

Certificate of Analysis

Certificate No.: 15939

Product: Dolocarp flavour 20mg tab 100er RO Manufacturing date: 01-12-17

Product-No.: 87391

Expiry date: 30-11-22

Batch-No.: 17L6301

Split: 0

Quantity: 48 Unit(s)

Parameter	Specification	Result
Appearance	beige to brown tablet with breaking notch	beige to brown tablet with breaking notch
Batch packaging record	batch packaging record complies	Corresponds to
Length x Width (quadratic)	11,0 +/- 0,2mm	11,0 mm
Height	4,4 +/- 0,2mm	4,5 mm
average weight	604,0 mg / Tablet +/- 5,0% (573,8 - 634,2 mg / Tablet)	607,3 mg/Tablet
Uniformity of mass	mind. 18 T. smaller +/- 5,0% max. 2 T. bigger +/- 5%und kleiner +/- 10% keine T. bigger/equal + 10%	complies
Uniformity of content	must match Ph. Eur. 2.9.40	complies
tablets hardness	80 ... 700 N	81 N
Fracture test	breakable	breakable
friability	Max. 1,0 %	0,3 %
loss of drying	Max. 6 %	4 %
active substance release	after 90 min. higher/equal 60% Q	Corresponds to
Identity Carprofen	Retention time, size, form of peak in standard and sample must be identical	Corresponds to
Assay Caprofen	19,0 ... 21,1	19,4 mg/Tabl.
Related Substances: Impurity C	Max. 0,3 %	< 0,1 %
Related Substances: Impurity D	Max. 0,3 %	< 0,1 %
Every other impurity	Max. 0,3 %	< 0,1 %
Unknown impurities, single	Max. 0,3 %	< 0,1 %
Unknown impurities, total	Max. 1,0 %	< 0,1 %
Microbial purity: TAMC	Max. 2000 KBE/g	< 2000 KBE/g
Microbial purity: TYMC	Max. 200 KBE/g	< 200 KBE/g
Microbial purity: Escherichia coli	Max. 0 KBE/g	0 KBE/g

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The finished product has been tested in accordance with the testing instruction and is of the required quality.

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

☒ no deviations/irregularities have been observed.

☐ the following deviations/irregularities have been observed:

These deviations/irregularities do not affect the quality of the product, because

The named batch has the required quality and is released

☐ for dispatch

☒ for the market

Comments

26.11.18

Date, Signature Qualified Person