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Standard solution: 0.1 mg/mL of [USP Doxorubicin Hydrochloride RS](#) in *Diluent*

Sample solution: 0.1 mg/mL of Doxorubicin Hydrochloride in *Diluent*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 2.1-mm × 10-cm; 1.7-μm packing L1

Temperatures

Column: 35°

Autosampler: 4°

Flow rate: 0.5 mL/min

Injection volume: 2 μL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for doxorubicin and epirubicin are 1.0 and 1.05, respectively.]

Suitability requirements

Resolution: NLT 1.5 between doxorubicin and epirubicin, *System suitability solution*

Tailing factor: 0.8–1.5, *Standard solution*

Relative standard deviation: NMT 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of doxorubicin hydrochloride ($C_{27}H_{29}NO_{11} \cdot HCl$) in the portion of Doxorubicin Hydrochloride taken:

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

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

r_S = peak response of doxorubicin from the *Standard solution*

C_S = concentration of [USP Doxorubicin Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Doxorubicin Hydrochloride in the *Sample solution* (mg/mL)

P = potency of doxorubicin hydrochloride in [USP Doxorubicin Hydrochloride RS](#) (μg/mg)

F = conversion factor, 0.001 mg/μg

Acceptance criteria: 98.0%–102.0% on the anhydrous, solvent-free basis

IMPURITIES

• ORGANIC IMPURITIES

Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

[NOTE—Protect solutions containing doxorubicin from light.]

Standard solution: 0.002 mg/mL each of [USP Doxorubicin Hydrochloride RS](#), [USP Doxorubicinone RS](#), [USP Daunorubicin Hydrochloride RS](#), and [USP Daunorubicinone RS](#) in *Diluent*

Sample solution: 0.4 mg/mL of Doxorubicin Hydrochloride in *Diluent*

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—See [Table 2](#) for the relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between doxorubicin and epirubicin, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of doxorubicinone in the portion of Doxorubicin Hydrochloride taken:

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

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

r_S = peak response of doxorubicinone from the *Standard solution*

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

C_U = concentration of Doxorubicin Hydrochloride in the *Sample solution* (mg/mL)