



anMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 59463

Product: Doxynyl 500 1kg RO
Article number: 00100649
Batch: 24009400 Split: 0
Quantity: 60 Units
Manufacturing date: 05.01.2024
Expiry date: 31.12.2025
Dosage form: Oral Powder
Package size: 1kg
Marketing authorisation holder: Livisto Int'l
Registration number:
Distributor / Importer:

Parameter	Specification	Result
Appearance	Yellow powder	Yellow powder
pH	2,0 ... 3,0	2,4
Water	Max. 3,0 %	1,2 %
Dissolution time	Max. 10 min	< 2 min
Filling weight	Min. 100 %	100 %
Identity: doxycycline	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Assay: doxycycline	475,0 ... 525,0 mg/g	507,6 mg/g
Impurity: 6-epidoxycycline	Max. 2,0 %	1,5 %
Known degradation product, single	Max. 1,0 %	< 0,1 %
Unknown degradation product, single	Max. 1,0 %	< 0,1 %
Sum of degradation products	Max. 5,0 %	1,6 %
Microbiological purity: TAMC	Max. 1000 CFU/g	Periodic test, no result
Microbiological purity: TYMC	Max. 100 CFU/g	Periodic test, no result
Microbiological purity: Escherichia coli	Absent/g	Periodic test, no result

Template: 3398

The finished product has been tested in accordance with the testing instruction and is of the required quality.

22. JAN. 2024

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

T +49 2536 33 02-0
F +49 2536 33 02-110

www.livisto.com

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