

FPR – 2015 / 0503

Vitamed 2015/12

CERTIFICATE of ANALYSIS

Product name: Carprox 100 mg flavour tablets
Batch number: 710095
Quantity: 100 x 100 tablets in strip foils and carton box
Date of manufacture: 09/2015
Date of expiry: 09/2017
No. of Analytical card: 0710/2015

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)	92.1
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 _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)	100.7 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

Qualification: *accepted*

Kistarcsa, 19/11/2015

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

dr. Zsuzsa Galambos
 dr. Zsuzsa Galambos
 Qualified person QA

