

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Methylene Chloride

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This draft proposal contains general chapter text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

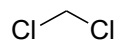
Please send any comments you may have on this draft document to arnd-ipc@gov.in , with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
Monograph proposed for inclusion	Addendum to IP 2026
Tentative effective date of monograph	April, 2028
First draft published on IPC website for public comments	
Draft revision published on IPC website for public comments	
Further follow-up action as required.	

Methylene Chloride

Dichloromethane



CH₂Cl₂

Mol. Wt. 84.9

Methylene Chloride contains not less than 99.0 per cent of CH₂Cl₂.

[Caution—Perform all steps involving evaporation of methylene chloride in a well-ventilated fume hood.]

Category. Pharmaceutical aid.

Description. A clear, colorless, volatile liquid.

Identification

A. To 5 ml of substance in a glass-stoppered, 10-ml conical flask, and shake for several minutes. Remove the stopper, quickly withdraw a portion of the vapor into a 50-ml syringe that is not fitted with a needle, and inject the vapor into a suitable evacuated gas cell. Determine by infrared absorption spectrophotometry (2.4.6), the spectrum of the vapor shows strong doublet peaks at 7.8 and 7.9 μm and at 13.2 μm and 13.4 μm and relatively few minor peaks.

B. Heat 2 ml with 2 g of *potassium hydroxide* and 20 ml of *ethanol (95 per cent)* under a reflux condenser for 30 minutes. Allow to cool, add 15 ml of *dilute sulphuric acid* and filter. 2 ml of filtrate gives reaction (A) of chlorides (2.3.1).

Tests

Limit of nonvolatile residue. Not more than 0.002 per cent. Evaporate 50 g of methylene chloride to dryness in a platinum or porcelain dish on a steam-bath and dry at 105° for 30 minutes.

Free chlorine. To 10 ml, add 10 ml of *water* and 0.1 ml of 1 M *potassium iodide*. Shake for 2 minutes and allow the liquid to separate; the lower layer does not show a violet tint.

Limit of Hydrogen chloride. Not more than 0.001 per cent.

Take two glass-stoppered, 50-ml colour-comparison cylinders having an internal diameter of 20 mm, place 10 ml of *water*, 2 drops of 1 per cent w/v solution of *phenolphthalein* and sufficient 0.01 M *sodium hydroxide* to produce a pink color that persists after vigorous shaking for 30 seconds and is of equal intensity in each cylinder. [Note—In the following step, take special care to avoid contamination with carbon dioxide.]

Into one of the cylinders, place 20 ml of methylene chloride and 0.7 ml of 0.01 M *sodium hydroxide*, and shake again. The pink color in this cylinder is at least as intense as that in the comparison cylinder, and the colour persists for not less than 15 minutes.

Specific gravity (2.4.29). 1.318 to 1.322.

Water (2.3.43). Not more than 0.02 per cent.

Assay. Determine by gas chromatography (2.4.13).

Test solution. The substance under examination.

Reference solution. Mix 3 volumes of *methylene chloride* and 7 volumes of *chloroform*.

Chromatographic system

- a packed column 1.8 m x 4 mm, packed with 15 per cent polyethylene (molecular weight ~15000) liquid phase on an unsilanized solid support prepared from crushed firebrick, 30 to 60 mesh,
- temperature:

- column 60°,
- inlet port at 200° and detector at 250°,
 - a thermal-conductivity detector,
 - flow rate: 20 ml per minute, using helium as the carrier gas,
 - injection volume: 1 µl.

Inject the reference solution. The test is not valid unless the resolution between the peaks due to methylene chloride and chloroform is not less than 4.0, the tailing factor is not more than 1.4 for methylene chloride and the relative standard deviation of peak area ratio of methylene chloride to that of peak area of chloroform for replicate injections is not more than 2.0 per cent.

Inject the reference solution and the test solution.

Calculate the percentage of methylene chloride (CH₂Cl₂), by area normalization.

Storage. Store at temperature not exceeding 30°.

Methylene Chloride

Solubility: Miscible with *ethanol (95 per cent)*; sparingly soluble in *water*.

DRAFT FOR COMMENTS