

# Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

## Pilocarpine Hydrochloride Eye Drops

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This draft proposal contains monograph 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. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. 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 [lab.ipc@gov.in](mailto:lab.ipc@gov.in), with a copy to Dr. Gaurav Pratap Singh (email: [gpsingh.ipc@gov.in](mailto:gpsingh.ipc@gov.in)) before the last date for comments.

### Document History and Schedule for the Adoption Process

Description	Details
Document version	2.0
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	06.06.2024
Draft revision published on IPC website for public comments	01.08.2024
Further follow-up action as required.	

# Pilocarpine Hydrochloride Eye Drops

## Pilocarpine Hydrochloride Ophthalmic Solution

Pilocarpine Hydrochloride Eye Drops is a sterile, buffered, aqueous solution of pilocarpine hydrochloride. It may contain suitable antimicrobial agents and stabilizers, and suitable additives to increase its viscosity.

Pilocarpine Hydrochloride Eye Drops contain not less than 90.0 per cent and not more than 110.0 per cent of the stated amount of pilocarpine hydrochloride,  $C_{11}H_{16}N_2O_2 \cdot HCl$ .

**Usual strengths.** 0.4 per cent w/v; 1 per cent w/v; 1.25 per cent w/v; 2 per cent w/v and 4 per cent w/v.

## Identification

In the Assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution.

## Tests

**pH** (2.4.24). 3.5 to 5.5.

**Sterility** (2.2.11). Complies with the test for sterility.

**Other tests.** Comply with the tests stated under Eye Drops.

**Assay.** Determine by liquid chromatography (2.4.14).

**Test solution.** Dilute a suitable volume of eye drop in *methanol* to obtain a solution containing 0.2 per cent w/v of Pilocarpine Hydrochloride.

**Reference solution.** A 0.2 per cent w/v solution of *pilocarpine hydrochloride IPRS* in *methanol*.

## Chromatographic system

- stainless steel column 25 cm x 4.6 mm, packed with porous silica particles (5  $\mu$ m) (Such as Zorbax Rx-SIL),
- mobile phase: a mixture of 70 volumes of *n-hexane* and 30 volumes of 2 per cent w/v solution of *ammonium hydroxide* in *isopropyl alcohol*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 220 nm,
- injection volume: 10  $\mu$ l.

The retention time of the pilocarpine peak is about 16 minutes.

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  $C_{11}H_{16}N_2O_2 \cdot HCl$  in eye drops.

**Storage.** Store at a temperature not exceeding 30°.

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