

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Propyl Gallate

Published on: 07 February, 2024

Last date for comments: 22 March, 2024

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.

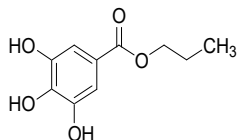
Please send any comments you may have on this draft document to lab.ipc@gov.in, with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

Description	Details
Document version	1.0
First draft published on IPC website for public comments	February 7, 2024
Last date for comments	March 22, 2024
Monograph revisions proposed for inclusion in	IP 2026
Tentative effective date of monograph revisions	July, 2026
Draft revision published on IPC website for public comments	--
Further follow-up action as required.	

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Change to: **Propyl Gallate**



$C_{10}H_{12}O_5$

Mol. Wt. 212.2

Propyl Gallate is propyl 3,4,5-trihydroxybenzoate.

Propyl Gallate contains not less than 98.0 per cent and not more than 102.0 per cent of $C_{10}H_{12}O_5$, calculated on the dried basis.

Category. Pharmaceutical aid (antioxidant).

Description. A white or creamy white crystalline powder.

Identification

A. Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *propyl gallate IPRS* or with the reference spectrum of propyl gallate.

B. When examined in the range of 200 nm to 400 nm (2.4.7), the final solution obtained in the Assay, shows absorption maxima, at about 273 nm.

Tests

Melting range (2.4.21). 146° to 150°.

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

Assay. Dissolve 50 mg of the substance under examination in 100.0 ml of *methanol*. Dilute 2.0 ml of the solution to 100.0 ml with *methanol*. Measure the absorbance of the resulting solution at the maximum at about 273 nm (2.4.7). Calculate the content of $C_{10}H_{12}O_5$ from the absorbance obtained from a 0.001 per cent w/v solution of *propyl gallate IPRS* in *methanol*.

Storage. Store protected from light and moisture, in non-metallic containers.