

Vitamed 2015/03

**CERTIFICATE of ANALYSIS**

**Product name:** Carprox 100 mg flavour tablets  
**Batch number:** 010015,  
**Quantity:** 33 x 100 tablets in strip foils and carton box  
**Date of manufacture:** 01/2015  
**Date of expiry:** 01/2017  
**No. of Batch release document:** 0010/2015

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 88.5
3. Dissolution		NLT 80 % (Q) of carprofen in 30 min (50 rpm)	
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
<i>Identification and assay of active ingredients</i>			
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)	98.3 mg/tablet
8. Packaging control		Complies with the Marketing Authorization	complies

**Qualification:** *accepted*

Kistarcsa, 05/03/2015

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 dr. Zsuzsa Galambos  
 Qualified person QA

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

