official Book of Drug Standards  
in India

IP REFERENCE SUBSTANCES  
(IPRS) AND IMPURITIES

Official Physical Standards for  
Assessing the Quality of Drugs

NATIONAL FORMULARY OF INDIA  
(NFI)

Reference Book to Promote Rational  
Use of Generic Medicines

PHARMACOVIGILANCE PROGRAMME OF INDIA  
(PvPI)



WHO Collaborating Centre for Pharmacovigilance  
in Public Health Programmes and Regulatory

**2.1.7. Balances used in Analytical Procedures.**

Page 25

**Repeatability. Equation 4**

Change from:  $M_{\min} = 200 \times s$   
 to:  $M_{\min} = 2000 \times s$

**2.4.35. Bulk Density of Powders. Page 352**

Page 354

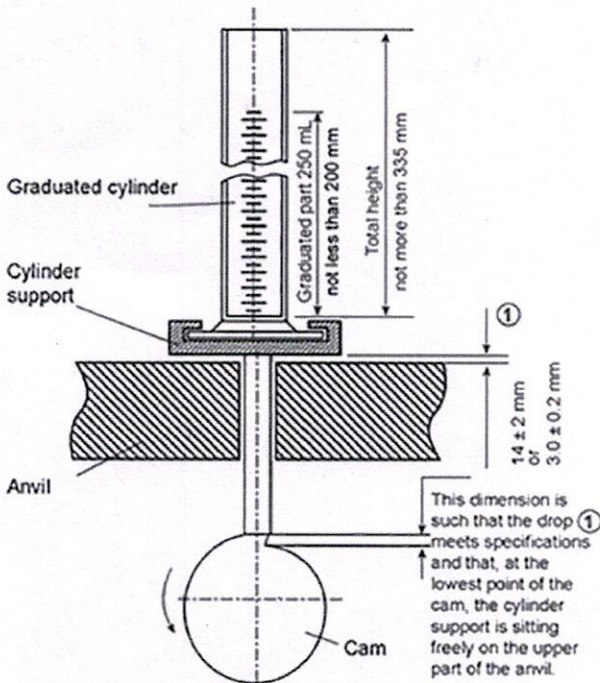
**Tapped Bulk Density**

Change from: **Method I – Measurement in a Graduated Cylinder**

to: **Method I – Measurement in a Graduated Cylinder - High Drop**

Fig. 2.4.35-3

Change to:



Page 355

Change from: **Method II – Measurement in a Volumeter**

to: **Method II – Measurement in a Graduated Cylinder - Low Drop**

**Measures of Powder Compressibility. Compressibility Index:**

Change from:

where,  $V_0$  = untapped bulk,  
 $V_f$  = final tapped bulk.

to:

where,  $V_0$  = untapped bulk volume,  
 $V_f$  = final tapped bulk volume.

**2.4.50. Chromatographic Separation Techniques. Page 386**

Page 386

**Dwell Volume (D) (also referred to as  $V_D$ ).** Line 19

Change from: (Fig. 2.4.50-1)

to: (Fig. 2.4.50-2)

Page 387

Figure 2.4.50-1

Insert after  $h/2$

$t_M$  = hold up time.

Page 388

**Relative retention, unadjusted ( $r_G$ ) ♦or (RRT)♦**

Change from:  $r_C = \frac{t_{Ri}}{t_{Rst}}$

to:  $r_G = \frac{t_{Ri}}{t_{Rst}}$

Page 389

**Resolution ( $R_s$ ). Equation 1**

Change from:  $R_S = \frac{1.18 (t_{R2} - t_{R1})}{(w_{h1} - w_{h2})}$

to:

$$R_S = \frac{1.18 (t_{R2} - t_{R1})}{W_{h1} + W_{h2}}$$

Equation 2

Change from:  $R_S = \frac{1.18a (R_{F2} - R_{F1})}{(w_{h1} - w_{h2})}$

to:

$$R_S = \frac{1.18a (R_{F2} - R_{F1})}{W_{h1} + W_{h2}}$$

**Retention factor (k)**

Change from:

$$k' = \frac{\text{amount of component in stationary phase}}{\text{amount of component in mobile phase}} = K_C \times \frac{V_S}{V_M}$$

to:

$$k = \frac{\text{amount of component in stationary phase}}{\text{amount of component in mobile phase}} = K_C \times \frac{V_S}{V_M}$$

