



INDIAN PHARMACOPOEIA COMMISSION

MINISTRY OF HEALTH & FAMILY WELFARE, GOVERNMENT OF INDIA

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To,

1. Drug 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 Drug Laboratories
7. IDMA/OPPI/BDMA/FSSAI/Small Scale Industry Associations

AMENDMENT LIST – 006 for IP-2014

As you are aware that 7th edition of Indian Pharmacopoeia has become official from 1st April, 2014. Based on Scientific inputs some monographs needed up-gradation, accordingly an Amendment List-006 is issued containing amendment and up-gradation. This is for notice and immediate compliance.

(Dr. G.N. Singh)

Secretary-cum-Scientific Director

Encl:- Amendment List – 006 for IP-2014

Cc to:- Publication Division to put up on IPC website.

Amendment List-006 to IP-2014

Ampicillin Sodium. Page 1066

Dichloromethane.

Change **to:** Not more than 0.2 percent w/w, determined by gas chromatography (2.4.13).

Test Solution. Dissolve 250 mg of the substance under examination in 2.0 ml of *water* into a headspace vial.

Reference solution. A 0.026 per cent w/v solution of dichloromethane in *water*. Transfer 2.0 ml of this solution to a headspace vial.

Chromatographic system.

- a capillary column 30 m x 0.25 mm packed with 6.0 per cent polycyanopropylphenyl siloxane and 94.0 per cent of polydimethyl siloxane (1.4 μ m) (Such as DB-624).
- temperature:
column 50° for 10 minutes, 50° to 130° @ 12° per minute and hold at 130° for 5 minutes. Post run 220° for 5 minutes.
- inlet port at 180° and detector at 250°,
- flame ionization detector,
- split ratio: 25:1,
- flow rate: 0.5 ml per minute using nitrogen as carrier gas.

Headspace conditions

- incubation/equilibrium temperature: 80°,
- incubation /equilibrium time: 1200 seconds,
- syringe temperature/transfer line temperature: 90°,
- injection volume: 500 μ l,

Inject the reference and the test solution.

The test is not valid unless the relative standard deviation for replicate injections is not more than 15.0 per cent (*NOTE- can be reduced to 8.0 per cent*).

Calculate the content of dichloromethane.

Dexamethasone Sodium Phosphate. Page 1525

Ethanol.

Change **to:** Not more than 8.0 percent w/w, determined by gas chromatography (2.4.13).

Internal Standard. A 1.0 per cent v/v solution of *1-propanol* in *water*.

Test solution. A 10.0 per cent w/v solution of the substance under examination in *internal standard solution*.

Reference solution. A solution containing 1.0 per cent w/v of *ethanol* in *internal standard solution*.

Chromatographic system.

- a capillary column 30 m x 0.25 mm packed with 6.0 per cent polycyanopropylphenyl siloxane and 94.0 per cent of polydimethyl siloxane (1.4 μm) (Such as DB-624).
- temperature:
column 50° for 2 minutes, 50° to 240° @ 20° per minute and hold at 240° for 2 minutes.
- inlet port at 250° and detector at 280°,
- flame ionization detector,
- split ratio: 25:1,
- flow rate: 0.5 ml per minute using nitrogen as carrier gas.

Inject 1 μl of each solution.

The resolution between the peaks due to ethanol and 1-propanol is not less than 2.0. The test is not valid unless the relative standard deviation of peak area ratio of ethanol and internal standard from replicate injections of reference solution is not more than 2.0 per cent.

Calculate the percentage w/w of ethanol, assuming the weight per ml at 25° to be 0.787 g.

Oral Rehydration Salts. Page 2381

Usual strength. Last para, line 5

Change **from:** Cl, and citrate, $\text{C}_6\text{H}_5\text{O}_7$,

to: Cl, citrate, $\text{C}_6\text{H}_5\text{O}_7$ and bicarbonate, HCO_3 ,

Assay. Para 1, line 7

Change **from:** potassium and for total chloride

to: potassium, for bicarbonate and for total chloride

Add the following after

For citrate —

For bicarbonate — Titrate 200.0 ml of solution A with 0.1M hydrochloric acid using methyl orange solution as indicator.

1 ml of 0.1M hydrochloric acid is equivalent to 0.006101 g of HCO_3 .

1 g of Sodium Bicarbonate is equivalent to 0.7263 g of HCO_3 .