or any mixture of official flavoring substances. Sixty mL of sweet orange peel tincture or 2 g of benzoic acid may be used as a preservative in place of the Alcohol.

For other permissible modifications, see *Emulsions* ⟨1151⟩.

Packaging and storage—Preserve in tight containers.

Alcohol content, *Method I* ⟨611⟩: between 4.0% and 6.0% of C_2H_5OH.

Mineral Oil, Rectal

» Mineral Oil, Rectal, is Mineral Oil that has been suitably packaged.

Packaging and storage—Preserve in tight, light-resistant, single-unit containers. No storage requirements specified.

USP Reference standards ⟨11⟩—
USP Mineral Oil RS

Identification—

A: *Infrared Absorption* ⟨197F⟩.

B: It meets the requirements of the test for *Viscosity*.

Specific gravity ⟨841⟩: between 0.845 and 0.905.

Viscosity ⟨911⟩—Perform the test at 40.0 ± 0.1° using a suitable capillary viscometer: the kinematic viscosity is between 34.5 and 150.0 $mm^2 \cdot s^{-1}$.

Acidity—Add 20 mL of boiling water to 10 mL of Mineral Oil, Rectal, and shake vigorously for about 1 minute. Allow to cool, and draw off the separated water. To 10 mL of the filtrated aqueous layer add 0.1 mL of phenolphthalein TS: the solution does not produce a pink color. Not more than 1.0 mL of 0.01 N sodium hydroxide is required to change the color to pink.

Topical Light Mineral Oil

» Topical Light Mineral Oil is Light Mineral Oil that has been suitably packaged.

Packaging and storage—Preserve in tight, light-resistant containers. No storage requirements specified.

Labeling—Label it to indicate the name and quantity of any substance added as a stabilizer, and label packages intended for direct use by the public to indicate that it is not intended for internal use.

USP Reference standards ⟨11⟩—
USP Mineral Oil RS

Identification—

A: *Infrared Absorption* ⟨197F⟩.

B: It meets the requirements of the test for *Viscosity*.

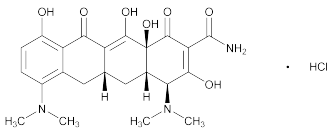
Specific gravity ⟨841⟩: between 0.818 and 0.880.

Viscosity ⟨911⟩—Perform the test at 40.0 ± 0.1° using a suitable capillary viscometer: the kinematic viscosity is between 3.0 and 34.4 $mm^2 \cdot s^{-1}$.

Acidity—Add 20 mL of boiling water to 10 mL of Topical Light Mineral Oil, and shake vigorously for about 1 minute. Allow to cool, and draw off the separated water. To 10 mL of the filtrated aqueous layer add 0.1 mL of phenolphthalein TS: the solution does not produce a pink color. Not more than 1.0 mL of 0.01 N sodium hydroxide is required to change the color to pink.

Solid paraffin—Fill a tall, cylindrical, standard oil-sample bottle of colorless glass of about 120-mL capacity with Topical Light Mineral Oil that has been dried previously in a beaker at 105° for 2 hours and cooled to room temperature in a desiccator over silica gel. Insert the stopper, and immerse the bottle in a mixture of ice and water for 4 hours: the test specimen is sufficiently clear that a black line 0.5 mm in width, on a white background, held vertically behind the bottle, is clearly visible.

Minocycline Hydrochloride



$C_{23}H_{27}N_3O_7 \cdot HCl$ 493.94

2-Naphthacenecarboxamide, 4,7-bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11dioxo-, monohydrochloride, [4*S*-(4α,4aα,5aα,12aα)]-;
4,7-Bis(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,10,12,12a-tetrahydroxy-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride [13614-98-7].

DEFINITION

Minocycline Hydrochloride contains the equivalent of NLT 890 µg and NMT 950 µg of minocycline ($C_{23}H_{27}N_3O_7$) per mg, calculated on the anhydrous basis.

IDENTIFICATION

• **INFRARED ABSORPTION** ⟨197K⟩**:** Dry the *Standard* and *Sample* at 100° for 2 h before use.

ASSAY

• **PROCEDURE**

[NOTE—Protect the *Standard solution* and *Sample solution* from light, store in a refrigerator, and use within 3 h.]

Mobile phase: Dimethylformamide, tetrahydrofuran, 0.2 M ammonium oxalate, and 0.01 M edetate disodium (120:80:600:180). Adjust with ammonium hydroxide to a pH of 7.2.

System suitability solution: Dissolve 10 mg of USP Minocycline Hydrochloride RS in 20 mL of 0.2 M ammonium oxalate. Heat on a water bath at 60° for 3 h, allow to cool, and dilute with water to 25.0 mL.