Page 391

**System repeatability.** Equation

Change from:

$$\text{per cent RSD} = \frac{100}{\bar{y}} \sqrt{\frac{\sum (y_i - \bar{y})}{n-1}}$$

to:

$$\text{per cent RSD} = \frac{100}{\bar{y}} \sqrt{\frac{\sum (y_i - \bar{y})^2}{n-1}}$$

Page 392

**System repeatability – assay of an active substance or an excipient.** After para 2, line 3Change from:  $K = \frac{0.6}{\sqrt{2}} \times \frac{t_{90 \text{ per cent}, 5}}{\sqrt{6}}$ 

to:

$$\text{where, } K = \frac{0.6}{\sqrt{2}} \times \frac{t_{90 \text{ per cent}, n-1}}{\sqrt{6}}$$

Page 395

Table 2 – Example of adjustments for liquid chromatography–gradient elution, line 4

Change from:  $L/dp12$ to:  $L/dp$ 

Page 395

**Column Parameters and flow rate.** Line before *Column temperature*

Change from: The example below illustrates this process.

to: Table – 2 illustrates the process.

**2.5.13. Particle Size Analysis by Dynamic Light Scattering.** Page 440

Page 443

**Definition of Terms.** Average particle diameter, line 3

Change from: nanometers.

to: meters.

**4.5. Volumetric Reagents and Solutions**

Page 1286

**Zinc Sulphate, 0.02 M,** Line 1

Change from: 4.88 g

to: 5.76 g

**Parenteral Preparations.** Page 1476**Injections. Single-dose containers**

Change to: **Single-dose containers.** Select 1 container if the nominal volume is 10 ml or more, 3 containers if the nominal volume is more than 3 ml and less than 10 ml, or 5 containers if the nominal volume is 3 ml or less. Take up individually the total contents of each container selected into a dry syringe of a capacity not exceeding 3 times the volume to be measured, and fitted with a 21-gauge needle not less than 2.5 cm in length. Expel any air bubbles from the syringe and needle, then discharge the contents of the syringe without emptying the needle into a standardised dry cylinder (graduated to contain rather than to deliver the designated volumes) of such size that the volume to be measured occupies at least 40 per cent of its graduated volume. Alternatively, the volume of the contents in millilitres may be calculated as the mass in grams divided by the density. For containers with a nominal volume of 2 ml or less, the contents of a sufficient number of containers may be pooled to obtain the volume required for the measurement provided that a separate, dry syringe assembly is used for each container. The contents of containers holding 10 ml or more may be determined by opening them and emptying the contents directly into the graduated cylinder or tared beaker.

The volume is not less than the nominal volume in case of containers examined individually, or, in case of containers with a nominal volume of 2 ml or less, is not less than the sum of the nominal volumes of the containers taken collectively.

**Acetylcysteine Injection.** Page 1519**Related substances.** RRT table

Insert after line 3

Acetylcysteine impurity C<sup>3</sup> 2.2

Insert at the end

<sup>3</sup>,3'-disulphanediybis[(2*R*)-2-acetamidopropanoic acid] (*N,N'*-diacetyl-*L*-cystine).

