LAVET PHARMACEUTICALS
YOU LOVE WE CARE

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Gyógyszergyártási engedély száma/
Manufacturing authorisation No.:
MA-HU/18V/2006/M9
GMP igazolás száma/
GMP certificate No.:
CG-HU/01V/2014

FPR – 2015 / 0398

Vitamed 2015/12

CERTIFICATE of ANALYSIS

Product name: **Carprox 20 mg flavour tablets**
Batch number: 576075
Quantity: 50 x 100 tabl.sztrip fóliában és papírdobozban
Date of manufacture: 07/2015
Date of expiry: 07/2017
No. of Analytical card: 0576/2015

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	complies
3. Dissolution	NLT 80 % (Q) of carprofen in 30 min (50 rpm)	87.9
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 (19.0 – 21.0 mg/tablet)	20.1 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

Qualification: ***accepted***

Kistarcsa, 30/10/2015

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

dr. Zsuzsa Galambos
Qualified person QA

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