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Dapsone Compounded Oral Suspension

DEFINITION

Dapsone Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$).

Prepare Dapsone Compounded Oral Suspension 2 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Dapsone tablets[a] equivalent to	200 mg of dapsone
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus[b], a sufficient quantity to make	100 mL

[a] Dapsone 25-mg tablets, Jacobus Pharmaceutical Company, Princeton, NJ.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Dapsone tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a dapsone liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 50 mM ammonium phosphate adjusted to a pH of 4.6

Mobile phase: Acetonitrile and *Solution A* (12:88). Filter and degas.

Internal standard solution: 1.0 mg/mL of diazoxide in methanol

Standard stock solution: 2.0 mg/mL of USP Dapsone RS in methanol

Standard solution: Pipet 2.5 mL of *Standard stock solution* into a 100-mL volumetric flask, add 5.0 mL of *Internal standard solution*, and dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of 50 µg/mL of dapsone and 50 µg/mL of diazoxide. Centrifuge.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Pipet 2.5 mL of Oral Suspension into a 100-mL volumetric flask, add 5.0 mL of *Internal standard solution*, and dilute with *Mobile phase* to volume to obtain a solution with a nominal concentration of 50 µg/mL of dapsone and 50 µg/mL of diazoxide. Centrifuge.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 295 nm

Column: 3.0-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.7 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention times for dapsone and diazoxide are about 8.9 and 12.9 min, respectively.]

Suitability requirements

Relative standard deviation: NMT 2.3% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of dapsone ($C_{12}H_{12}N_2O_2S$) in the portion of Oral Suspension taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of dapsone to the internal standard from the *Sample solution*

R_S = peak response ratio of dapsone to the internal standard from the *Standard solution*

C_S = concentration of USP Dapsone RS in the *Standard solution* (µg/mL)

C_U = nominal concentration of dapsone in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Dapsone RS

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

Topic/Question	Contact	Expert Committee
DAPSONE COMPOUNDED ORAL SUSPENSION	Documentary Standards Support Associate Scientific Liaison.	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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