LAVET
YOU LOVE WE CARE

FPR – 2020 / 1366

Vitamed / Magyarország 2020/08

CERTIFICATE of ANALYSIS

Product name: Carprox 50 mg flavour tablets
Batch number: 690060
Quantity: 100 x 100 tablets in strip foils and carton box
Date of manufacture: 06/2020
Date of expiry: 06/2022
No. of Analytical card: QC-0690-01-01/2020

Determinations	Specifications	Results
General characters		
Appearance	almost white to beige, uncoated, bare, flat, centre scored tablets	complies
Tests		
1. Uniformity of mass	NMT 2 of the individual masses deviate from the average mass by > 5%	complies
2. Disintegration time	< 15 min	
3. Dissolution	NLT 80 % (Q) of carprofen in 30 min (50 rpm)	complies 90.7
4. Microbiological quality		
4.1. Total viable aerobic count	$< 10^3$/g	$< 10^3$
4.2. Fungi	$< 10^2$/g	$< 10^2$
4.3. Escherichia coli	absent	absent
5. Related substances		
5.1. total impurities	max. 1.0 %	< 0.2
5.2. identified purity	≤ 0.5 %	< 0.2
5.3. any other, unidentified impurity	max.0.3 %	< 0.2
Identification and assay of active ingredients		
6. Identification		
6.1. Carprofen	R_t and the size of principal peak is similar to standard CRS	complies
7. Assay		
7.1. Carprofen	95.0 - 105.0 % of the labelled amount of carprofen per tablet (47.5 – 52.5 mg/tablet)	50.9

Qualification: *accepted*

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 of the EU, and with the requirements of the Marketing Authorisation of the destination country.

Kistarcsa, 04/09/2020

LAVET Gyógyszeripari Kft.
Minőségbiztosítási Osztály
Qualified person (1)

dr. Brigitta Szabó
Qualified person

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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