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Add the following:

▲Vancomycin Hydrochloride Compounded Oral Solution

DEFINITION

Vancomycin Hydrochloride Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of vancomycin ($C_{66}H_{75}Cl_2N_9O_{24}$).

Prepare Vancomycin Hydrochloride Compounded Oral Solution 50 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Vancomycin (as Vancomycin Hydrochloride)	5 g (calculate)[a]
SyrSpend SF PH4 (Liquid Cherry Flavored),[b] a sufficient quantity to make	100 mL

[a] Calculate the amount of vancomycin hydrochloride needed based on the potency equivalent (activity) of vancomycin.

[b] Fagron Inc., St. Paul, MN.

Calculate the amount of *Vancomycin Hydrochloride* needed based on the potency equivalent (activity) of vancomycin. Pour the *Vancomycin Hydrochloride* into a suitable container. Wet the powder with a small amount of *SyrSpend SF PH4 (Liquid Cherry Flavored)* and triturate to make a smooth paste. Add the *SyrSpend SF PH4 (Liquid Cherry Flavored)* to make the contents pourable. Transfer the contents stepwise and quantitatively to a calibrated container using the remainder of the *SyrSpend SF PH4 (Liquid Cherry Flavored)*. Add sufficient *SyrSpend SF PH4 (Liquid Cherry Flavored)* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 50 mM ammonium acetate adjusted with ammonium hydroxide to a pH of 8.0

Solution B: Methanol and water (35:65)

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	50	50
20	30	70
25	0	100
25.01	50	50

Standard solution: 0.5 mg/mL of vancomycin B prepared from USP Vancomycin B RS in water

Sample solution: Transfer 1 mL of Oral Solution to a 100-mL volumetric flask and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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Column: 2.1-mm × 15-cm; 5-µm packing L1

Column temperature: 40°

Flow rate: 0.2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for vancomycin B is about 14.8 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 vancomycin ($C_{66}H_{75}Cl_2N_9O_{24}$) in the portion of Oral Solution taken:

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

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

r_S = peak response of vancomycin B from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.5–3.5

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant plastic containers. Store in a refrigerator.

• **BEYOND-USE DATE:** NMT 60 days after the date on which it was compounded when stored in a refrigerator.

• **LABELING:** Label it to state the *Beyond-Use Date*.

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Vancomycin B RS▲ (USP 1-May-2020)

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

Topic/Question	Contact	Expert Committee
VANCOMYCIN HYDROCHLORIDE COMPOUNDED ORAL SOLUTION	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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