

FPR – 2016 / 0988

Vitamed / 2016/06

CERTIFICATE of ANALYSIS

Product name: Carprox 20 mg flavour tablets
Batch number: 525056
Quantity: 100 x 100 tabl.sztrip fóliában és papírdobozban
Date of manufacture: 05/2016
Date of expiry: 05/2018
No. of Analytical card: 0525/2016

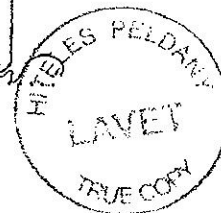
Determinations	Specifications	Results
<i>General characters</i>		
Appearance	almost white to beige, uncoated, bare, flat, centre scored tablets	complies
<i>Tests</i>		
1. Uniformity of mass	NMT 2 of the individual masses deviate from the average mass by > 5%	complies
2. Disintegration time	< 15 min	complies
3. Dissolution	NLT 80 % (Q) of carprofen in 30 min (50 rpm)	87.4
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 (19.0 – 21.0 mg/tablet)	20.3 mg/tablet
8. Packaging control	Complies with the Marketing Authorization	complies

Qualification: *accepted*

Kistarcsa, 24/06/2016

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

dr. Zsuzsa Galambos
 Qualified person QA



V-2016/042783

redeti állomány: M525056.pdf Nyomtatás dátuma: 2016.08.03.