**Amlodipine and Olmesartan Medoxomil Tablets.** Page 1616**Related substances.** After RRT Table, para 4, line 3

Change from: Unspecified Amlodipine impurity D

$$= \frac{At_2}{As_2} \times \frac{Cs_2}{Ct_2} \times \frac{Mb_1}{Mb_2} \times 100$$

to: Any unspecified amlodipine related impurity

$$= \frac{At_2}{As_2} \times \frac{Cs_2}{Ct_2} \times \frac{Mb_1}{Mb_2} \times 100$$

Line 8 and 9

Change **from**:  $Cs_2$  = concentration of amlodipine besylate IPRS in reference solution (d) (mg/ml),

**to**:  $Cs_2$  = concentration of amlodipine besylate IPRS in reference solution (f) (mg/ml),

### Barium Sulphate for Suspension. Page 1761

#### Other tests

Change **from**: Oral Liquids.

**to**: Oral Powders.

### Beclomethasone Dipropionate. Page 1762

**Related substances.** *Reference solution (a)*, line 2 and 3

Change **from**: 2.8 ml of mobile phase A and dilute to 10.0 ml with mobile phase B.

**to**: 5.6 ml of mobile phase B and dilute to 10.0 ml with mobile phase A.

### Benazepril Hydrochloride Tablets. Page 1770

**Assay.** Chromatographic system, insert before line 5

– flow rate: 1 ml per minute,

### Bendamustine for Injection. Page 1773

**Related substances.** RRT table, line 10

Change **from**: Bendamustine related compound G<sup>7</sup> -- 1.11

**to**: Bendamustine related compound G<sup>7</sup> -- 0.90

### Benzoic Acid Solution. Page 1788

Insert before **Assay**

**Other tests.** Comply with the tests stated under Liquids for Cutaneous Application.

### Benzhexol Tablets. Page 1784

Insert before **Other tests**

**Uniformity of dosage units** (2.5.4). Complies with the test stated under Uniformity of dosage units.

### Compound Benzoin Tincture. Page 1789

Insert before **Assay**

**Other tests.** Comply with the tests stated under Liquids for Cutaneous Application.

### Betamethasone Valerate. Page 1819

#### Identification

Insert after **Identification**

*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.*

C.

Change **to**: C. 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).

#### Assay

After chromatographic system, line 7

Change **from**: the reference solution

**to**: reference solution (a)

### Caffeine. Page 1918

Para 2, line 3 and 4

Change **from**: anhydrous basis

**to**: dried basis

#### Loss on drying

Insert at the end

, determined on 1.0 g by drying in an oven at 80° for 4 hours.

### Calcium Orotate. Page 1932

**pH.** Insert at the end

(NOTE — Dissolve the substance in boiling water, cool to room temperature before pH determination)

**Assay.** Line 9

Change **from**: 0.019315 g

**to**: 0.017515 g

**Dibasic Calcium Phosphate, Anhydrous.**

Page 1933

**Fluorides.** *Reference solution*, line 1 and 2Change **from**: Dissolve 0.1105 g of *sodium fluoride IPRS* in *water*.to: Dissolve 0.1105 g of *sodium fluoride IPRS* in 100.0 ml *water*.**Carboprost Tromethamine Injection.**

Page 1968

**Identification.** Last lineChange **from**: carboprost tromethamine.

to: carboprost.

