

FPR – 2020 / 0681

Pharmarom / Romania No 13

Certificate of Analysis / Certificat de analiza

Product name / Numele produsului: **LAMULIN 45 % granule**
 Batch number / Lot numărul: **450040**
 Quantity / Cantitatea: **197 x 1 kg in PP container with PP lid and inner bag of LDPE**
 Date of manufacture / Data producerii: **04/2020**
 Date of expiry / Data expirării: **04/2022**
 No. of Analytical card / Nr. anal.doc.: **QC-0450-01-01/2020**

Tests parameters / Parametri testati	Requirements / Cerinte	Results / Rezultate
1. Appearance / Aspect	White-yellowish white granules / Granule albe, alb galbui	complies / conforme
2. Filling weight / Greutatea umpluturi	98 - 102% of nominal value / 98-102 % din volumul nominal	99
3. pH / pH	3.5 - 4.5	4.0
4. Particle size / Dimensiune particule	max. 5% > 1 mm max 10% < 125 µm	complies / conforme complies / conforme
5. Dissolution time / Timp dizolvare	NMT 10 min	4'08"
6. Microbiological quality / Calitate microbiologica		
6.1. TAMC / TAMC	< 10 ³ / g	< 10 ³
6.2. TYMC / TYMC	< 10 ² / g	< 10 ²
6.3. E.coli / E.coli	absent / absent	absent / absent
7. Chemical purity / Puritate chimica		
7.1 Impurities / Impuritati B,H	≤ 1.5 %	< 0.3
7.2. Impurities / Impuritati A, C, D, E, F, G, I, J, K, L, M, S, T	≤ 1.0 %	0.6
7.3. other impurities / Alte impuritati	≤ 0.2 %	< 0.1
7.4 total impurities / Total impuritati	≤ 3.0 %	0.6
8. Identification / Identificare		
8.1. Tiamuline hydrogen fumarate / Tiamulin hidrogen fumarat	R _i conforms to the standard / R _i conform standard	complies / conforme
9. Assay of active ingredient / Analiza substanta activa		
9.1. Tiamuline hydrogen fumarate / Tiamulin hidrogen fumarat	42.75 - 47.25 mg (95 - 105%) tiamulin hydrogen fumarate per 100 mg	44.86

Qualification / Calificare comercializare: **accepted / acceptat**

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the cGMP requirements and with the requirements of the Marketing Authorisation of the destination country. / Prin prezenta se certifica faptul că toate etapele de fabricare a acestui lot de produs finit au fost efectuate în deplină conformitate cu cerințele GMP și cerințele autorizației de punere pe piață a țării de destinație.

Kistarsca, 06/05/2020

LAVET Kft./Ltd.
Meghatalmazott személy/
Qualified person (1.)

dr. Brigitta Szabó

dr. Brigitta Szabó
Qualified person / Persoana calificata



LAVET GYÓGYSZERIPARI KFT. / LAVET PHARMACEUTICALS LTD.
 Minőségbiztosítási Osztály / Quality Assurance/ Meghatalmazott személy / Qualified Person
 Gyógyszergyártási engedély száma / Manufacturing authorisation No.: MA-HU/18V/2006/M14
 GMP igazolás száma/GMP certificate No.: CG-HU/18V/2019, CG-HU/04V/2019
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