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# Idarubicin Hydrochloride Injection

## DEFINITION

Idarubicin Hydrochloride Injection is a sterile solution in water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of idarubicin hydrochloride ($C_{26}H_{27}NO_9 \cdot HCl$).

## IDENTIFICATION

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

## ASSAY

• **Procedure**

**Solution A:** 2.9 g/L of sodium lauryl sulfate in water. To each liter of this solution add 1.3 mL of phosphoric acid.

**Mobile phase:** Acetonitrile and *Solution A* (1:1)

**Standard solution:** 0.04 mg/mL of USP Idarubicin Hydrochloride RS in water

**Sample solution:** Nominally 0.04 mg/mL of idarubicin hydrochloride in water

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254 nm

**Column:** 4.6-mm × 50-mm; 5-µm packing L7

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 10 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Tailing factor:** NMT 2.0

**Relative standard deviation:** NMT 2.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of idarubicin hydrochloride ($C_{26}H_{27}NO_9 \cdot HCl$) in the portion of Injection taken:

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

$r_U$ = peak response from the *Sample solution*

$r_S$ = peak response from the *Standard solution*

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

$C_U$ = nominal concentration of idarubicin hydrochloride in the *Sample solution* (mg/mL)

$P$ = potency of USP Idarubicin Hydrochloride RS (µg/mg)

$F$ = conversion factor, 0.001 mg/µg

**Acceptance criteria:** 90.0%–110.0%

## IMPURITIES

• **Organic Impurities**

**Solution A:** 2.9 g/L of sodium lauryl sulfate and 2.3 g/L of phosphoric acid in water

**Mobile phase:** Tetrahydrofuran, methanol, and *Solution A* (25:15:60)

**Diluent A:** 2.3 g/L of phosphoric acid in water

**Diluent B:** Tetrahydrofuran, methanol, and *Diluent A* (25:15:60). Adjust with 2 N sodium hydroxide to a pH of 3.6.

**Standard solution:** 0.01 mg/mL of USP Idarubicin Hydrochloride RS in *Diluent B*

**Sample solution:** Nominally 0.5 mg/mL of idarubicin hydrochloride in *Diluent B*

**Chromatographic system**

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

**Mode:** LC

**Detector:** UV 254

**Column:** 4.6-mm × 25-cm; 5-µm packing L7

**Column temperature:** 40°

**Flow rate:** 1.5 mL/min

**Injection volume:** 20 µL

**System suitability**

**Sample:** *Standard solution*

**Suitability requirements**

**Relative standard deviation:** NMT 5.0%

**Analysis**

**Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P \times F_1 \times (1/F_2) \times 100$$

$r_U$ = peak response of each individual impurity from the *Sample solution*

$r_S$ = peak response of idarubicin from the *Standard solution*

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

$C_U$ = nominal concentration of idarubicin hydrochloride in the *Sample solution* (mg/mL)

$P$ = potency of USP Idarubicin Hydrochloride RS (µg/mg)

$F_1$ = conversion factor, 0.001 mg/µg

$F_2$ = relative response factor (see *Table 1*)

**Acceptance criteria:** See *Table 1*. The reporting threshold is 0.04%.

**Table 1**

| Name | Relative Retention Time | Relative Response Factor | Acceptance Criteria, NMT (%) |
|---|---|---|---|
| Idarubicin aglycone[a] | 0.3 | 1.5 | 2.5 |
| Dianhydro idarubicinaglycone[b] | 0.9 | 1.3 | 0.5 |
| Idarubicin hydrochloride | 1.0 | — | — |
| Any other individual impurity | — | 1.0 | 0.5 |
| Total impurities | — | — | 3.5 |

[a] (7*S*,9*S*)-9-Acetyl-6,7,9,11-tetrahydroxy-7,8,9,10-tetrahydrotetracene-5,12-dione.

[b] 8-Acetyl-6,11-dihydroxynaphthacene-5,12-dione.

**SPECIFIC TESTS**

- **Bacterial Endotoxins Test ⟨85⟩:** Contains NMT 8.9 USP Endotoxin Units/mg of idarubicin hydrochloride
- **Sterility Tests ⟨71⟩**, *Test for Sterility of the Product to Be Examined, Membrane Filtration*: Meets the requirements
- **pH ⟨791⟩:** 3.0–4.5
- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

**ADDITIONAL REQUIREMENTS**

- **Packaging and Storage:** Preserve in tight containers as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*. Store at 2°–8°, protected from light.
- **Labeling:** Meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*
- **USP Reference Standards ⟨11⟩**

USP Idarubicin Hydrochloride RS

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

| Topic/Question | Contact | Expert Committee |
|---|---|---|
| IDARUBICIN HYDROCHLORIDE INJECTION | Documentary Standards Support | SM12020 Small Molecules 1 |
| REFERENCE STANDARD SUPPORT | RS Technical Services<br>RSTECH@usp.org | SM12020 Small Molecules 1 |

**Chromatographic Database Information:** Chromatographic Database

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