LAVET PHARMACEUTICALS
YOU LOVE WE CARE

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Vitamed 2014/11

CERTIFICATE of ANALYSIS

Product name: **Carprox 50 mg flavour tablets**
Batch number: 935094
Quantity: 55 x 20
Date of manufacture: 09/2014
Date of expiry: 09/2016
No. of Batch release document: 0935/2014

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)	84.7
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)	50.60 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

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