Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Sep-2023
Document Type: USP Monographs
DocId: GUID-CFA1C316-4D16-4B63-9020-B9C5A261355A_2_en-US
DOI: https://doi.org/10.31003/USPNF_M24150_02_01
DOI Ref: pbi81

Dextromethorphan Hydrobromide Oral Solution

» Dextromethorphan Hydrobromide Oral Solution contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dextromethorphan hydrobromide ($C_{18}H_{25}NO \cdot HBr \cdot H_2O$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Dextromethorphan Hydrobromide RS

Identification—

A: Transfer about 50 mL of Oral Solution to a 250-mL separator, add 20 mL of water, 5 mL of 2.5 N sodium hydroxide, and 40 mL of solvent hexane, and shake thoroughly. Remove the solvent hexane layer, and filter through anhydrous sodium sulfate into a 150-mL beaker. Repeat the solvent hexane extraction, using two 40-mL portions and collecting the extracts in the beaker after filtering. Evaporate the combined extracts at 50° under nitrogen to dryness, and dissolve the residue in, and dilute with, 10 mL of chloroform: the solution is dextrorotatory (see *Optical Rotation* ⟨781⟩). Retain the chloroform solution for *Identification* test *B*.

B: Evaporate the chloroform solution from *Identification* test *A* on a steam bath to dryness, dissolve the residue in 2 mL of 2 N sulfuric acid, and add 1 mL of a freshly prepared solution of mercuric nitrate (prepared by dissolving 700 mg of mercuric nitrate in 4 mL of water, adding 100 mg of sodium nitrate, mixing, and filtering): no red color is produced immediately, but after heating, a yellow to red color develops in about 15 minutes.

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.

Assay—

Mobile phase and *Standard preparation*—Prepare as directed in the *Assay* under *Dextromethorphan Hydrobromide*.

Assay preparation—Pipet, using a to-contain pipet, a volume of Oral Solution, equivalent to about 10 mg of dextromethorphan hydrobromide, into a 100-mL volumetric flask, dilute with water to volume, and mix.

Change to read:

Chromatographic system and *Procedure* (see *Chromatography* ⟨621⟩)—Proceed as directed in the *Assay* under *Dextromethorphan Hydrobromide*. Calculate the quantity, in mg, of dextromethorphan hydrobromide ($C_{18}H_{25}NO \cdot HBr \cdot H_2O$) in the volume of Oral Solution taken by the formula:

$$(370.32/352.32)(100C)(r_U/r_S)$$

in which 370.32 and 352.32 are the molecular weights of dextromethorphan hydrobromide and anhydrous dextromethorphan hydrobromide, respectively; C is the concentration, in mg per mL, of USP Dextromethorphan Hydrobromide RS ▲(ERR 1-Sep-2023) in the *Standard preparation;* and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
DEXTROMETHORPHAN HYDROBROMIDE ORAL SOLUTION	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 49(5)

Current DocID: GUID-CFA1C316-4D16-4B63-9020-B9C5A261355A_2_en-US
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