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Tylosin Granulated

» Tylosin Granulated contains tylosin phosphate mixed with suitable carriers and inactive ingredients. It contains not less than 80.0 percent and not more than 120.0 percent of the labeled amount of tylosin.

Packaging and storage—Preserve in well-closed, polyethylene-lined or polypropylene-lined containers, protected from moisture and excessive heat.

Labeling—Label it to indicate that it is for animal use only. Label it also to indicate that it is for manufacturing, processing, or repackaging.

USP Reference standards ⟨11⟩—

USP Tylosin RS

Identification—

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

B: Transfer 2 g of Tylosin Granulated to a test tube, add 10 mL of water, and shake for 5 minutes. Filter the resulting suspension, and if necessary adjust the pH of the filtrate to a pH between 6 and 8 with 0.1 N sodium hydroxide or 0.1 N hydrochloric acid. This solution responds to the tests for *Phosphate ⟨191⟩*.

Loss on drying ⟨731⟩—Dry about 1 g of it, accurately weighed, in vacuum at a pressure of not more than 5 mm of mercury at 60° for 5 hours: it loses not more than 12.0% of its weight.

Powder fineness ⟨811⟩: not less than 99% passes a No. 20 sieve, and not more than 10% passes a No. 80 sieve.

Content of tylosins—

Mobile phase, *Standard solution*, and *Chromatographic system*—Proceed as directed in the test for *Content of tylosins* under *Tylosin.*

pH 7.0 buffer—Dissolve 13.6 g of monobasic potassium phosphate in 1000 mL of water, and adjust with 12 N sodium hydroxide to a pH of 7.0.

Test solution—Transfer about 1.4 g of Tylosin Granulated, accurately weighed, to a 250-mL volumetric flask, add 100 mL of *pH 7.0 buffer*, and shake by mechanical means for about 30 minutes. Dilute with water to volume, mix, and filter. Transfer 10.0 mL of the filtrate to a 50-mL volumetric flask, dilute with water to volume, and mix. Filter a portion of this solution through a filter having a porosity of 0.5 µm or finer, and use the filtrate as the *Test solution*.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard solutions* and the *Test solution* into the chromatograph, record the chromatograms over a period of time that is about twice the elution time of the main tylosin A peak, and measure the areas for all the major peaks: the relative retention times are about 0.5 for tylosin C, 0.7 for tylosin B, 0.9 for tylosin D, and 1.0 for tylosin A. 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, tylosin B peak, tylosin C peak, or tylosin D peak, as appropriate, in the chromatogram obtained from the *Test solution*, and r_s is the sum of the areas of all of 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 about 2 g of Tylosin Granulated, accurately weighed, to a suitable container, add 200.0 mL of a mixture of *Buffer B.3* and methanol (1:1), seal to prevent evaporation, and shake by mechanical means for about 60 minutes. Filter the suspension so obtained, discarding the first 5 mL of the filtrate. Dilute an accurately measured portion of the filtrate quantitatively and stepwise with a mixture of *Buffer B.3* and methanol (1:1) to obtain a *Test Dilution* having an estimated concentration of about 4 µg of tylosin per mL.

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

Chromatographic Database Information: Chromatographic Database

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