

CERTIFICATE OF ANALYSIS



Product: Doxycare 40mg 25B10D PL-HU-RO-CY
Product code: AC8103
Customer: AnimalCare
MA number: 3013/20; 4094/11/19 NÉBIH ÁTI; 190266; CY00761V; 11075/4-2-20

Batch number: 24E20
Man. date: 05-2024
Exp. date: 11-2026
Production number bulk: PR25771.001
Production number final packaging: PR25788.001
Packaging: Blisterpack (ALU-ALU)

<u>Test:</u>	<u>Requirement:</u>	<u>Result:</u>
Aspect	yellowish, round and convex tablet with a cross-shaped break line on one side, 8 mm in diameter	conform
Appearance blister	no deviation	conform
Identification Doxycycline	conform reference	conform
Assay Doxycycline base	38.0 – 42.0 mg/tab	40.2 mg/tab
Average tablet weight	133.0 – 147.0 mg/tab	143.1 mg/tab
Uniformity of weight, whole tablets	min 18/20: 92.5 - 107.5 % max 2/20: 85 - 115 %	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	4.3
Disintegration time	≤ 15 minutes	02 min 22 sec
Friability	≤ 1 %	0.1 %
Resistance to crushing	35 - 65 N	67; 38 - 96 ¹ N
Thickness	informative (mm)	3.1 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 %	1.4 % <0.1 % 0.4 % 0.1 % <0.1 % 1.9 %
Dissolution rate	≥ 85 % (Q=80%) of the labelled amount in 15 minutes	105; 102 - 109 %
Microbiological purity*	Aerobic bacteria ≤ 10 ³ CFU / g fungi ≤ 10 ² CFU / g E. coli absent / g	<100 CFU / g <10 CFU / g absent

*Tested not routinely, once each year.
 Remark 1) see DEV2024-114

Ilona Heerdt QP

07-08-2024 09:53:46

Ciska Rijnbeek QC

02-08-2024 15:23:35