**Cefadroxil.** Page 1985**Identification**Change **to**: A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *cefadroxil IPRS* or with the reference spectrum of cefadroxil.B. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel H* and impregnating the dry plate by placing it in a tank containing a shallow layer of about 1 cm of a mixture of 95 volumes of *n-hexane* and 5 volumes of *1-tetradecane*, allowing the solvent to ascend to the top, removing the plate and allowing the solvent to evaporate.*Mobile phase.* A mixture of 60 volumes of 0.1 M *citric acid*, 40 volumes of 0.1 M *disodium hydrogen orthophosphate* and 1.5 volumes of 6.66 per cent w/v solution of *ninhydrin* in *acetone*.*Test solution.* A 0.2 per cent w/v solution of the substance under examination in *water*.*Reference solution (a).* A 0.2 per cent w/v solution of *cefadroxil IPRS* in *water*.*Reference solution (b).* A mixture of equal volumes of the test solution and reference solution (a).Apply to the plate 20 µl of each solution. After development, dry the plate in air, spray with a 0.2 per cent w/v solution of *ninhydrin* in *ethanol*, dry at 110° for 10 minutes and examine. The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (a). The principal spot in the chromatogram obtained with reference solution (b) appears as a single compact spot.Insert before **Water****Sulphated ash** (2.3.18). Not more than 0.1 per cent.**Cefpodoxime for Oral Suspension.** Page 2018**Assay.** *Reference solution*Change **to**: *Reference solution.* A solution of *cefpodoxime proxetil IPRS* containing 0.0025 per cent w/v solution of cefpodoxime in the solvent mixture.**Hard Cellulose Capsule Shells.** Page 2045**Disintegration.** Insert at the end*(NOTE — This test is not applicable to the capsules intended to use for inhalation preparations).***Arsenic.** Change **to**:**Arsenic** (2.3.10). Dissolve 3.3 g of capsule shells in 15 ml of *hydrochloric acid* and dilute to 50.0 ml with *carbon dioxide-free water*. The resulting solution complies with the limit test for arsenic (3 ppm) or determined by ICPMS (2.4.42).**Chlordiazepoxide.** Page 2072**Related substances.** *Reference solution (a).* Insert at the end

“Dilute 2.0 ml of the solution to 10.0 ml with the mobile phase.”

**Chlorothiazide Tablets.** Page 2091**Assay.** Change **to**:**Assay.** Determine by liquid chromatography (2.4.14), as described under Related substances with the following modifications.*Test solution.* Weigh and powder 20 Tablets. Disperse a quantity of the powder containing 25 mg of Chlorothiazide in 40 ml of the solvent mixture, with the aid of ultrasound and dilute to 50.0 ml with the solvent mixture, centrifuge. Dilute 2.0 ml of the clear supernatant liquid to 10.0 ml with the solvent mixture.*Reference solution.* A 0.01 per cent w/v solution of *chlorothiazide IPRS* in the solvent mixture.

Inject the reference solution. The test is not valid unless the tailing factor is not more than 2.0 and the relative standard

deviation for replicate injection is not more than 1.0 per cent.  
Inject the reference solution and the test solution.  
Calculate the content of  $C_7H_6ClN_3O_4S_2$  in the tablets.

**Chloroxylenol.** Page 2092

**Assay.** Change to:

**Assay.** Weigh accurately about 70 mg, dissolve in 30 ml of *glacial acetic acid*, add 25.0 ml of 0.0167 M *potassium bromate*, 20 ml of 15 per cent w/v solution of *potassium bromide* and 10 ml of *hydrochloric acid*, stopper the flask and allow to stand protected from light for 15 minutes. Add 1 g of *potassium iodide* and 100 ml of *water* and titrate with 0.1 M *sodium thiosulphate*, shaking vigorously and using 1 ml of *starch solution* as indicator. Repeat the procedure without the substance under examination. The difference between the titrations represents the amount of *potassium bromate* required.

1 ml of 0.0167 M *potassium bromate* is equivalent to 0.003915 g of  $C_8H_9ClO$ .

**Chlorpheniramine Maleate.** Page 2093

**Related substances.** After chromatographic system, para 1, line 5

Change **from:** chlorpheniramine  
**to:** pheniramine

**Cinnarizine.** Page 2120

**Related substances.** *Reference solution (b)*

Insert at the end

Dilute 5.0 ml of the solution to 20.0 ml with *methanol*.

**Cisplatin Injection.** Page 2133

Para 1

Change **from:** Cisplatin Injection is a sterile solution of Cisplatin in water for injections. It is either supplied as a ready-to-use solution or it is prepared by dissolving Cisplatin for Injection in the requisite amount of water for injections immediately before use.