Standard solution: Equivalent to 500 µg/mL of minocycline ($C_{23}H_{27}N_3O_7$) from USP Minocycline Hydrochloride RS in water

Sample solution: Equivalent to 500 µg/mL of minocycline ($C_{23}H_{27}N_3O_7$) from Minocycline Hydrochloride in water

Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 280 nm
Column: 4.6-mm × 25-cm; 5-µm packing L1
Column temperature: 40°
Flow rate: 1.5 mL/min
Injection size: 20 µL

System suitability
Samples: *System suitability solution* and *Standard solution*
[NOTE—The relative retention times for epiminocycline and minocycline are 0.7 and 1.0, respectively.]
Suitability requirements
Resolution: NLT 4.6 between epiminocycline and minocycline, *System suitability solution*
Tailing factor: 0.9–2.0 for the analyte peak, *Standard solution*
Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the quantity, in µg/mg, of minocycline ($C_{23}H_{27}N_3O_7$) in the portion of Minocycline Hydrochloride taken:

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

r_U = peak response from the *Sample solution*
r_S = peak response from the *Standard solution*
C_S = concentration of minocycline in the *Standard solution* (µg/mL)
C_U = concentration of the *Sample solution* (µg/mL)
P = potency of USP Minocycline Hydrochloride RS (µg/mg)

Acceptance criteria: 890–950 µg/mg on the anhydrous basis

IMPURITIES
Inorganic Impurities
- **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.15%
- **HEAVY METALS,** *Method II* **⟨231⟩:** NMT 50 ppm

Organic Impurities
- **PROCEDURE**

Mobile phase and **System suitability solution:** Proceed as directed in the *Assay*
[NOTE—Protect the *Sample solutions* from light, store in a refrigerator, and use within 3 h.]
Sample solution 1: 0.25 mg/mL of Minocycline Hydrochloride
Sample solution 2: 5 µg/mL of Minocycline Hydrochloride in water
Sample solution 3: 3 µg/mL of Minocycline Hydrochloride in water
Chromatographic system: Proceed as directed in the *Assay*.
Run time: 2.6 times the retention time of minocycline, *Sample solution 1*
Analysis
Samples: *Sample solution 1*, *Sample solution 2*, and *Sample solution 3*
Calculate the percentage of epiminocycline in the portion of Minocycline Hydrochloride taken:

$$\text{Result} = (r_{E1}/r_{M3}) \times D_1 \times 100$$

r_{E1} = peak response of epiminocycline from *Sample solution 1*
r_{M3} = peak response of minocycline from *Sample solution 3*
D_1 = dilution factor for *Sample solution 3*

Calculate the total percentage of impurities other than epiminocycline in the portion of Minocycline Hydrochloride taken:

$$\text{Result} = (r_T/r_{M2}) \times D_2 \times 100$$

r_T = sum of peak responses of all impurities other than epiminocycline from *Sample solution 1*
r_{M2} = peak response of minocycline from *Sample solution 2*
D_2 = dilution factor for *Sample solution 2*

Acceptance criteria
Individual impurities: NMT 1.2% epiminocycline
Total impurities (excluding epiminocycline): NMT 2.0%

SPECIFIC TESTS
- **CRYSTALLINITY ⟨695⟩:** Meets the requirements
- **pH ⟨791⟩:** 3.5–4.5, in a solution equivalent to 10 mg/mL of minocycline
- **WATER DETERMINATION,** *Method I* **⟨921⟩:** 4.3%–8.0%
- **STERILITY TESTS ⟨71⟩:** Where the label states that Minocycline Hydrochloride is sterile, it meets the requirements.
- **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** Where the label states that Minocycline Hydrochloride is sterile or must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 1.25 USP Endotoxin Units/mg of minocycline.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light.
- **LABELING:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.
- **USP REFERENCE STANDARDS ⟨11⟩**
  USP Endotoxin RS
  USP Minocycline Hydrochloride RS

Minocycline Hydrochloride Capsules

» Minocycline Hydrochloride Capsules contain the equivalent of not less than 90.0 percent and not more than 115.0 percent of the labeled amount of minocycline ($C_{23}H_{27}N_3O_7$).

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—
USP Minocycline Hydrochloride RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* obtained as directed in the *Assay*.

Dissolution ⟨711⟩—
Medium: water; 900 mL.
Apparatus 2: 50 rpm.
Time: 45 minutes.

Procedure—Determine the amount of $C_{23}H_{27}N_3O_7$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 348 nm of filtered portions of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Minocycline Hydrochloride RS in the same medium.

Tolerances—Not less than 75% *(Q)* of the labeled amount of $C_{23}H_{27}N_3O_7$ is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Water, *Method I* **⟨921⟩:** not more than 12.0%.

Assay—
Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Minocycline Hydrochloride*.

Assay preparation—Weigh the contents of not less than 20 Capsules, and calculate the average weight per Capsule. Mix the combined contents of the Capsules, transfer an accurately weighed portion, equivalent to about 50 mg of minocycline ($C_{23}H_{27}N_3O_7$), to a 100-mL volumetric flask, add about 50 mL of water, and shake to dissolve. Dilute with water to volume, mix, and filter.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Minocycline Hydrochloride*. Calculate the quantity, in mg,