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

डा. वी. कलईशेलवण
सचिव-सह-वैज्ञानिक निदेशक

Dr. V. Kalaiselvan
Secretary-cum-Scientific Director

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

Date: June ~~23~~ 25, 2026

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: Amendment List 01 to IP 2026

The 10th Edition of Indian Pharmacopoeia (IP) 2026 shall become effective from 1st July, 2026. Based on the scientific inputs, some monographs of the IP 2026 need revisions/amendments for their effective implementation. Accordingly, Amendment List 01 to IP 2026 is being issued containing such amendments and this shall become effective from July 1, 2026 except for amendments in Dapagliflozin and Metformin Hydrochloride Prolonged-release Tablets and Vildagliptin and Metformin Prolonged-release Tablets for which effective date is mentioned along with the amendments issued.

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. Amendment List 01 to IP 2026

Aciclovir. Page 1521

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b).

Aciclovir Cream. Page 1522

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b).

Aciclovir Dispersible Tablets. Page 1524

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b) (*NOTE — Prepare the solution immediately before use*).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b). *(NOTE — Prepare the solution immediately before use).*

Aciclovir Eye Ointment. Page 1525

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b) (*NOTE — Prepare the solution immediately before use*).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b). *(NOTE — Prepare the solution immediately before use).*

Aciclovir for Intravenous Infusion. Page 1527

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b).

Aciclovir Oral Suspension. Page 1528

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b).

Aciclovir Tablets. Page 1530

Related substances. *Reference solution (d)*

Change **from**: Dissolve the content of a vial of *aciclovir for impurity G identification IPRS* in 1 ml of reference solution (b).

to: Dissolve 0.002 mg of *aciclovir impurity G IPRS* in 1 ml of reference solution (b).

Azilsartan Kamedoxomil. Page 1731

Related substances. After impurity table, para 3, lines 10 to 13

Change **from**: the area of any peak corresponding to azilsartan kamedoxomil impurity B is not more than 0.6 times the area of the principal peak in the chromatogram obtained with reference solution (a) (0.3 per cent),

to: the area of any peak corresponding to azilsartan kamedoxomil impurity B is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent),

Lines 17 to 20

Change **from**: and the sum of the areas of all secondary peaks is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent).

to: and the sum of the areas of all secondary peaks, excluding azilsartan kamedoxomil impurity B is not more than twice the area of the principal peak in the chromatogram obtained with reference solution (a) (1.0 per cent).

Clarithromycin. Page 2144

Related substances. Insert after RRT table

NOTE — Not more than four impurities exceed 0.4 per cent.

Last para, lines 7 to 9

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

to: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) (0.1 per cent) and the peaks eluting before impurity I and after impurity H.

Clarithromycin Tablets. Page 2148

Related substances. Insert after RRT table

NOTE — Not more than four impurities exceed 0.4 per cent.

Dapagliflozin and Metformin Hydrochloride Prolonged-release Tablets. Page 2284 (*effective from 01.12.2026*)

Dissolution. Change **to**:

Dissolution. (2.5.2).

For Dapagliflozin —

Apparatus No. 1 (Basket),
Medium. 1000 ml of phosphate buffer pH 6.8, prepared by dissolving 6.8 g of *potassium dihydrogen orthophosphate* and 0.9 g of *sodium hydroxide* in 1000 ml of *water*, adjusted to pH 6.8 with *dilute orthophosphoric acid* or *dilute sodium hydroxide solution*.
Speed and time. 100 rpm and 20 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Test solution. Use the filtrate, dilute if necessary, with the dissolution medium.

Reference solution. Weight and transfer 25 mg of *dapagliflozin IPRS* to a 100-ml volumetric flask, add 10 ml of *acetonitrile*, sonicate for 5 minutes to dissolve and dilute to volume with the dissolution medium. Dilute 2.0 ml of the solution to 100.0 ml with the dissolution medium.

