

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

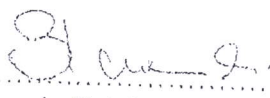
Determinations	Specifications	Results
<i>General characters</i>		
Appearance	almost white to beige, uncoated, bare, flat, centre scored tablets	complies
<i>Tests</i>		
1. Uniformity of mass	NMT 2 of the individual masses deviate from the average mass by > 5%	complies
2. Disintegration time	< 15 min	complies
3. Dissolution	NLT 80 % (Q) of carprofen in 30 min (50 rpm)	90.7
4. Microbiological quality		
4.1. Total viable aerobic count	< 10 <sup>3</sup> /g	< 10 <sup>3</sup>
4.2. Fungi	< 10 <sup>2</sup> /g	< 10 <sup>2</sup>
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
<i>Identification and assay of active ingredients</i>		
6. Identification		
6.1. Carprofen	R <sub>t</sub> 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 PHARMACEUTICALS LTD.  
 Meghatalmazott személy /  
 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-111/18V/2006/M14  
 GMP igazolás száma / GMP certificate No.: CG-111/18V/2019, CG-111/04V/2019  
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