

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Aluminium Sulphate

Published on: 01.08.2024

Last date for comments: 14.09.2024

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).

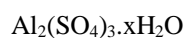
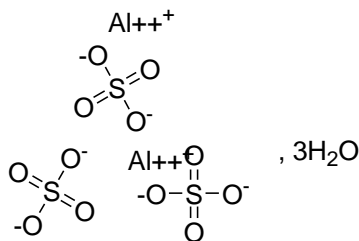
Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls 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	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.	

Aluminium Sulphate



Mol. Wt. 342.1 (anhydrous form)

Aluminium Sulphate contains a variable quantity water of crystallisation.

Aluminium Sulphate contains not less than 51.0 per cent and not more than 59.0 per cent of $\text{Al}_2(\text{SO}_4)_3$.

Category. Pharmaceutical aid.

Description. A colourless, lustrous crystals or crystalline masses.

Identification

A. A 5 per cent w/v solution of the substance under examination in *water* (solution A), gives the reaction (A) of sulphates (2.3.1).

B. Solution A gives the reactions of aluminium salts (2.3.1).

Tests

Appearance of solution. Solution A is not more opalescent than reference suspension (OS3) (2.4.1) and colourless (2.4.1).

pH (2.4.24). 2.5 to 4.0, determined in a 2.0 per cent w/v solution in *carbon dioxide-free water*.

Alkali and alkaline-earth metals. Not more than 0.4 per cent.

To 20 ml of solution A add 100 ml of *water*, heat and add 0.1 ml of *methyl red solution*. Add *dilute ammonia* until the colour of the indicator changes to yellow. Dilute to 150 ml with *water*, heat to boiling and filter. Evaporate 75 ml of the filtrate to dryness on a water-bath and ignite. The weight of the residue does not exceed 2 mg.

Ammonium (2.3.53). Not more than 500 ppm, using Method A, determined on 0.4 ml of solution A.

Iron (2.3.14). Not more than 100 ppm, determined on 8 ml of solution A. Using 0.3 ml of *thioglycollic acid*.

Assay. Dissolve 0.5 g of the substance under examination in 20 ml of *water*. Add 25.0 ml of 0.1 M *sodium edetate* and 10 ml of a mixture of equal volumes of a 15.5 per cent w/v solution of *ammonium acetate* and *dilute acetic acid*. Boil for 2 minutes, then cool. Add 50 ml of *ethanol* and 3 ml of a freshly prepared 0.025 per cent w/v solution of *dithiron* in *ethanol*. Titrate the excess of *sodium edetate* with 0.1 M *zinc sulphate* until the colour changes from greenish-blue to reddish-violet.

1 ml of 0.1 M *sodium edetate* is equivalent to 0.1711 g of $\text{Al}_2(\text{SO}_4)_3$.

Storage. Store protected from moisture.

Solubility.

Aluminium Sulphate. Freely soluble in hot *water*, soluble in cold *water* and practically insoluble in *ethanol (95 per cent)*.

DRAFT FOR COMMENTS