

FPR – 2016 / 0372

Vitamed / 2016/03

CERTIFICATE of ANALYSIS

Product name: Carprox 50 mg flavour tablets
Batch number: 194026
Quantity: 100 x 20 tablets in strip foils and carton box
Date of manufacture: 02/2016
Date of expiry: 02/2018
No. of Analytical card: 0194/2016

Determinations	Specifications	Results
General characters		
Appearance	almost white to beige, uncoated, bare, flat, centre scored tablets	complies
Tests		
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)	89.3
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
Identification and assay of active ingredients		
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)	49.7 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

Qualification:

accepted

Kistarcsa, 08/03/2016

LAVET Kft./Ltd.
 Meghatalmazott személy/
 Qualified person (1.)
 dr. Zsuzsa Galambos
 Qualified person QA

