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Clopidogrel Compounded Oral Suspension

DEFINITION

Clopidogrel Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of clopidogrel ($C_{16}H_{16}ClNO_2S$).

Prepare Clopidogrel Compounded Oral Suspension 5 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Clopidogrel tablet(s)[a] equivalent to	525 mg
Vehicle: A 1:1 mixture of Ora-Plus[b] and Ora-Sweet[b], a sufficient quantity to make	105 mL

[a] Clopidogrel 75-mg tablets, Dr. Reddy's Laboratory Limited, Bridgewater, NJ.

[b] Perrigo Pharmaceuticals, Allegan, MI.

Crush the *Clopidogrel tablet(s)* to a fine powder using a mortar and pestle or by other mechanical means. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 10 mM sodium phosphate adjusted with phosphoric acid to a pH of 3.0. Pass through a nylon filter of 0.45-µm pore size, and degas.

Mobile phase: Acetonitrile and *Solution A* (65:35)

Diluent: Water adjusted with phosphoric acid to a pH of 3.0

Standard stock solution: 5 mg/mL of clopidogrel prepared from USP Clopidogrel Bisulfate RS and *Diluent*. Mix well, and sonicate for 3 min. Store at 2°–8°.

Standard solution: Transfer 2.0 mL of the *Standard stock solution* to a 1-L volumetric flask, and dilute with *Diluent* to volume. Mix well, centrifuge a portion 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 the Oral Suspension to a 1-L volumetric flask, and dilute with *Diluent* to volume. Mix well, centrifuge a portion 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 235 nm

Column: 2.1-mm × 25-cm; 5-µm packing L7

Temperatures

Column: 35°

Autosampler: 5°

Flow rate: 0.3 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for clopidogrel is about 7.4 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of clopidogrel ($C_{16}H_{16}ClNO_2S$) 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 clopidogrel from the *Sample solution*

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

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.1–3.1

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at 2°–8° 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*.

• **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 Clopidogrel Bisulfate RS

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

Topic/Question	Contact	Expert Committee
CLOPIDOGREL COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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