Chromatographic system
- a stainless steel column 15 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as Kromasil C18),
- column temperature: 30°,
- sample temperature: 25°,
- mobile phase: a mixture of 65 volumes of a buffer solution prepared by dissolving 1.36 g of *potassium dihydrogen orthophosphate* in 1000 ml of *water*, adjusted to pH 2.0 with *dilute orthophosphoric acid* and 35 volumes of *acetonitrile*,
- flow rate: 1.4 ml per minute,
- spectrophotometer set at 225 nm,
- injection volume: 50 µl.

Inject the reference solution. The test is not valid unless the column efficiency is not less than 4000 theoretical plates, the tailing factor is not more than 1.5 and the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{21}H_{25}ClO_6$ in the medium.

Q. Not less than 80 per cent of the stated amount of $C_{21}H_{25}ClO_6$.

For Metformin Hydrochloride — Complies with the test stated under Tablets.

3-O-desacyl-4′-monophosphoryl lipid A. Page 2315

Pyrogens

Insert at the end

NOTE — It is recommended to perform the monocyte-activation test during development of the production process to verify the presence of any non-endotoxin pyrogens; if any changes are made to the production process that could influence the quality of the product with regard to pyrogenicity. It is recommended to repeat the monocyte-activation test.

Dextrose. Page 2355

Identification. A

Change **to**: A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *dextrose IPRS* or with the reference spectrum of dextrose. *(NOTE —Dry the substance under vacuum at 70° for 2 hours for dextrose monohydrate).*

Menthol. Page 3230

Assay. Para 2

Change **to**: Inject the reference solution. The test is not valid unless the tailing factor is not less than 0.5 and not more than 1.0 for the menthol peak and the relative standard deviation for replicate injections is not more than 2 per cent.

Metformin Hydrochloride. Page 3251

Related substances. Last para

Insert at the end

except for the peak corresponding to dicyandiamide.

Nitrofurantoin. Page 3484

Para 2, line 3

Change **from**: anhydrous basis.

to: dried basis.

Water. Change **to**:

Loss on drying (2.4.19). Not more than 1.0 per cent for anhydrous form and 6.5 per cent to 7.5 per cent for hydrous form, determined on 1.0 g by drying in an oven at 140° for 30 minutes.

Phenytoin Tablets. Page 3705

Assay. Chromatographic system, line 4 to 7

Change **to**: – mobile phase: a mixture of 27 volumes of *methanol*, 23 volumes of *acetonitrile*, 50 volumes of *water*, 0.5 volumes of solution A and 0.1 volumes of *glacial acetic acid*,

Pregabalin Capsules. Page 3792

Related substances. After impurity table, para 2, line 3

Change **from**: not less than 13.

to: not less than 10.

Assay. Chromatographic system, line 8 and 9

Change **from**: 5 volumes of *methanol* and 3 volumes of *acetonitrile* and dilute to 1000 ml with *water*,

to: and dilute to 1000 ml with *water*, 5 volumes of *methanol* and 3 volumes of *acetonitrile*,

Vildagliptin and Metformin Prolonged-release Tablets. Page 4451 (*effective from 01.12.2026*)

Dissolution. Change **to**:

Dissolution (2.5.2).

For Vildagliptin —

Apparatus No. 2 (Paddle),

Medium. 900 ml of *0.1 M hydrochloric acid*,

Speed and time. 75 rpm and 45 minutes.

Withdraw a suitable volume of the medium and filter.

Determine by liquid chromatography (2.4.14).

Solvent mixture. 85 volumes of *water* and 15 volumes of *acetonitrile*.

Test solution. Use the filtrate, dilute if necessary, with the dissolution medium.

Reference solution. A 0.055 per cent w/v solution of *vildagliptin IPRS* in the solvent mixture. Dilute 5.0 ml of the filtrate to 50.0 ml with the dissolution medium.

