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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 idarubicin aglycone ^b	0.9	1.3	0.5
Idarubicin hydrochloride	1.0	—	—
Any other individual impurity	—	1.0	0.5
Total impurities	—	—	3.5

^a (7S,9S)-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](#)