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Valrubicin Intravesical Solution

DEFINITION

Valrubicin Intravesical Solution is a sterile solution of Valrubicin in a suitable vehicle. It contains NLT 95.0% and NMT 105.0% of the labeled amount of valrubicin ($C_{34}H_{36}F_3NO_{13}$).

IDENTIFICATION

Change to read:

• **A.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Buffer: 0.1 M ammonium formate. Adjust with formic acid to a pH of 4.0.

Mobile phase: Acetonitrile and *Buffer* (45:55)

Standard solution: 0.2 mg/mL of USP Valrubicin RS in methanol

Sample solution: ▲Nominally equivalent to 0.2 mg/mL of valrubicin prepared as follows. Transfer a portion of Intravesical Solution to a suitable volumetric flask and dilute with methanol to volume.▲ (USP 1-Aug-2020)

Chromatographic system

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

Mode: LC

Detector: UV 254 mm. ▲For *Identification A*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-Aug-2020)

Columns: 5-mm × 10-cm; 4-µm packing L1; and a guard column

Flow rate: 2.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

▲**Tailing factor:** NMT 2.0▲ (USP 1-Aug-2020)

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of valrubicin ($C_{34}H_{36}F_3NO_{13}$) in the portion of Intravesical Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Valrubicin RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

IMPURITIES

Change to read:

• **Organic Impurities**

Buffer, Mobile phase, and **Chromatographic system:** Proceed as directed in the *Assay*.

Sample solution: 0.2 mg/mL of valrubicin in methanol

Analysis

Sample: *Sample solution*

▲▲ (USP 1-Aug-2020) Calculate the percentage of ▲any specified and unspecified▲ (USP 1-Aug-2020) impurities in the portion of Intravesical Solution taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak area for ▲any specified or unspecified▲ (USP 1-Aug-2020) impurity

r_T = sum of the areas of all the peaks

▲▲ (USP 1-Aug-2020)

Acceptance criteria: See *Table 1*.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Valrubicin impurity 1	0.11	0.5
Valrubicin impurity 2	0.16	0.8
Valrubicin impurity 3	0.51	0.8
Valrubicin impurity 4	0.71	0.8
▲Valrubicin	1.0	—▲ (USP 1-Aug-2020)
Any unspecified impurity	—	0.5
Total impurities	—	3.5

SPECIFIC TESTS

Change to read:

• **Bacterial Endotoxins Test** ⟨85⟩**:** ▲Meets the requirements▲ (USP 1-Aug-2020)

Add the following:

▲• **Sterility Tests** ⟨71⟩**:** Meets the requirements▲ (USP 1-Aug-2020)

• **pH** ⟨791⟩

Sample solution: 1 in 15 solution in 0.9% sodium chloride solution

Acceptance criteria: 4.0–7.0

• **Other Requirements:** Meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Store in a refrigerator.

• **Labeling:** Label it to indicate that it is not intended for intravenous or intramuscular injection but is to be used for intravesical instillation.

• **USP Reference Standards** ⟨11⟩

USP Valrubicin RS

Topic/Question	Contact	Expert Committee
VALRUBICIN INTRAVESICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

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