

FPR – 2016 / 0681

Vitamed 2016/04

**CERTIFICATE of ANALYSIS**

**Product name:** Carprox 100 mg flavour tablets  
**Batch number:** 413046  
**Quantity:** 263 x 100 tablets in strip foils and carton box  
**Date of manufacture:** 04/2016  
**Date of expiry:** 04/2018  
**No. of Analytical card:** 0413/2016

Determinations	Specifications	Results
<b>General characters</b>		
Appearance	almost white to beige, uncoated, bare, flat, centre scored tablets	complies
<b>Tests</b>		
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)	88.6
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
<b>Identification and assay of active ingredients</b>		
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 (95 – 105 mg/tablet)	101.7 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

**Qualification:** *accepted*

Kistarcsa, 03/05/2016

**LAVET Kft./Ltd.**  
 Meghatalmazott személy/  
 Qualified person (QP)  
 dr. Zsuzsa Galambos  
 Qualified person QA

