

Vitamed 2014/11

**CERTIFICATE of ANALYSIS**

Product name: Carprox 20 mg flavour tablets  
 Batch number: 936094  
 Quantity: 50 x 100  
 Date of manufacture: 09/2014  
 Date of expiry: 09/2016  
 No. of Batch release document: 0936/2014

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)	83.6
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
<i>Identification and assay of active ingredients</i>		
6. Identification		
6.1. Carprofen	R <sub>i</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 (19.0 – 21.0 mg/tablet)	19.9 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

Qualification: *accepted*

Kistarcsa, 06/11/2014

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

dr. Zsuzsa Galambos  
 Qualified person QA

