Isoniazid Oral Solution

Published on: 18 January, 2024 **Last date for comments:** 03 March, 2024

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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
Category	New Inclusion
Monograph proposed for inclusion	IP 2026
Tentative effective date of monograph	July, 2026
First draft published on IPC website for public comments	18 January, 2024
Draft revision published on IPC website for public comments	--
Further follow-up action as required.	

Isoniazid Oral Solution

Isoniazid Oral Solution is a solution of Isoniazid in a suitable vehicle. It contains a suitable flavouring agent. It is filled in a sealed container.

Isoniazid Oral Solution contains not less than 93.0 per cent and not more than 110.0 per cent of the stated amount of Isoniazid, $C_6H_7N_3O$.

Usual strength. 50 mg per 5 ml.

Identification

Transfer a volume of the oral solution containing 50 mg of isoniazid to a 500-ml volumetric flask, add 200 ml of *water*. Shake to dissolve and dilute to volume with *water*. Transfer 10 ml of the solution to a 100 ml volumetric flask, add 2.0 ml of *0.1 M hydrochloric acid* and dilute to volume with *water*. The UV absorption spectrum (2.4.7) of the solution so obtained exhibits maxima and minima at the same wavelengths as that of a solution of the similar concentration of *isoniazid IPRS,* concomitantly measured.

Other tests. Comply with the tests stated under Oral Liquids.

Assay.

Dissolve a quantity of the oral solution containing 100 mg of isoniazid in 50 ml of 1 per cent w/v solution of *potassium bromide* in *dilute hydrochloric acid*, stir until dissolved, cool the solution to 15˚. Titrate with *0.1 M sodium nitrite*, determine by nitrite titration (2.3.31). Carry out a blank titration.

1 ml of *0.01 M sodium nitrite* is equivalent to 0.01371 g of $C_6H_7N_3O$.

Storage. Store protected from light and moisture.