**to:** Cisplatin Injection is a sterile solution of Cisplatin in water for injections.

Para 2

Change **from:** *The injection complies with the requirements stated under Parenteral Preparations.*

**to:** *The injection complies with the requirements stated under Parenteral Preparations (Injections).*

Para 3

Delete the requirement.

**Clobetasol Propionate.** Page 2167

**Specific optical rotation**

Insert at the end

“at 20°”.

**Related substances.** *Reference solution (c)*, line 1 and 2

Change **from:** Dissolve the contents of a vial of *clobetasol impurity J* IPRS

**to:** Dissolve 0.4 mg of *clobetasol impurity J* IPRS

**Cloxacillin for Oral Solution.** Page 2198

Insert before **Assay**

**Other tests.** Comply with the tests stated under Oral Powders.

**Cyproheptadine Hydrochloride.** Page 2254

Para 2

Delete the following requirement.

“Cyproheptadine Hydrochloride contains not less than 98.5 per cent and not more than 101.0 per cent of  $C_{21}H_{21}N, HCl$ , calculated on anhydrous basis.”

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

Change **from:** 0.002 per cent

**to:** 0.0002 per cent

**Dapagliflozin Propanediol Monohydrate.** Page 2287

**Water.** Line 2

Change **from:** 0.1 g.

**to:** 0.5 g.

**Dasatinib.** Page 2303**Related Substances.** After RRT table, IUPAC names

Change to:

<sup>1</sup>2-amino-*N*-(2-chloro-6-methylphenyl)-thiazole-5-carbomide,<sup>2</sup>*N*-(2-chloro-6-methylphenyl)-2-[[6-chloro-2-methyl-4-pyrimidinyl]amino]-5-thiazolecarboxamide.**Dicloxacillin for Oral Suspension.** Page

2377

**Other tests**

Change from: Oral Liquids.

to: Oral Powders.

**Dipivefrine Hydrochloride.** Page 2420**Assay.** Insert after para 1

*Test solution.* Dissolve 50 mg of the substance under examination in the solvent mixture and dilute to 5.0 ml with the solvent mixture. Dilute 1.0 ml of the solution to 100.0 ml with the solvent mixture.

**Docetaxel Anhydrous.** Page 2440**Specific optical rotation.** Insert at the end

“at 20°”.

**Docetaxel Trihydrate.** Page 2441**Specific optical rotation.** Insert at the end

“at 20°”.

**Dutasteride.** Page 2491**Water.** Insert at the end

, using Method 3.

**Eribulin Injection.** Page 2557**Related substances.** After chromatographic system, para 2, line 21 and 22

Change from: and the sum of the areas of all secondary peaks other than eribulin impurity E is not more than

to: and the sum of the areas of all the secondary peaks is not more than

**Ethylcellulose.** Page 2600**Chlorides.** Insert at the endusing 10 ml of *chloride standard solution (5 ppm Cl)*.**Fentanyl Injection.** Page 2654**Related substances.** *Reference solution (a)*, line 1

Change from: 0.125 per cent

to: 0.0000125 per cent

**Ferric Carboxymaltose.** Page 2655**Zeta potential.** Line 1

Change from: Limit not less than +3.0.

to: Limit not less than +3.0 (mV).

**Fexofenadine Hydrochloride.** Page 2663**Chlorides.** Line 1

Insert at the end

, calculated on anhydrous basis.

**Finasteride.** Page 2671**Related substances.** After RRT table, line 2Change from: carboxamide ( $\Delta$ -1,5-aza amide),

to: (dihydrofinasteride),

Line 4

Change from: (dihydrofinasteride).

to: carboxamide ( $\Delta$ 5-finasteride).**Flucloxacillin for Oral Solution.** Page 2679**Other tests**

Change from: Oral Liquids.

to: Oral Powders.