Chromatographic system

- a stainless steel column 15 cm × 4.6 mm, packed with octadecylsilane bonded to porous silica (5 µm) (Such as X bridge C18),
- column temperature: 35°,
- mobile phase: a mixture of 85 volumes of a buffer solution prepared by dissolving 0.25 g of *sodium octanesulphonate* in 1000 ml of *water*, add 2 ml of *triethylamine*, adjusted to pH 3.0 with *orthophosphoric acid* and 15 volumes of *acetonitrile*,
- flow rate: 1 ml per minute,
- spectrophotometer set at 210 nm,
- injection volume: 10 µl.

Inject the reference solution. The test is not valid unless the relative standard deviation for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the content of $C_{17}H_{25}N_3O_2$ in the medium.

Q. Not less than 75 per cent of the stated amount of $C_{17}H_{25}N_3O_2$.

For Metformin Hydrochloride — Complies with the test state under Tablets.

VACCINES AND IMMUNOSERA FOR HUMAN USE

BCG for Immunotherapy. Page 4825

FINAL BULK

Count of viable units

Change **from**: Determine the number of viable units per milliliter on solid medium using a method suitable for the product (Using not less than 5 containers before freeze drying) to be examined or by a suitable biochemical method. Carry out the test in parallel on a reference preparation of the same strain.

to: Determine the number of viable units per milliliter on solid medium using a method suitable for the product to be examined or by a suitable biochemical method. Carry out the test in parallel on a reference preparation of the same strain.

BIOTECHNOLOGY DERIVED THERAPEUTIC PRODUCTS

Follicle Stimulating Hormone. Page 5106

Line 2

Insert before α-subunit

NOTE — This monograph is applicable to Follicle Stimulating Hormone Alfa and Follicle Stimulating Hormone Beta.

Follicle Stimulating Hormone Concentrated Solution. Page 5113

Line 2

Insert before α-subunit

NOTE — This monograph is applicable to Follicle Stimulating Hormone Alfa and Follicle Stimulating Hormone Beta.

Follicle Stimulating Hormone Injection. Page 5121

Insert before para 1

NOTE — This monograph is applicable to Follicle Stimulating Hormone Alfa and Follicle Stimulating Hormone Beta.

Identification. Para 1

Change **from**: *NOTE — Identification B. Determine by Isoelectric focusing (2.4.33) may be omitted if the Follicle Stimulating Hormone injection is prepared from Follicle Stimulating Hormone/Follicle Stimulating Hormone Concentrated Solution complied as per monograph in current edition of IP.*

to: *NOTE — Identification B. Determine by Isoelectric focusing (2.4.33) and Identification D. Immunoblotting. Determine by electrophoresis (Sodium dodecyl sulphate polyacrylamide gel electrophoresis) (SDS-PAGE) followed by immunoblotting (2.4.12) may be omitted if the Follicle Stimulating Hormone injection is prepared from Follicle Stimulating Hormone/ Follicle Stimulating Hormone Concentrated Solution complied as per monograph in current edition of IP.*

Free subunits. Last para, line 2

Change **from**: not more than 3 per cent.

to: not more than 5 per cent.

Interferon Beta-1a Injection. Page 5157

pH

Change **from**: 4.5 to 5.1

to: 3.5 to 5.1

VETERINARY MONOGRAPHS

Foot-and-Mouth Disease Vaccine, Inactivated. Page 5513

Batch tests. Safety

Change **from**: Use two cattle ..... from causes attributable to the vaccine.

to: **Vaccine intended for cattle and other ruminants.** Use two cattle ..... from causes attributable to the vaccine.

Vaccine intended for pigs. Use two pigs not less than two months old that do not have antibodies against foot and mouth disease virus. Administer to each animal a double dose of the vaccine by the prescribed route of administration stated on the label. Observe the animals daily for at least 14 days. The vaccine complies with the test if no animal shows abnormal local or systemic reactions or dies from causes attributable to the vaccine.

Vaccines for use in other ruminants

Change **to**: **Vaccines for use in other ruminants and pigs.** The potency of each batch shall be demonstrated in a suitable validated test. A test carried out in cattle is acceptable for other ruminant species and pigs.