

CERTIFICATE OF ANALYSIS



Product: Doxycare 200mg 25B10D PL-HU-RO-CY
Product code: AC8104
Customer: AnimalCare
MA number: 3014/20; 4095/11/19 NÉBIH ÁTI; 190267; CY00762V; 13763/4-2-2020

Batch number: 24E22B
Man. date: 05-2024
Exp. date: 11-2026
Production number bulk: PR25771.003
Production number final packaging: PR25788.008
Packaging: Blisterpack (ALU-ALU)

Test:	Requirement:	Result:
Aspect	yellowish, round and convex tablet with a cross-shaped break line on one side, 13 mm in diameter	conform
Appearance blister	no deviation	conform
Identification Doxycycline	conform reference	conform
Assay Doxycycline base	190.0 – 210.0 mg/tab	201.9 mg/tab
Average tablet weight	686.0 – 714.0 mg/tab	711.1 mg/tab
Uniformity of weight, whole tablets	min 18/20: 95 – 105 % max 2/20: 90 – 110 %	20 0
Uniformity of weight, ¼ tablet	min 29/30: 85 - 115 % max 1/30: 75 – 125 %	30 0
Uniformity of Dosage Units	Acceptance value ≤ 15.0	2.7
Disintegration time	≤ 15 minutes	01 min 31 sec
Friability	≤ 1 %	0.1 %
Resistance to crushing	125 – 165 N	186; 152 - 214 ¹ N
Thickness	informative (mm)	5.8 mm
Related substances	6-epidoxycycline ≤ 2.0 % metacycline ≤ 1.0 % 2-acetyl-decarbamooyldoxycycline ≤ 1.2 % 4-epidoxycycline ≤ 1.0 % each individual ≤ 1.0 % total ≤ 4.0 %	1.5 % <0.1 % 0.4 % 0.1 % <0.1 % 2.1 %
Dissolution rate	≥ 85 % (Q=80%) of the labelled amount in 15 minutes	103; 101 - 104 %
Microbiological purity*	TAMC ≤ 10 ³ CFU / g TYMC ≤ 10 ² CFU / g E. coli absent / g	<100 CFU / g <10 CFU / g absent

*first 3 batches; then every 10th batch or once per year.
remark1) see DEV2024-116

Ilona Heerdt QP

09-08-2024 13:24:57

Leon Smids QC

07-08-2024 16:03:52

BATCH CERTIFICATE

Product: Doxycare 200mg 25B10D PL-HU-RO-CY
Product code: AC8104
Customer: AnimalCare
MA number: 3014/20; 4095/11/19 NÉBIH ÁTI; 190267; CY00762V; 13763/4-2-2020

Batch number: 24E22B
Man. date: 05-2024
Exp. date: 11-2026
Production number bulk: PR25771.003
Production number final packaging: PR25788.008
Packaging: Blisterpack (ALU-ALU)

Number of units 285

Manufacturing and quality control site:

LelyPharma bv
Zuiveringweg 42
8243PZ Lelystad
The Netherlands
Manufacturing and quality control license no: 2004-FGL

Contract testing sites:

Eurofins Bactimm bv
Middenkampweg 19
6545 CH Nijmegen
The Netherlands

Remarks:DEV2024-116

Release statement:

I hereby certify that the above information is authentic and accurate. I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in accordance with the approved manufacturing instructions and test procedures and in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with the requirements of the GMP and the Marketing Authorisation. This batch of product meets all acceptance criteria and is released to the market.



Ilona Heerdt QP

09-08-2024 13:24:57