

Vifamed 2014/10

CERTIFICATE of ANALYSIS

Product name: **Carprox 100 mg flavour tablets**
 Batch number: 934094
 Quantity: 100 x 100 tbl
 Date of manufacture: 09/2014
 Date of expiry: 09/2016
 No. of Batch release document: 0934/2014

| 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) | 85.7 |
| 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 (95 – 105 mg/tablet) | 101.2 mg/tablet |
| 8. Packaging control | Complies with the Marketing Authorization | complies |

Qualification:

accepted

Kistarcsa, 2014.10.10.

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

dr. Zsuzsa Galambos
 dr. Zsuzsa Galambos
 Qualified person QA

