

Vitamed 2014/07

**CERTIFICATE of ANALYSIS**

**Product name:** Carprox 50 mg flavour tablets  
**Batch number:** 348034  
**Quantity:** 150 x 20  
**Date of manufacture:** 03/2014  
**Date of expiry:** 03/2016  
**No. of Batch release document:** 0348/2014

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)	90.0
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 (47.5 – 52.5 mg/tablet)	50.60 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

**Qualification:** *accepted*

Kistarcsa, 30/07/2014

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

*Dr. Zsuzsa Galambos*  
 dr. Zsuzsa Galambos  
 Qualified person QA

