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Tylosin Injection

DEFINITION
Tylosin Injection is a sterile solution of tylosin in a suitable vehicle. It contains NLT 85.0% and NMT 115.0% of the labeled amount of tylosin.

IDENTIFICATION
The retention time of the major peak for tylosin A in the *Sample solution* corresponds to that in the *Standard solution*, as obtained in the test for *Content of Tylosins*.

ASSAY

• **Procedure**

Standard: USP Tylosin RS

Analysis: Proceed as directed for *Tylosin* under *Antibiotics—Microbial Assays* ⟨81⟩. Prepare the *Test Dilution* as follows. Transfer a measured volume of Injection, 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 No. 3* to volume, and mix. Transfer 4.0 mL of this solution to a second 500-mL volumetric flask, dilute with a mixture of methanol and *Buffer No. 3* (1:1), and mix. This solution contains about 4 µg of tylosin/mL.

Acceptance criteria: 85.0%–115.0%

SPECIFIC TESTS

• **Content of Tylosins**

Solution A: 184 g/L of sodium perchlorate in water.

Mobile phase: Acetonitrile and *Solution A* (2:3). Adjust with 1 N hydrochloric acid to a pH of 2.5 ± 0.1, and filter. [Note—Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).]

Diluent: Methanol and water (1:9)

Standard solution: 0.3 mg/mL of USP Tylosin RS in *Diluent*

Sample solution: Dilute an accurately measured volume of Injection with *Diluent* to obtain a solution having a nominal concentration of 0.25 mg/mL.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 20-cm column; 5-µm packing L1

Column temperature: 25°

Flow rate: 0.7 mL/min

Injection volume: 20 µL

Run time: 1.5 times the retention time of tylosin A peak

System suitability

Sample: *Standard solution*

[Note—The relative retention times in *Table 1* are provided as information that aid in peak assignment.]

Table 1

Name	Relative Retention Time
Tylosin C[a]	0.5
Tylosin B[b]	0.6

Name	Relative Retention Time
Tylosin D[c]	0.8
Tylosin A[d]	1.0

[a] (10*E*,12*E*)-(3*R*,4*S*,5*S*,6*R*,8*R*,14*S*,15*R*)-14-[(6-Deoxy-2-*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.

[b] (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-3-dimethylamino-β-D-glucopyranosyl]oxy]-6-formylmethyl-3-hydroxy-4,8,12-trimethyl-9-oxoheptadeca-10,12-dien-15-olide.

[c] (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-(2-hydroxyethyl)-3-hydroxy-4,8,12-trimethyl-9-oxoheptadeca-10,12-dien-15-olide.

[d] (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.

Suitability requirements

Resolution: NLT 2.8 between tylosin D and tylosin A peaks

Tailing factor: NMT 1.5 for tylosin A peak

Analysis

Samples: *Sample solution*

Calculate the percentages of tylosin A, tylosin B, tylosin C, and tylosin D in the portion of Injection taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = response of the tylosin A peak, the tylosin B peak, the tylosin C peak, or the tylosin D peak, as appropriate, from the *Sample solution*

r_T = sum of responses of all peaks from the *Sample solution*

Acceptance criteria

Content of tylosin A: NLT 75%

Sum of contents of tylosin A, tylosin B, tylosin C, and tylosin D: NLT 85%

• **Particulate Matter in Injections ⟨788⟩:** Use the procedure in *Method 2—Microscopic Particle Count Test:* NMT 50 particles/mL that are equal to or greater than 10 µm in effective spherical diameter are found, and NMT 5 particles/mL that are equal to or greater than 25 µm in effective spherical diameter are found.

• **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.28 USP Endotoxin Units/mg of tylosin

• **Sterility Tests ⟨71⟩:** Meets the requirements

Change to read:

• **▲pH ⟨791⟩:▲** (ERR 1-Jun-2024) 8.0–9.5

• **Other Requirements:** It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, amber glass, preferably Type I or Type II, and store at a temperature not to exceed 22°.

• **Labeling:** Label it to indicate that it is for veterinary use only.

• **USP Reference Standards ⟨11⟩**

USP Tylosin RS

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

Topic/Question	Contact	Expert Committee
TYLOSIN INJECTION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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