

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-decarbamoxyldoxycycline ≤ 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.
 remark 1) see DEV2024-116

Ilona Heerdt QP

09-08-2024 13:24:57

Leon Smids QC

07-08-2024 16:03:52