

Status: Currently Official on 15-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-CC6091C2-1C66-4BC4-B917-D01634C67F88_1_en-US
DOI: https://doi.org/10.31003/USPNF_M43540_01_01
DOI Ref: 42ik6

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Do not distribute

Isosorbide Oral Solution

» Isosorbide Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of isosorbide ($C_6H_{10}O_4$).

Packaging and storage—Preserve in tight containers.

USP REFERENCE STANDARDS (11)—

[USP Isosorbide RS](#)

Identification—The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatograms of the *Standard preparations*, as obtained in the Assay.

UNIFORMITY OF DOSAGE UNITS (905)—

FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

DELIVERABLE VOLUME (698)—

FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

pH (791): between 3.2 and 3.8.

Assay—

Internal standard solution, Standard solution, Standard preparations, Chromatographic system, and System suitability and standard curve—
Proceed as directed in the Assay under [Isosorbide Concentrate](#).

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 450 mg of isosorbide, to a 250-mL volumetric flask, add 25.0 mL of *Internal standard solution*, then add water to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the Assay under [Isosorbide Concentrate](#). Calculate the quantity, in mg, of isosorbide ($C_6H_{10}O_4$) in each mL of the Oral Solution taken by the formula:

$$250(C/V)$$

in which C is the concentration, in mg per mL, of isosorbide in the *Assay preparation* found by reference to the *Standard curve*; and V is the volume, in mL, of Oral Solution taken.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
ISOSORBIDE ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. 45(4)

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