LAVET PHARMACEUTICALS
YOU LOVE WE CARE

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Gyógyszergyártási engedély száma/
Manufacturing authorisation No.:
MA-HU/18V/2006/M12
GMP igazolás száma/
GMP certificate No.:
CG-HU/23V/2016

FPR – 2017 / 1848

Vitamed 2017/10

CERTIFICATE of ANALYSIS

Product name: **Carprox 100 mg flavour tablets**
Batch number: 032107
Quantity: 50 x 100 tablets in strip foils and carton box
Date of manufacture: 10/2017
Date of expiry: 10/2019
No. of Analytical card: 1032/2017

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 82.6
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 (95 – 105 mg/tablet)	99.6

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, 21/11/2017

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

dr. Zsuzsa Galambos
Qualified person QA

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