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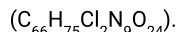
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**Add the following:**

## ^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



Prepare Vancomycin Hydrochloride Compounded Oral Solution 50 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Vancomycin (as Vancomycin Hydrochloride)	5 g (calculate) <sup>a</sup>
SyrSpend SF PH4 (Liquid Cherry Flavored), <sup>b</sup> a sufficient quantity to make	100 mL

<sup>a</sup> Calculate the amount of vancomycin hydrochloride needed based on the potency equivalent (activity) of vancomycin.

<sup>b</sup> 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

**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<sub>66</sub>H<sub>75</sub>Cl<sub>2</sub>N<sub>9</sub>O<sub>24</sub>) 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	<a href="#">Brian Serumaga</a> Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	CMP2020 Compounding 2020

**Chromatographic Database Information:** [Chromatographic Database](#)

**Most Recently Appeared In:**

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