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Hydralazine Hydrochloride Compounded Oral Solution

DEFINITION

Hydralazine Hydrochloride Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of hydralazine hydrochloride ($C_8H_8N_4 \cdot HCl$).

Prepare Hydralazine Hydrochloride Compounded Oral Solution of the designated percentage strength as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Hydralazine Hydrochloride	
For 0.1% Oral Solution	100 mg
For 1.0% Oral Solution	1.0 g
Sorbitol Solution (70%)	40 g
Methylparaben	65 mg
Propylparaben	35 mg
Propylene Glycol	10 g
Aspartame	50 mg
Purified Water, a sufficient quantity to make	100 mL

Dissolve the *Hydralazine Hydrochloride* in 30 mL of *Purified Water*, add the *Aspartame*, and shake or stir until the solids have dissolved. Add the *Sorbitol Solution*. In a separate container, dissolve an aliquot portion of an intimate homogeneous mixture of accurately weighed quantities of *Methylparaben* and *Propylparaben* in the *Propylene Glycol*, and, with stirring, add this mixture to the solution containing the *Hydralazine Hydrochloride*. Add sufficient *Purified Water* to make the preparation measure 100 mL, and mix.

[Note—Hydralazine reacts with many flavors; do not add flavors when compounding.]

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 3.0–5.0

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Package in a suitable light-resistant glass or plastic bottle, with a child-resistant closure. Store in a refrigerator.
- **Beyond-Use Date:** NMT 30 days after the date on which it was compounded when stored in a refrigerator
- **Labeling:** Label it to state the *Beyond-Use Date* and that it is to be stored in a refrigerator.

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

Topic/Question	Contact	Expert Committee
HYDRALAZINE HYDROCHLORIDE COMPOUNDED ORAL SOLUTION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

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