

**TILOSINA TARTRATO USO VETERINARIO (EUR. PH.)**

PRODUCT CODE: 94	CAS Nº: 1405-54-5	ANALYSIS Nº: 228/25
MANUFACTURER BATCH: J250203002	CERTIFICATE ID: 47.492	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 10/02/2025	
METAPH BATCH: 0260725	EXPIRY DATE: 09/02/2027	

ATTRIBUTES	SHOULD BE	IS
Appearance	Almost white or slightly yellow, hygroscopic powder	Slightly yellow, hygroscopic powder
Solubility	Freely soluble in water, in ethanol (96 %) and in methylene chloride, practically insoluble in heptane	Complies (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. Y3	Complies
pH	5.0 - 7.2	6.3
Composition		
Tylosin A	=> 80.0 %	92.2 %
Tylosin A+B+C+D	=> 95.0 %	99.1 %
Related substances		
Impurity A	=< 2.0 %	0.2 %
Sum impurities between impurity A and Tylosin C	=< 2.0 %	0.9 %
Impurity N	=< 1.0 %	0.1 %
Impurity O	=< 1.0 %	0.5 %
Impurity E	=< 0.5 %	0.1 %
Impurity R	=< 0.5 %	< 0.1 %
Impurity S	=< 0.5 %	0.2 %
Any other impurity	=< 0.50 %	Not Detected
Total impurities	=< 5.0 %	2.0 %
Tyramine	=< 0.35 %	< 0.35 %
Loss on drying	=< 4.5 %	0.8 %
Sulfated ash	=< 2.5 %	0.1 %
Assay	=> 900 IU/mg	968.2 IU/mg

**COMPLIES WITH**

European Pharmacopoeia 11.0

**REMARKS**

Product fully analyzed within the EU, in compliance with the current regulations "EudraLex - Volume 4 - Good Manufacturing Practice (GMP) guidelines" Part-II.

Tylosin Tartrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

All data controlled by Metapharmaceutical Industrial SL.

(\*) Data adapted from the manufacturer's certificate of analysis.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

Analysis date: 16/09/2025  
 Signature: Albert Sánchez López (QP)  
 Conclusion: Complies  
 Original certificate available upon request

Manufacturer: 40001573  
 NINGXIA TAIYICIN BIOTECH CO., LTD.  
 Pacific Road, Nuanquan Economic Zone, Helan  
 County, 1  
 750205 YINCHUAN





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All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.

### STORAGE

Store in a cool and well ventilated place, and protected from light.

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