**Fluconazole for Oral Suspension.** Page 2682

**Other tests** before Assay

Delete the requirement

**Fluocinolone Acetonide.** Page 2698

**Related substances.** *Reference solution (a)*, line 1 and 2

Change **from**: *fluocinolone acetonide IPRS*

**to**: the substance under examination

**Frusemide.** Page 2752

**Assay.** After chromatographic system, para 1, line 3

Change **from**: 2.5

**to**: 1.5

**Fulvestrant.** Page 2756

**Enantiomeric purity.** Line 1 and 2

Change **from**: Fulvestrant epimer B is 52.0 to 58.0 per cent and Fulvestrant epimer A is 42.0 to 48.0 per cent.

**to**: Fulvestrant epimer B is 52 to 58 per cent and Fulvestrant epimer A is 42 to 48 per cent.

**Gelatin.** Page 2779

**Peroxides.** Lines 3 to 7

Change **from**: Remove the test strip, shake off excess liquid and compare the reaction zone after 15 seconds with the colour scale provided with the test strips used. The colour must match that of the 10 ppm concentration, otherwise the test is invalid.

**to**: Remove the test strip, shake off excess liquid and after 15 seconds, compare the reaction zone with the colour scale provided. The test strips are suitable if the colour matches that of the 2 ppm concentration.

**Glipizide.** 2805

*B. Limit of Glipizide related compounds A, B and C.*

After Chromatographic system, line 13 and 14

Change **from**: glipizide related compounds A, B and C peaks

**to**: glipizide related compound A and B peaks

**Assay.** Line 15 and 16

Change **from**: glipizide related compounds A, B and C peaks

**to**: glipizide related compound A and B peaks

**Hydrochlorothiazide.** Page 2858

**Assay.** *Test solution*, line 1

Change **from**: *Test solution*.

**to**: *Test solution (a)*.

*Reference solution*, line 1

Change **from**: *Reference solution*.

**to**: *Reference solution (c)*.

After impurity table, line 1

Change **from**: the reference solution

**to**: reference solution (a)

Line 4

Change **from**: Inject the reference solution and the test solution.

**to**: Inject reference solution (c) and test solution (a).

**Hydrocortisone Sodium Succinate for Injection.** Page 2869

**Related substances.** *Reference solution (b)*

Change **to**: *Reference solution (b)*. A 0.035 per cent w/v solution of *hydrocortisone IPRS* in *acetonitrile*. Dilute 5.0 ml of the solution to 10.0 ml with *water*.

**Hydroxyethyl Cellulose.** Page 2877

**Nitrates.** Para 1, line 2 and 5

Change **from**: 100 mPa.s

**to**: 1000 mPa.s

**Hydroxyzine Oral Solution.** Page 2890

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

Change **from**: 1.0 ml

**to**: 2.0 ml

*Reference solution (c)*. Insert at the end

Dilute 5.0 ml of the solution to 10.0 ml with the mobile phase.

### **Hyoscine Butylbromide**. Page 2892

**Related substances.** *Reference solution (a)*, line 2

Change **from**: the mobile phase.

**to**: mobile phase B.

### **Hyoscyamine for Oral Solution**. Page 2901

Para before **Identification**, line 2

Change **from**: *Oral liquids*

**to**: *Oral powders*

### **Isopropyl Alcohol**. Page 2979

**Benzene and related substances.** Insert after chromatographic system, para 1

Inject reference solution (a). The test is not valid unless the resolution between the peak due to 1-propanol and 2-butanol is not less than 10.

### **Melphalan Tablets**. Page 3222

**Assay.** After chromatographic system, para 2 and 3

Change **to**: Calculate the content of  $C_{13}H_{18}Cl_2N_2O_2$  in the tablets.

### **Meropenem for Injection**. Page 3240

Insert before **Bacterial endotoxins**

**Content of Sodium.** 80 per cent to 120 per cent of the labelled amount of sodium.

Weigh a quantity of the injection containing 50 mg of anhydrous meropenem and dissolve in sufficient *water* to produce 100.0 ml. Dilute the resulting solution appropriately with *water* and determine by Method A for flame photometry (2.4.4), measuring at 589 nm or by Method A for atomic absorption spectrophotometry (2.4.2), using *sodium solution FP* or *sodium solution AAS* respectively, suitably diluted with *water* for the reference solutions.

