Packaging and storage—Preserve in tight, light-resistant containers, and store in a cool place.

USP Reference standards ⟨11⟩—
USP Oxytetracycline RS

Identification—Dissolve a suitable quantity in methanol to obtain a *Test Solution* containing 1 mg of oxytetracycline per mL, and proceed as directed for *Method II* under *Identification—Tetracyclines* ⟨193⟩.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 6.0 and 8.0, in an aqueous suspension containing 25 mg per mL.

Water, *Method I* ⟨921⟩: between 8.0% and 14.0%.

Calcium content—Proceed as directed under *Residue on Ignition* ⟨281⟩, except to ignite at 550 ± 50° instead of at 800 ± 25°: the weight of residue so obtained, multiplied by 0.2944, gives the equivalent of calcium in the Oxytetracycline Calcium taken. The calcium content is between 3.85% and 4.35%, calculated on the anhydrous basis.

Assay—Dissolve an accurately weighed quantity of Oxytetracycline Calcium in an accurately measured volume of 0.1 N hydrochloric acid to obtain a stock solution having a concentration of about 1000 µg of oxytetracycline per mL. Proceed as directed for oxytetracycline under *Antibiotics—Microbial* ⟨81⟩, using an accurately measured volume of the stock solution diluted quantitatively and stepwise with water to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Oxytetracycline Calcium Oral Suspension

» Oxytetracycline Calcium Oral Suspension contains the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$). It contains one or more suitable buffers, colors, flavors, preservatives, stabilizers, and suspending agents. In addition, it may contain N-acetylglucosamine.

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

USP Reference standards ⟨11⟩—
USP Oxytetracycline RS

Identification—Shake a suitable quantity of Oral Suspension with methanol to obtain a solution containing 1 mg of oxytetracycline per mL, and filter. Using the filtrate as the *Test Solution*, proceed as directed for *Method II* under *Identification—Tetracyclines* ⟨193⟩.

Uniformity of dosage units ⟨905⟩—

FOR SOLID PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

Deliverable volume ⟨698⟩: meets the requirements.

pH ⟨791⟩: between 5.0 and 8.0.

Assay—Transfer an accurately measured quantity of Oral Suspension, freshly mixed and free from air bubbles, equivalent to about 150 mg of oxytetracycline, to a 1000-mL volumetric flask, dilute with 0.1 N hydrochloric acid to volume, and mix. Proceed as directed for oxytetracycline under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of this stock solution diluted quantitatively and stepwise with water to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Oxytetracycline Hydrochloride

$C_{22}H_{24}N_2O_9 \cdot HCl$ 496.90

2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-, monohydrochloride, [4*S*-(4α,4aα,5α,5aα,6β,12aα)]-.

4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,6,10,12,12a-hexahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrochloride [2058-46-0].

» Oxytetracycline Hydrochloride has a potency equivalent to not less than 835 µg of oxytetracycline ($C_{22}H_{24}N_2O_9$) per mg, calculated on the dried basis.

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

Labeling—Where it is intended for use in preparing injectable or ophthalmic dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable or ophthalmic dosage forms.

USP Reference standards ⟨11⟩—
USP Endotoxin RS
USP Oxytetracycline RS

Identification—

A: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 20 µg per mL.

Medium: 0.1 N hydrochloric acid.

Absorptivity, calculated on the dried basis, at 353 nm is between 88.2% and 96.8% of that of USP Oxytetracycline RS, the potency of the Reference Standard being taken into account.

B: To 1 mg add 2 mL of sulfuric acid: a light red color is produced.

Crystallinity ⟨695⟩: meets the requirements.

pH ⟨791⟩: between 2.0 and 3.0, in a solution containing 10 mg per mL.

Loss on drying ⟨731⟩—Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 2.0% of its weight.

Other requirements—Where the label states that Oxytetracycline Hydrochloride is sterile, it meets the requirements for *Sterility* and *Bacterial endotoxins* under *Oxytetracycline for Injection*. Where the label states that Oxytetracycline Hydrochloride must be subjected to further processing during the preparation of injectable dosage forms, it meets the requirements for *Bacterial endotoxins* under *Oxytetracycline for Injection*. Where it is intended for use in preparing ophthalmic dosage forms, it is exempt from the requirements for *Bacterial endotoxins.*

Assay—

Tetrabutylammonium hydrogen sulfate solution, Edetate disodium solution, pH 7.5 Phosphate buffer, Mobile phase, Standard preparation, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Oxytetracycline*.

Assay preparation—Transfer about 44 mg of Oxytetracycline Hydrochloride to a 200-mL volumetric flask, add about 25 mL of 0.01 N hydrochloric acid, swirl to dissolve, dilute with 0.01 N hydrochloric acid to volume, and mix.

Procedure—Proceed as directed in the *Assay* under *Oxytetracycline*. Calculate the quantity, in µg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in each mg of Oxytetracycline Hydrochloride taken by the formula:

$$200(CP / W)(r_U / r_S)$$

in which the terms are as defined therein.

