Tylosin Tartrate

(10*E*,12*E*)-(3*R*,4*S*,5*S*,6*R*,8*R*,14*S*,15*R*)-14-[(6-deoxy-2,3-di-*O*-methyl-β-D-allopyranosyl)oxymethyl]-5-[[3,6-dideoxy-4-*O*-(2,6-dideoxy-3-*C*-methyl-α-L-ribo-hexopyranosyl)-3-dimethylamino-β-D-glucopyranosyl]oxy]-6-formylmethyl-3-hydroxy-4,8,12-trimethyl-9-oxoheptadeca-10,12-dien-15-olide.
Tylosin A (Tylosin)

916.10 CAS RN®: 1401-69-0; UNII: YEF4JXN031.

» Tylosin Tartrate is a tartrate of a mixture of macrolide antibiotic substances, or the mixture of such substances, produced by the growth of *Streptomyces fradiae,* or by any other means. Its potency is not less than 800 µg of tylosin per mg, calculated on the dried basis.

Packaging and storage—Preserve in well-closed containers, protected from light, moisture, and excessive heat. Store at 25°, excursions permitted between 15° and 30°.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference Standards ⟨11⟩—
USP Tylosin RS
USP Tylosin Tartrate RS

Change to read:

Identification—

A: ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy*: 197K▲ (CN 1-May-2020)

B: The retention time of the major peak for tylosin A in the chromatogram of the *Test solution* corresponds to that in the chromatogram of the *Standard solution,* as obtained in the test for *Content of tylosins*.

C: It meets the requirements of the test for *Tartrate* ⟨191⟩.

pH ⟨791⟩**:** between 5.0 and 7.2 in a solution prepared by dissolving 0.25 g in 10 mL of carbon dioxide-free water.

Loss on Drying ⟨731⟩—Dry about 1 g, accurately weighed, in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 4.5% of its weight.

Residue on Ignition ⟨281⟩**:** not more than 2.5%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Limit of tyramine—In a 25-mL volumetric flask, dissolve 50.0 mg of tylosin in 5.0 mL of a 3.4 g per L solution of phosphoric acid. Add 1.0 mL of pyridine and 2.0 mL of a saturated solution of ninhydrin (about 40 g per L). Close the flask with aluminum foil, and heat in a water bath at 85° for 30 minutes. Cool the solution rapidly to room temperature, and dilute with water to volume. Mix, and measure immediately the absorbance (see *Ultraviolet-Visible Spectroscopy* ⟨857⟩) of the solution at 570 nm against a blank solution prepared in a similar manner. The absorbance is not greater than that of a standard prepared at the same time and in the same manner using 5.0 mL of a 35 mg per L solution of tyramine in a 3.4 g per L solution of phosphoric acid. If intended for use in the manufacture of parenteral dosage forms, the absorbance is not greater than that of a standard prepared at the same time and in the same manner using 5.0 mL of a 15 mg per L solution of tyramine in a 3.4 g per L solution of phosphoric acid.

Content of tylosins—

Mobile phase—Prepare a mixture of filtered 200 g per L of sodium perchlorate, previously adjusted with 1 N hydrochloric acid to a pH of 2.5 ± 0.1, and acetonitrile (60:40). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard solution—Dissolve an accurately weighed quantity of USP Tylosin RS in a mixture of acetonitrile and water (1:1) to obtain a solution having a known concentration of about 0.2 mg per mL. [Note—Prepare the *Standard solution* immediately before use.]

Test solution—Dissolve an accurately weighed quantity of Tylosin in a mixture of acetonitrile and water (1:1) to obtain a solution having a known concentration of about 0.2 mg per mL. [Note—Prepare the *Test solution* immediately before use.]

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 290-nm detector and a 4.6-mm × 20-cm column that contains 5-µm packing L1. The flow rate is about 1.0 mL per minute and the column temperature is maintained at 35°. Chromatograph the *Standard solution,* and record the peak responses as directed for *Procedure:* the order of elution is tylosin C, tylosin B, tylosin D, and tylosin A with relative retention times of about 0.5, 0.6, 0.8, and 1.0 minutes, respectively; the resolution of the peaks representing tylosin D and tylosin A is not less than 2.0; the tailing factors are not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solution* and the *Test solution* into the chromatograph, record the

chromatograms over a period of time equivalent to 1.5 times the elution time of the main tylosin A peak, and measure the peak areas for all the peaks. Calculate the percentages of tylosin A, tylosin B, tylosin C, and tylosin D in the Tylosin taken by the formula:

$$100(r_I/r_S)$$

in which r_I is the area of the tylosin A peak, the tylosin B peak, the tylosin C peak, or the tylosin D peak, as appropriate, in the chromatogram obtained from the *Test solution;* and r_S is the sum of the areas of all the peaks in the chromatogram obtained from the *Test solution:* the content of tylosin A is not less than 80%; and the sum of the contents of tylosin A, tylosin B, tylosin C, and tylosin D is not less than 95%.

Assay—Proceed as directed for Tylosin under *Antibiotics—Microbial Assays* ⟨81⟩. Prepare the *Test Dilution* as follows. Transfer an accurately weighed quantity of Tylosin Tartrate, equivalent to about 250 mg of tylosin, to a 500-mL volumetric flask, add 50 mL of methanol, and swirl to dissolve. Dilute with *Buffer B.3* to volume, and mix. Transfer 4.0 mL of this solution to a second 500-mL volumetric flask, dilute with a mixture of *Buffer B.3* and methanol (1:1), and mix. This solution contains about 4 µg of tylosin per mL.

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

Topic/Question	Contact	Expert Committee
TYLOSIN TARTRATE	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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