Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-Aug-2022
Document Type: USP Monographs
DocId: GUID-B2EAE65B-9EB1-4E4E-9CD4-0274EA10C4F8_3_en-US
DOI: https://doi.org/10.31003/USPNF_M1023_03_01
DOI Ref: u7wz5

© 2025 USPC
Do not distribute

Ciprofloxacin and Dexamethasone Otic Suspension

DEFINITION

Ciprofloxacin and Dexamethasone Otic Suspension is a sterile, aqueous suspension containing ciprofloxacin hydrochloride and dexamethasone. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$) and NLT 90.0% and NMT 110.0% of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$).

IDENTIFICATION

• **A.** The *Sample solution*, obtained as directed in the *Assay* for *Ciprofloxacin*, exhibits a major peak for ciprofloxacin, the retention time of which corresponds to that of the *Standard solution*, obtained as directed in the *Assay* for *Ciprofloxacin*.

• **B.** The *Sample solution*, obtained as directed in the *Assay* for *Dexamethasone*, exhibits a major peak for dexamethasone, the retention time of which corresponds to that of the *Standard solution*, obtained as directed in the *Assay* for *Dexamethasone*.

ASSAY

• **Ciprofloxacin**

Buffer: Add 6.0 mL of phosphoric acid and 8 g of diethylamine phosphate to 2.0 L of water. Adjust with 50% sodium hydroxide to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (11:89)

System suitability solution: 1.6 µg/mL each of USP Ciprofloxacin Hydrochloride RS and USP Ciprofloxacin Ethylenediamine Analog RS in *Mobile phase*

Standard solution A: 1.48 mg/mL of USP Ciprofloxacin Hydrochloride RS in 0.1 N hydrochloric acid. Dilute with *Mobile phase* to 0.13 mg/mL of ciprofloxacin.

Standard solution B: 0.0025 mg/mL of ciprofloxacin from *Standard solution A* in *Mobile phase*

Sample solution: Nominally 0.12 mg/mL in *Mobile phase* prepared as follows. Transfer the equivalent to 3 mg of ciprofloxacin from freshly mixed Otic Suspension to a 25-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution, Standard solution A,* and *Standard solution B*

Suitability requirements

Resolution: NLT 3.0 between ciprofloxacin and the ciprofloxacin ethylenediamine analog, *System suitability solution*

Column efficiency: NLT 2500 theoretical plates for ciprofloxacin, *System suitability solution*

Tailing factor: NMT 2.0 for ciprofloxacin, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution A* and *Standard solution B*

Analysis

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

Calculate the percentage of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$) in the portion of Otic Suspension taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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

r_S = peak response of ciprofloxacin from *Standard solution A*

C_S = concentration of USP Ciprofloxacin Hydrochloride RS in *Standard solution A* (mg/mL)

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

M_{r1} = molecular weight of ciprofloxacin, 331.34

OFFICIAL

Documents
Document Sharing Hub

Full document details: Ciprofloxacin and Dexamethasone Otic Suspension

M_{r2} = molecular weight of anhydrous ciprofloxacin hydrochloride, 367.81

Acceptance criteria: 90.0%–110.0% of the labeled amount of ciprofloxacin ($C_{17}H_{18}FN_3O_3$)

- **Dexamethasone**

Buffer and **Mobile phase:** Prepare as directed in the test for *Limit of Ciprofloxacin Formamide*.

Standard stock solution: 2 mg/mL of USP Dexamethasone RS in acetonitrile

System suitability solution: 0.2 mg/mL of USP Dexamethasone RS and 0.2 mg/mL of USP Dexamethasone Acetate RS in *Mobile phase*

Standard solution A: 0.2 mg/mL of USP Dexamethasone RS from *Standard stock solution* in *Mobile phase*

Standard solution B: 0.004 mg/mL of USP Dexamethasone RS from *Standard solution A* in *Mobile phase*

Sample solution: Nominally 0.2 mg/mL in *Mobile phase* prepared as follows. Transfer freshly mixed Otic Suspension equivalent to 2 mg of dexamethasone to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution, Standard solution A,* and *Standard solution B*

Suitability requirements

Resolution: NLT 12 between dexamethasone and dexamethasone acetate, *System suitability solution*

Column efficiency: NLT 2000 theoretical plates for dexamethasone, *System suitability solution*

Tailing factor: NMT 2.0 for dexamethasone, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution A* and *Standard solution B*

Analysis

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

Calculate the percentage of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$) in the portion of Otic Suspension taken:

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

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

r_S = peak response of dexamethasone from *Standard solution A*

C_S = concentration of USP Dexamethasone RS in *Standard solution A* (mg/mL)

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

Acceptance criteria: 90.0%–110.0% of the labeled amount of dexamethasone ($C_{22}H_{29}FO_5$)

IMPURITIES

- **Limit of Ciprofloxacin Formamide**

Buffer: Phosphoric acid and water (3:997). Adjust with 50% sodium hydroxide to a pH of 3.0.

Mobile phase: Acetonitrile and *Buffer* (27:73)

Standard stock solution: 0.25 mg/mL of USP Ciprofloxacin Formamide RS in methanol

System suitability solution: 0.025 mg/mL of USP Dexamethasone RS and 0.025 mg/mL of USP Ciprofloxacin Formamide RS prepared as follows. Transfer 2.5 mg of USP Dexamethasone RS and 2.5 mg of USP Ciprofloxacin Formamide RS in a 100-mL volumetric flask, and dissolve in 15 mL of methanol before diluting with *Mobile phase* to volume.

Standard solution: 0.015 mg/mL from *Standard stock solution* in *Mobile phase*

Sample solution: Nominally 0.6 mg/mL in *Mobile phase* prepared as follows. Transfer an amount of freshly mixed Otic Suspension, equivalent to 6 mg, to a 10-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 3.9-mm × 15-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

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

Suitability requirements

Resolution: NLT 8 between ciprofloxacin formamide and dexamethasone, *System suitability solution*

OFFICIAL

Documents
Document Sharing Hub
Full document details: Ciprofloxacin and Dexamethasone Otic Suspension