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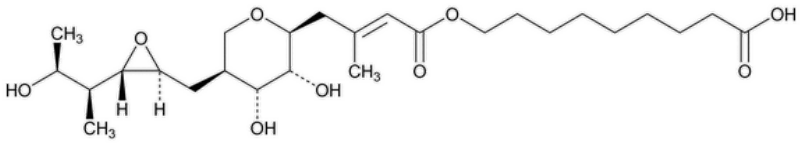
Mupirocin



$C_{26}H_{44}O_9$ 500.62

Nonanoic acid, 9-[[3-methyl-1-oxo-4-[tetrahydro-3,4-dihydroxy-5-[[3-(2-hydroxy-1-methylpropyl)oxiran yl]methyl]-2*H*-pyran-2-yl]-2-butenyl]oxy]-,[2*S*-2α(*E*),3β,4β,5α[2*R**, 3*R**(1*R**,[2*R**)]]]-.

(*E*)-(2*S*,3*R*,4*R*,5*S*)-5-[(2*S*,3*S*,4*S*,5*S*)-2,3-Epoxy-5-hydroxy-4-methylhexyl]tetrahydro-3,4-dihydroxy-β-methyl-2*H*-pyran-2-crotonic acid, ester with 9-hydroxynonanoic acid CAS RN®: 12650-69-0; UNII: D0GX863OA5.

» Mupirocin contains not less than 920 µg and not more than 1020 µg of mupirocin ($C_{26}H_{44}O_9$) per mg, calculated on the anhydrous basis.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—
- USP Mupirocin RS
- USP Mupirocin Lithium RS

Identification—The IR absorption spectrum of a mineral oil dispersion of it exhibits maxima only at the same wavelengths as that of a similar preparation of USP Mupirocin RS.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 3.5 and 4.5, in a saturated aqueous solution.

Water Determination, *Method I* ⟨921⟩: not more than 1.0%.

Assay—

pH 6.3 phosphate buffer—Prepare 0.05 M monobasic sodium phosphate, and adjust with 10 N sodium hydroxide to a pH of 6.3 ± 0.2.

Mobile phase—Prepare a suitable mixture of *pH 6.3 phosphate buffer* and acetonitrile (750:250), pass through a suitable filter of 0.5 µm or finer porosity, and degas. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Transfer about 11 mg of USP Mupirocin Lithium RS, accurately weighed, to a 100-mL volumetric flask, add 25 mL of acetonitrile, and swirl to dissolve. Dilute with *pH 6.3 phosphate buffer* to volume, and mix.

Resolution solution—Adjust 10 mL of *Standard preparation* with 6 N hydrochloric acid to a pH of 2.0, allow to stand for 2 hours, and adjust with 5 N sodium hydroxide to a pH of 6.3 ± 0.2.

Assay preparation—Transfer about 11 mg of Mupirocin, accurately weighed, to a 100-mL volumetric flask, add 25 mL of acetonitrile, and swirl to dissolve. Dilute with *pH 6.3 phosphate buffer* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 229-nm detector and a 4.6-mm × 25-cm column that contains packing L1 based on spherical silica particles. The flow rate is about 2 mL per minute. Chromatograph the *Resolution solution*, and record the peak responses as directed for *Procedure:* the relative retention times are about 0.9 for the mupirocin acid hydrolysis product and 1.0 for mupirocin, and the resolution, *R,* between the mupirocin acid hydrolysis product and mupirocin is not less than 2.0. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2, the column efficiency is not less than 1500 theoretical plates when calculated by the formula:

$$5.545(t_r/W_{h/2})^2$$

in which the terms are as defined therein. The relative standard deviation for replicate injections is not more than 2.0%.

Procedure—[Note—Use peak areas where peak responses are indicated.] Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in µg, of mupirocin ($C_{26}H_{44}O_9$) in each mg of Mupirocin taken by the formula:

$$(M_S E/M_U)(r_U/r_S)$$

in which M_S is the weight, in mg, of USP Mupirocin Lithium RS taken to prepare the *Standard preparation; E* is the mupirocin equivalent, in µg per mg, of USP Mupirocin Lithium RS; M_U is the weight, in mg, of mupirocin taken to prepare the *Assay preparation;* and r_U and r_S are the mupirocin peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
MUPIROCIN	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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