

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

2.3.18. Sulphated Ash

Published on: 30.12.2024

Last date for comments: 13.02.2025

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 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 | 2.0 |
| Monograph proposed for inclusion | IP 2026 |
| Tentative effective date of monograph | July, 2026 |
| First draft published on IPC website for public comments | 30.12.2024 |
| Draft revision published on IPC website for public comments | |
| Further follow-up action as required. | |

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Change to: 2.3.18. Sulphated Ash

This General Chapter has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopoeia.

Portions of the IP text that and are not part of the PDG harmonized text, are marked with symbols (◆◆).

◆The Sulphated Ash test uses a procedure to measure the amount of residual substance not volatilized from a sample when the sample is ignited in the presence of sulphuric acid according to the procedure described below. This test is usually used for determining the content of inorganic impurities in an organic substance ◆.

Procedure. Ignite a suitable crucible (for example, silica, platinum, porcelain or quartz) at $600 \pm 50^\circ$ for 30 minutes, cool the crucible in a desiccator (silica gel or other suitable desiccant), and weigh it accurately. Weigh accurately ◆ 1 to 2 g of the substance, or ◆ the amount specified in the individual monograph, in the crucible. Moisten the sample with a small amount (usually 1 ml) of sulphuric acid then heat gently at a temperature as low as practicable until the sample is thoroughly charred. Cool; then, ◆ unless otherwise directed in the individual monograph, ◆ moisten the residue with a small amount (usually 1 ml) of sulphuric acid, heat gently until white fumes are no longer evolved; and ignite at $600 \pm 50^\circ$, ◆ unless another temperature is specified in the individual monograph, ◆ until the residue is completely incinerated. Ensure that flames are not produced at any time during the procedure. Cool the crucible in a desiccator (silica gel or other suitable desiccant), weigh accurately, and calculate the percentage of residue.

Unless otherwise specified, if the amount of the residue so obtained exceeds the limit specified in the individual monograph, repeat the moistening with sulphuric acid, heating and igniting as before, using a 30-minute ignition period, until 2 consecutive weighings of the residue do not differ by more than 0.5 mg or until the percentage of residue complies with the limit in the individual monograph.