### **Microcrystalline Cellulose**. Page 3323

**Bulk density.** Line 1

Change **from**: **Bulk density**

**to**: **Bulk density of powders**

### **Minocycline Hydrochloride**. Page 3334

**Related substances.** *Buffer solution*, line 2

Change **from**: 0.28 per cent

**to**: 2.8 per cent

### **Minocycline Capsules**. Page 3336

**Related substances.** *Buffer solution*, line 2

Change **from**: 0.28 per cent

**to**: 2.8 per cent

### **Minocycline Tablets**. Page 3338

**Related substances.** *Buffer solution*, line 2

Change **from**: 0.28 per cent

**to**: 2.8 per cent

### **Montelukast Sodium**. Page 3358

**Related substances.** After RRT table, para 2, line 2

Change **from**: montelukast impurity B

**to**: montelukast impurity G

### **Naloxone Hydrochloride**. Page 3426

**Related substances.** Chromatographic system, mobile phase A, line 2

Change **from**: 40 volumes of *tetrahydrofuran*

**to**: 4 volumes of *tetrahydrofuran*

### **Neotame**. Page 3453

**Related substances.** Last para, lines 2 to 6

Change **from**: In the chromatogram obtained with the test solution, the area of peak corresponding to neotame impurity

A is not more than 1.5 times the area of the principal peak in the chromatogram obtained with reference solution (b) (1.5 per cent)

**to:** In the chromatogram obtained with the test solution, the area of peak corresponding to neotame impurity A is not more than the area of the principal peak in the chromatogram obtained with reference solution (b) (1.5 per cent)

### Nifedipine. Page 3471

**Related substances.** After chromatographic system, para 2, lines 1 to 3

**Change from:** The test is not valid unless the resolution between the peaks due to the nitrosophenylpyridine analogue and nifedipine is not less than 1.5,

**to:** The test is not valid unless the resolution between the peaks due to the nitrophenylpyridine analogue and nitrosophenylpyridine analogue is not less than 1.5,

### Nitroglycerin Injection. Page 3487

**Change from:** Nitroglycerin Injection is a sterile solution of Diluted Nitro4 colourless solution.

**to:** Nitroglycerin Injection is a sterile solution of Diluted Nitroglycerin, which may contain alcohol and propylene glycol in Water for Injections.

Nitroglycerin Injection contains not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of nitroglycerin ( $C_3H_5N_3O_9$ ).

**Description.** A clear colourless solution.

### Omeprazole Gastro-resistant Capsules.

Page 3532

**Dissolution.** A

*Test solution:* Last line

**Change from:** mobile phase.

**to:** solvent mixture.

*Reference solution:* Last line

**Change from:** mobile phase.

**to:** solvent mixture.

### Paracetamol. Page 3616

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

**Change from:** 0.0002 per cent

**to:** 0.002 per cent

### Poloxamers. Page 3744

**Ethylene oxide, propylene oxide and dioxan.** *Ethylene oxide stock solution*

**Change to:** *Ethylene oxide stock solution.* A 5 per cent w/v solution of *ethylene oxide* in *dichloromethane*. Dilute 0.5 ml of the solution to 50.0 ml with *dimethyl sulphoxide*.

After chromatographic system, para 1, line 1

**Change from:** 1  $\mu$ l

**to:** 1 ml

### Rosuvastatin Tablets. Page 4000

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

**Change from:** 0.0001 per cent

**to:** 0.1 per cent

### Salbutamol Tablets. Page 4026

**Related substances.** Chromatographic system, line 2

**Change from:** (3  $\mu$ m)

**to:** (5  $\mu$ m)

### Sodium Carbonate. Page 4075

Insert before **Appearance of solution**

*Solution A.* Dissolve 2.0 g in a mixture of 5 ml of *hydrochloric acid* and 25 ml of *water*. Heat the solution to boiling and cool. Add *dilute sodium hydroxide solution* until the solution is neutral and dilute to 50 ml with *water*.

