

Vitamed 2015/08 pót

CERTIFICATE of ANALYSIS

Product name: Carprox 50 mg flavour tablets
Batch number: 078015
Quantity: 50 x 100 tablets in strip foils and carton box
Date of manufacture: 01/2015
Date of expiry: 01/2017
No. of Batch release document: 0078/2015

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)	89.1
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 (47.5 - 52.5 mg/tablet)	49.9 mg/tablet
8. Packaging control		Complies with the Marketing Authorization	complies

Qualification: *accepted*

Kistarcsa, 15/07/2015

LAVET Kft./A.td.
 Meghatalmazott személy/
 Qualified person (1.)

[Signature]
 dr. Zsuzsa Galambos
 Qualified person QA

