

Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-May-2022
 Document Type: USP Monographs
 DocId: GUID-923961F5-304D-4264-A068-C381CDEF6872_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M55038_03_01
 DOI Ref: wsi8n

© 2025 USPC
 Do not distribute

Mupirocin Ointment

DEFINITION

Mupirocin Ointment contains NLT 90.0% and NMT 110.0% of the labeled amount of mupirocin ($C_{26}H_{44}O_9$).

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.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 6.0 g/L of [sodium phosphate, monobasic](#). Adjust with [10 N sodium hydroxide TS](#) to a pH of 6.3.

Mobile phase: [Acetonitrile](#) and *Buffer* (1:3)

Standard solution: 0.11 mg/mL of [USP Mupirocin Lithium RS](#) prepared as follows. Transfer a suitable amount of [USP Mupirocin Lithium RS](#) to an adequate volumetric flask, add 25% of the total volume of [acetonitrile](#), and swirl to dissolve. Dilute with *Buffer* to volume.

System suitability solution: Adjust 10 mL of *Standard solution* with [6 N hydrochloric acid TS](#) to a pH of 2.0, allow to stand for 2 h, and adjust with [5 N sodium hydroxide TS](#) to a pH of 6.3.

Sample solution: Nominally 0.1 mg/mL of mupirocin from Ointment prepared as follows. Dissolve a quantity of Ointment, equivalent to 10 mg of mupirocin, in 25 mL of acetonitrile. Transfer this solution, with the aid of *Buffer*, to a 100-mL volumetric flask, and dilute with *Buffer* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 229 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 10-μm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 20 μL

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between mupirocin pyranil analog and mupirocin, *System suitability solution*

[NOTE— Two hydrolysis products are formed, with the following elution order: mupirocin furonyl analog, mupirocin pyranil analog, and mupirocin.]

Tailing factor: NMT 2, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mupirocin ($C_{26}H_{44}O_9$) in the portion of Ointment taken:

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

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

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

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

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

P = potency of mupirocin in [USP Mupirocin Lithium RS](#) (μg/mg)

F = conversion factor, 0.001 mg/μg

Acceptance criteria: 90.0%–110.0%

IMPURITIES**Change to read:**• **ORGANIC IMPURITIES****Solution A:** 10.5 g/L of [ammonium acetate](#). Adjust with [acetic acid, glacial](#) to a pH of 5.7.**Solution B:** [Tetrahydrofuran](#) and [water](#) (1:1)**Solution C:** 13.6 g/L of [sodium acetate, anhydrous](#). Adjust with [acetic acid, glacial](#) to a pH of 4.0.**Mobile phase:** See [Table 1](#).**Table 1**

Time (min)	Solution A (%)	Solution B (%)
0	58	42
25	58	42
45	20	80
60	20	80
65	58	42
75	58	42

Diluent: [Methanol](#) and *Solution C* (1:1)**System suitability solution:** 0.1 mg/mL of [USP Mupirocin Lithium RS](#) in *Diluent*. Adjust with [6 N Hydrochloric Acid TS](#) to a pH of 2.0 and allow to stand for 2 h.**Sensitivity solution:** 0.002 mg/mL of mupirocin from [USP Mupirocin Lithium RS](#) in *Diluent***Standard solution:** 0.025 mg/mL of mupirocin from [USP Mupirocin Lithium RS](#) in *Diluent***Sample solution:** Nominally 5 mg/mL of mupirocin in *Diluent*, prepared as follows. Accurately weigh 5.0 g of Ointment (equivalent to about 100 mg of mupirocin) and transfer it to a 50-mL glass centrifuge test tube. Add 20.0 mL of *Diluent* and sonicate in ice cold water for 5 min to dissolve. Pass through a suitable filter prior to use. Use freshly prepared solution.**Chromatographic system**(See [Chromatography \(621\)](#), [System Suitability](#).)**Mode:** LC**Detector:** UV 240 nm**Column:** 4.6-mm × 25-cm; 5-μm packing [L1](#)**Column temperature:** 30°**Flow rate:** 1.0 mL/min**Injection volume:** 20 μL**System suitability****Samples:** *System suitability solution*, *Sensitivity solution*, and *Standard solution***Suitability requirements****Resolution:** NLT 7.0 between mupirocin pyranil analog and mupirocin, *System suitability solution***Relative standard deviation:** NMT 5.0%, *Standard solution***Signal-to-noise ratio:** NLT 10, *Sensitivity solution***Analysis****Samples:** *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Ointment taken:

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

 r_U = peak area of any impurity from the *Sample solution* r_S = peak area of mupirocin from the *Standard solution* C_S = concentration of [USP Mupirocin Lithium RS](#) in the *Standard solution* (mg/mL) C_U = nominal concentration of mupirocin in the *Sample solution* (mg/mL) P = potency of mupirocin in [USP Mupirocin Lithium RS](#) (μg/mg) F = conversion factor, 0.001 mg/μg