



TECHNICAL DATA SHEET

94-TDS-ENG-2024

TILOSINA TARTRATO USO VETERINARIO (EUR. PH.)		
DESCRIPTION DCI: TYLOSIN TARTRATE		DESCRIPTION DOE: TILOSINA TARTRATO
CAS N°: 1405-54-5	EC N°: 215-781-5	AEMPS CODE: 90052T
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 94

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

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

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

REMARKS

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

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.



TECHNICAL DATA SHEET

94-TDS-ENG-2024

TILOSINA TARTRATO USO VETERINARIO (EUR. PH.)		
DESCRIPTION DCI: TYLOSIN TARTRATE		DESCRIPTION DOE: TILOSINA TARTRATO
CAS N°: 1405-54-5	EC N°: 215-781-5	AEMPS CODE: 90052T
MOL. WEIGHT: ---	MOL. FORMULA: ---	ARTICLE CODE: 94

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.