### Stavudine for Oral Solution. Page 4140

Para before **Identification**, line 2

**Change from:** *Oral Liquids*

**to:** *Oral powders*

**Tenofovir Disoproxil Fumarate Tablets.**

Page 4233

**Related substances.** *Reference solution (a)*, line 3Change **from**: the solvent mixture.**to**: mobile phase A.**Tranexamic Acid.** Page 4343**Related substances.** Last para, line 15 and 16Change **form**: the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent)**to**: the area of any other secondary peak is not more than 0.1 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.05 per cent)**Ursodeoxycholic Acid.** Page 4400**Identification.** B, line 1 and 3Change **from**: spot**to**: peak**Vancomycin for Intravenous Infusion.**

Page 4426

**Related substances and vancomycin B.** After Chromatographic system, para 3 line 1Change **from**: Inject the test solution.**to**: Inject the test solution and reference solution (c). In the chromatogram obtained with the test solution, integrate all peaks present with an area more than the area of the principal peak in the chromatogram obtained with reference solution (c) to determine the total peak area.**Vildagliptin and Metformin Prolonged-release Tablets.** Page 4451

Para 2, line 1

Change **from**: capsules**to**: tablets**Related substances***For Metformin Hydrochloride* —*Reference solution (b)*, line 2

Insert at the end

Dilute 1.0 ml of the solution to 10.0 ml with the solvent mixture.

**Xanthan Gum.** Page 4487**Viscosity.** Line 12Change **from**: diameter and .6 mm high**to**: diameter and 1.6 mm high**BIOTECHNOLOGY DERIVED  
THERAPEUTIC PRODUCTS****Trastuzumab Concentrated Solution.**

Page 5204

Para 1 and 2

Change **to**: Trastuzumab Heavy Chain Chimeric

EVQLVESGGGLVQPGGSLRLSCAASGFSNIKDTYIHWVRQAPGKLEWVARIYPTNGYTRY  
 ADSVKGRFTISADTSKNTAYLQMNSLRAEDTAVYYCSRWGGDGFYAMDYWGQGLVTVSS  
 ASTKGPSVFPLAPSSKSTSGGTAALGCLVKDYFPEPVTVSWNSGALTSQVHFFPAVLQSS  
 GLYSLSSVTVPSSSLGTQTYICNVNHKPSNTKVDKVEPKSCDKHTHTCPPCPAPPELLGG  
 PSVFLFPPKPKDTLMISRTPEVTCVVVDVSHEDPEVKFNWYVDGVEVHNAKTKPREEQYN  
 STYRVVSVLTVLHQDWLNGKEYKCKVSNKALPAPIEKTISKAKGQPREPQVYTLPPSREE  
 MTKNQVSLTCLVKGFYPSDIAVEWESNGQPENNYKTPPVLDSDGGSFFLYSKLTVDKSRW  
 QQGNVVFSCSVMEALHNHYTQKLSLSLSPGK

Trastuzumab Light Chain Chimeric

DIQMTQSPSSLSASVGDRTITCRASQDVNTAVAWYQQKPGKAPKLLIYSASFLYSGVPS  
 RFGSGRSGTDFTLTISLQPEDFATYYCQQHYTTPPTFGQGTKVEIKRTVAAPSVFIFPP  
 SDEQLKSGTASVCLLNNFYPREAKVQWKVDNALQSGNSQESVTEQDSKSTYLSLSTLT  
 LSKADYEKHKVYACEVTHQGLSSPVTKSFNRGEC

**VETERINARY PRODUCTS****Ampicillin Injection.** Page 5355Title Change **to**: **Ampicillin for Injection**