constant temperature up to 35°. The chromatograph is programmed as follows.

Time (minutes)	*Solution A* (%)	*Solution B* (%)	Elution
0	100	0	equilibration
0–6	100	0	isocratic
6–35	100→0	0→100	linear gradient
35–55	0	100	isocratic
55–55.01	0→100	100→0	immediate
55.01–65	100	0	isocratic

Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure.* [NOTE—Pseudomonic acid D is a minor component that is always present in mupirocin calcium.] Identify the peaks by their retention times which are about 0.75 for pseudomonic acid D and 1.0 for mupirocin: the resolution, *R,* between pseudomonic acid D and mupirocin is not less than 3; the column efficiency for the mupirocin peak is not less than 7000 theoretical plates; the tailing factor for the mupirocin peak is not more than 1.75; and the relative standard deviation of the mupirocin peak for replicate injections is not more than 2%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak area responses for the major peaks. Calculate the percent label claim of mupirocin in the portion of Cream taken by the formula:

$$(P / 1000)(C_S / C_U)(r_U / r_S)(100)$$

in which $P / 1000$ is the potency of mupirocin, converted from µg per mg to mg per mg, in USP Mupirocin Lithium RS; C_S is the concentration, in mg per mL, of USP Mupirocin Lithium RS in the *Standard preparation;* C_U is the nominal concentration, in mg per mL, of Cream in the *Assay preparation;* and r_U and r_S are the mupirocin peak area responses obtained from the *Assay preparation* and the *Standard preparation,* respectively.

Mupirocin Ointment

» Mupirocin Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of mupirocin ($C_{26}H_{44}O_9$).

Packaging and storage—Preserve in collapsible tubes or in well-closed containers.

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

Identification—The chromatogram of the *Assay preparation* obtained as directed in the *Assay* exhibits a major peak for mupirocin, the retention time of which corresponds to that exhibited in the chromatogram of the *Standard preparation* obtained as directed in the *Assay*.

Minimum fill ⟨755⟩**:** meets the requirements.

Assay—

pH 6.3 phosphate buffer, Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Mupirocin*.

Assay preparation—Dissolve an accurately weighed quantity of Ointment, equivalent to about 10 mg of mupirocin, in 25 mL of acetonitrile. Transfer this solution, with the aid of *pH 6.3 phosphate buffer*, to a 100-mL volumetric flask, dilute with *pH 6.3 phosphate buffer* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Mupirocin*. Calculate the quantity, in mg, of mupirocin ($C_{26}H_{44}O_9$) in the portion of Ointment taken by the formula:

$$(M_S E / 1000)(r_U / r_S)$$

in which the terms are as defined therein.

Mupirocin Nasal Ointment

» Mupirocin Nasal Ointment contains a quantity of Mupirocin Calcium equivalent to not less than 90.0 percent and not more than 105.0 percent of the labeled amount of mupirocin ($C_{26}H_{44}O_9$).

Packaging and storage—Preserve in collapsible tubes or in well-closed containers, and store at controlled room temperature.

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

Identification—

A: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay*.

Microbial enumeration tests ⟨61⟩ **and Tests for specified microorganisms** ⟨62⟩**—**The total aerobic microbial count does not exceed 100 cfu per g, and the total combined molds and yeasts count does not exceed 10 cfu per g. It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

Minimum fill ⟨755⟩**:** meets the requirements.

Uniformity of dosage units ⟨905⟩**:** meets the requirements.

Related compounds—

Ammonium acetate buffer, Mobile phase, Sodium acetate buffer, Diluent A, Diluent B, and *Chromatographic system*—Prepare as directed in the *Assay.*

Test solution—Transfer an accurately weighed portion of Mupirocin Nasal Ointment, equivalent to about 50 mg of mupirocin, to a suitable stoppered conical flask, add 5 mL of *Diluent A,* and shake vigorously on a mechanical shaker at full speed for 1 hour to disperse the ointment. Add 5 mL of *Sodium acetate buffer,* and shake vigorously on a mechanical shaker at full speed for 15 minutes. Pass through a filter having a porosity of 0.45 µm.

Diluted test solution—Dilute a portion of the *Test solution* quantitatively, and stepwise if necessary, with *Diluent B* to obtain a solution having a nominal concentration of about 0.1 mg of mupirocin per mL, based on the label claim.

Procedure—Separately inject equal volumes (about 20 µL) of the *Test solution* and the *Diluted test solution* into the chromatograph, and measure the peak area responses for all the peaks. Identify the peaks by the relative retention times shown in *Table 1.*