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TILOSINA TARTRATO USO VETERINARIO (EUR. PH.)

PRODUCT CODE: 94	CAS Nº: 1405-54-5	ANALYSIS Nº: 258/22	
MANUFACTURER BATCH:	TYTB2209185	CERTIFICATE ID:	36.635
SUPPLIER BATCH:	----	MANUFACTURING DATE:	18/09/2022
METAPH BATCH:	0171122	RETEST DATE:	17/09/2025

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	5.4
Composition		
Tylosin A	=> 80.0 %	93.2 %
Tylosin A+B+C+D	=> 95.0 %	98.3 %
Related substances		
Impurity A	=< 2.0 %	< 0.10 %
Sum impurities between impurity A and Tylosin C	=< 2.0 %	0.22 %
Impurity N	=< 1.0 %	< 0.10 %
Impurity O	=< 1.0 %	0.69 %
Impurity E	=< 0.5 %	< 0.10 %
Impurity R	=< 0.5 %	Not Detected
Impurity S	=< 0.5 %	Not Detected
Any other impurity	=< 0.50 %	0.14 % (RT = 52.75 min)
Total impurities	=< 5.0 %	1.1 %
Tyramine	=< 0.35 %	< 0.35 %
Loss on drying	=< 4.5 %	2.6 %
Sulfated ash	=< 2.5 %	0.08 %
Assay	=> 900 IU/mg	950.5 IU/mg
Residual solvents		(*) (**)
Butyl acetate	=< 5000 ppm	418 ppm
Microbiological control		(*)
TAMC	=< 1000 CFU/g	100 CFU/g
TYMC	=< 100 CFU/g	5 CFU/g
Histamine	=< 2 ppm	Not Detected (*)

COMPLIES WITH

European Pharmacopoeia 10.0

REMARKS

Tylosin Tartrate is subjected to the requirements of the ICH Q3D "Elemental Impurities".

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.

Analysis date: 23/12/2022
Signature: Ferran Gonzalez de Rivera Rier
Conclusion: Complies
Original certificate available upon request

Manufacturer: 40000936
SHANDONG LUKANG BIOMANUFACTURING, Co., Ltd.
88 Hualu Road Zoucheng Industrial Park
Jining

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(*) Data adapted from the certificate of analysis of the manufacturer.
(**) According to the requirements of guides EMA/CHMP/ICH/82260/2006.

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

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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