Oxytetracycline Hydrochloride Capsules

» Oxytetracycline Hydrochloride Capsules contain the equivalent of not less than 90.0 percent and not more than 120.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$).

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

USP Reference standards ⟨11⟩**—**
USP Oxytetracycline RS

Identification—Shake a suitable quantity of Capsule contents with methanol to obtain a solution containing 1 mg of oxytetracycline per mL, and filter. Using the filtrate as the *Test Solution*, proceed as directed for *Method II* under *Identification—Tetracyclines* ⟨193⟩.

Dissolution ⟨711⟩**—**

Medium: water; 900 mL.

Apparatus 2: 75 rpm.

Time: 60 minutes.

Procedure—Determine the amount of $C_{22}H_{24}N_2O_9$ dissolved from UV absorbances at the wavelength of maximum absorbance at about 273 nm of filtered portions of the solution under test, suitably diluted with water, in comparison with a Standard solution having a known concentration of USP Oxytetracycline RS in the same medium, using 5 mL of 0.1 N hydrochloric acid to dissolve the Standard.

Tolerances—Not less than 80% *(Q)* of the labeled amount of $C_{22}H_{24}N_2O_9$ is dissolved in 60 minutes.

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

Loss on drying ⟨731⟩**—**Dry about 100 mg of Capsule contents, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 5.0% of its weight.

Assay—

Tetrabutylammonium hydrogen sulfate solution, *Edetate disodium solution*, *pH 7.5 Phosphate buffer*, *Mobile phase*, *Standard preparation*, *Resolution solution*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Oxytetracycline*.

Assay preparation—Remove, as completely as possible, the contents of not less than 20 Capsules, and mix. Transfer an accurately weighed portion of the powder, equivalent to about 100 mg of oxytetracycline, to a 500-mL volumetric flask, add about 50 mL of 0.01 N hydrochloric acid, and swirl to dissolve. Dilute with 0.01 N hydrochloric acid to volume, mix, and filter a portion of the solution through a 0.5-µm or finer porosity filter. Use the filtrate as the *Assay preparation.*

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in the portion of Capsules taken by the formula:

$$0.5(CP)(r_U / r_S)$$

in which the terms are as defined therein.

Oxytetracycline for Injection

» Oxytetracycline for Injection contains an amount of Oxytetracycline Hydrochloride equivalent to not less than 90.0 percent and not more than 115.0 percent of the labeled amount of oxytetracycline ($C_{22}H_{24}N_2O_9$).

Packaging and storage—Preserve in *Containers for Sterile Solids* as described under *Injections* ⟨1⟩, protected from light.

USP Reference standards ⟨11⟩**—**
USP Endotoxin RS
USP Oxytetracycline RS

Constituted solution—At the time of use, it meets the requirements for *Constituted Solutions* under *Injections* ⟨1⟩.

Bacterial endotoxins ⟨85⟩**—**It contains not more than 0.4 USP Endotoxin Unit per mg of oxytetracycline.

Sterility ⟨71⟩**—**It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*, *Fluid D* being used instead of *Fluid A*.

pH ⟨791⟩: between 1.8 and 2.8, in a solution containing 25 mg per mL.

Loss on drying ⟨731⟩**—**Dry about 100 mg, accurately weighed, in a capillary-stoppered bottle in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 3.0% of its weight.

Particulate matter ⟨788⟩: meets the requirements for small-volume injections.

Other requirements—It responds to *Identification* test *B* under *Oxytetracycline Hydrochloride*. It also meets the requirements for *Uniformity of Dosage Units* ⟨905⟩ and *Labeling* under *Injections* ⟨1⟩.

Assay—

Tetrabutylammonium hydrogen sulfate solution, Edetate disodium solution, pH 7.5 Phosphate buffer, Mobile phase, Standard preparation, System suitability solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Oxytetracycline*.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Oxytetracycline for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with 0.01 N hydrochloric acid to obtain a solution having a concentration of about 0.2 mg of oxytetracycline per mL.

Assay preparation 2 (where the label states the quantity of oxytetracycline in a given volume of constituted solution)—Constitute Oxytetracycline for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with 0.01 N hydrochloric acid to obtain a solution having a concentration of about 0.2 mg of oxytetracycline per mL.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Oxytetracycline*. Calculate the quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) withdrawn from the container or in the portion of constituted solution taken by the formula:

$$(L / D)(CP)(r_U / r_S)$$

in which L is the labeled quantity, in mg, of oxytetracycline ($C_{22}H_{24}N_2O_9$) in the container or in the portion of constituted solution taken; D is the concentration, in mg per mL, of oxytetracycline in *Assay preparation 1* or in *Assay preparation 2*, based on the labeled quantity in the container or in the portion of constituted solution taken, respectively, and the extent of dilution; and the other terms are as defined therein.

Oxytetracycline Hydrochloride Soluble Powder

» Oxytetracycline Hydrochloride Soluble Powder is a dry mixture of Oxytetracycline Hydrochloride and one or more suitable excipients. It contains not less than 90.0 percent and not more than