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Lansoprazole Compounded Oral Suspension

DEFINITION

Lansoprazole Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$).

Prepare Lansoprazole Compounded Oral Suspension 3 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Lansoprazole delayed-release capsule(s)[a] equivalent to	300 mg
Vehicle: A mixture of Ora-Blend[b] and Sodium Bicarbonate Injection (8.4%) (1:1), a sufficient quantity to make	100 mL

[a] Lansoprazole 30-mg delayed-release capsules, Dr. Reddy's Laboratory Limited, Bridgewater, NJ.

[b] Perrigo Pharmaceuticals, Allegan, MI.

Empty the required number of delayed-release capsules, and pour the contents into a mortar or other suitable container. If necessary, crush the contents into a fine powder by using a pestle or other mechanical means. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add *Vehicle* to make the mortar contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

Alternatively, a compounded 8.4% sodium bicarbonate solution may be used instead of *Sodium Bicarbonate Injection (8.4%)*. Prepare an 8.4% sodium bicarbonate solution by dissolving 8.4 g of Sodium Bicarbonate in sufficient Purified Water to make 100 mL.

ASSAY

• **Procedure**

Solution A: 10 mM sodium phosphate adjusted with sodium hydroxide to a pH of 7.5. Pass through a nylon filter of 0.45-µm pore size, and degas.

Solution B: Acetonitrile and water (50:50)

Solution C: Water adjusted with 1 M sodium hydroxide to a pH of 6.5

Mobile phase: Acetonitrile and *Solution A* (45:55)

Standard stock solution: 3 mg/mL of USP Lansoprazole RS in *Solution B*. Mix well, and sonicate for 3 min. Store at 2°–8°.

Standard solution: Transfer 2.0 mL of the *Standard stock solution* to a 500-mL volumetric flask, and dilute with *Solution C* to volume. Centrifuge an aliquot of the solution for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Sample solution: Shake each bottle of Oral Suspension thoroughly. Transfer 2.0 mL of Oral Suspension to a 500-mL volumetric flask, and dilute with *Solution C* to volume. Centrifuge an aliquot of the solution for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Chromatographic system

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

Mode: LC

Detector: UV 285 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Temperatures

Column: 35°

Autosampler: 5°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for lansoprazole is about 5.2 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lansoprazole ($C_{16}H_{14}F_3N_3O_2S$) in the portion of Oral Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of lansoprazole from the *Sample solution*

r_S = peak response of lansoprazole from the *Standard solution*

C_S = concentration of lansoprazole in the *Standard solution* (mg/mL)

C_U = nominal concentration of lansoprazole in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 8.0–8.5

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.

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

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded, when stored at 2°–8° or at controlled room temperature

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Lansoprazole RS

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

Topic/Question	Contact	Expert Committee
LANSOPRAZOLE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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