



Székhely/Office:
H-1161 Budapest
Ottó u. 14.
Phone: +36-1/405-7660
Fax: +36-1/405-7670
E-mail: lavet@lavet.hu
Web: www.lavet.hu

Üzem/Plant:
H-2143 Kistarcsa
Batthyány u. 6.
Phone: +36-28/506-445
Fax: +36-28/506-446
E-mail: lavet@lavet.hu

Gyógyszergyártást engedély száma/
Manufacturing authorisation No.:
MA-HU/18V/2006/M11
GMP igazolás száma/
GMP certificate No.:
CG-HU/23V/2016

FPR - 2017 / 1239

Vitamed / 2017/07

CERTIFICATE of ANALYSIS

Product name: Carprox 50 mg flavour tablets
Batch number: 161126
Quantity: 395 x 20 tablets in strip foils and carton box
Date of manufacture: 12/2016
Date of expiry: 12/2018
No. of Analytical card: 0161/2016

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 90.1
3. Dissolution	NLT 80 % (Q) of carprofen in 30 min (50 rpm)	
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
<i>Identification and assay of active ingredients</i>		
6. Identification		
6.1. Carprofen	R ₁ 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)	51.0 mg/tablet

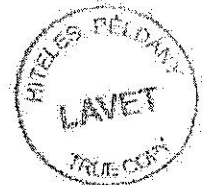
Qualification: *accepted*

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, 26/07/2017

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

[Signature]
dr. Zsuzsa Galambos
Qualified person QA



FV-2018/000127

Eredeti állomány: M161126.pdf Nyomtatás dátuma: 2018.01.02.