

Status: Currently Official on 13-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
Docld: GUID-C786BE04-2206-4985-B1B7-832DDB74E476_1_en-US
DOI: https://doi.org/10.31003/USPNF_M3798_01_01

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Ammonium Molybdate Injection

» Ammonium Molybdate Injection is a sterile solution of Ammonium Molybdate in Water for Injection. It contains not less than 85.0 percent and not more than 115.0 percent of the labeled amount of molybdenum (Mo).

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I or Type II glass.

Labeling—Label the Injection to indicate that it is to be diluted to the appropriate strength with Sterile Water for Injection or other suitable fluid prior to administration.

Identification-

A: The Assay preparation, prepared as directed in the Assay, exhibits an absorption maximum at about 313 nm when tested as directed for *Procedure* in the Assay.

B: Add 0.3 mL of alkaline mercuric-potassium iodide TS to 5 mL of Injection: a reddish-brown color develops.

C: Evaporate 50 mL of Injection on a steam bath to a volume of about 0.3 mL, and add 0.3 mL of ammonium hydroxide. Cool, and add slowly, with mixing, a well-cooled mixture of 1 mL of nitric acid and 1.2 mL of water. Allow to stand for 24 to 48 hours, and pass through a sintered-glass filter. To the filtrate add 0.5 mL of dibasic sodium phosphate TS: a yellow precipitate is formed, and it dissolves in an excess of 6 N ammonium hydroxide.

Pyrogen (151)—It meets the requirements, the test dose being 10 mL of Injection per kg.

PH (791): between 3.0 and 6.0.

Particulate Matter in Injections (788): meets the requirements for small-volume injections.

Other requirements—It meets the requirements under Injections and Implanted Drug Products (1).

Assav-

Ammonium hydroxide diluent—Dilute 40 mL of ammonium hydroxide with water to 1000 mL. Store in a plastic bottle.

Sodium sulfate solution—Dissolve 1 g of sodium sulfate in water to make 100 mL.

Molybdenum stock solution—Transfer about 1.84 g of previously assayed Ammonium Molybdate, accurately weighed, to a 1000-mL volumetric flask, dilute with Ammonium hydroxide diluent to volume, and mix. This solution contains the equivalent of 1000 μg of molybdenum per ml

Standard preparations—Transfer 0, 1.0, 2.0, 3.0, and 4.0 mL, respectively, of *Molybdenum stock solution* to separate 100-mL volumetric flasks, and to the respective flasks add 5.0, 4.0, 3.0, 2.0, and 1.0 mL of *Ammonium hydroxide diluent*. To each flask add 10 mL of *Sodium sulfate solution*, dilute with water to volume, and mix. These *Standard preparations* contain, respectively, 0, 10, 20, 30, and 40 µg of molybdenum per mL.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 500 µg of molybdenum, to a 25-mL volumetric flask, add 1.25 mL of Ammonium hydroxide diluent and 2.5 mL of Sodium sulfate solution, dilute with water to volume, and mix. Procedure—Concomitantly determine the absorbances of the Standard preparations and the Assay preparation at the molybdenum emission line of 313.3 nm with a suitable atomic absorption spectrophotometer (see Atomic Absorption Spectroscopy (852)) equipped with a molybdenum hollow-cathode lamp and a nitrous oxide—acetylene reducing flame, using water as the blank. Plot the absorbances of the Standard preparations versus concentration, in µg per mL, of molybdenum, and draw the straight line best fitting the five plotted points. From the graph so obtained, determine the concentration, in µg per mL, of molybdenum in the Assay preparation. Calculate the quantity, in µg, of molybdenum (Mo) in each mL of the Injection taken by the formula:

25C/V

in which C is the concentration, in µg per mL, of molybdenum in the Assay preparation; and V is the volume, in mL, of Injection taken.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
AMMONIUM MOLYBDATE INJECTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

h2/13/25-4:58/fwungtamthuoc.com

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Current DocID: GUID-C7B6BE04-22C6-4985-B1B7-832DDB74E476_1_en-US

DOI: https://doi.org/10.31003/USPNF_M3798_01_01

DOI ref: 1fp4o

