

Certificate of Analysis

Certificate No.: 30145

Product: Dolocarp flavour 50mg tab 100er RO

Dosage form:

Package size: XXg (Tabletten)

Product: 87320

Marketing authorisation holder:

Batch: 19A3504 Split: 0

Registration number:

Quantity: 150 Units

Manufacturing date: 01.01.2019

Expiry date: 31.12.2023

Parameter	Specification	Result
Appearance	beige to brown tablet with a break notch	beige to brown tablet with a break notch
Batch packaging record	batch packaging record complies	Corresponds to
Length x Width	15,0 +/- 0,3mm	15,0 mm
Height	6,1 +/- 0,2mm	6,3 mm
Mass	1510,0 mg / tablet +/- 5,0% (1434,5 - 1585,5 mg / tablet)	1497,0 mg/ tablet
Uniformity of mass	min. 18 T. < +/- 5,0% max. 2 T. > +/- 5% and < +/- 10% no T. < / = + 10%	complies
Uniformity of single dose unit	conforms Ph. Eur. 2.9.40	complies
Hardness	100 ... 700 N	111 N
Break test	breakable	breakable
Friability	Max. 1,0 %	2,0 %
Loss of drying	Max. 6 %	4 %
Activ substance release	after 90 min. > / = 60% Q	Corresponds to
Identity Carprofen	Retention times, size and form of the peak of standard and sample must be identical	Corresponds to
Assay Caprofen	47,5 ... 52,5 mg	51,8 mg
Impurity C	Max. 0,3 %	< 0,1 %
Impurity D	Max. 0,3 %	< 0,1 %
Any known impurity	Max. 0,3 %	< 0,1 %
Unkown impurity, single	Max. 0,3 %	< 0,1 %
Unknown impurity, total	Max. 1,0 %	0,1 %

Template: 1080

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

28. Mai 2020



Date, Signature Head of Quality Control

Batch certificate

Certificate No.: 30145

Product:	Dolocarp flavour 50mg tab 100er RO	Dosage form:	
Product	87320	Package size:	XXg (Tabletten)
Batch:	19A3504 Split: 0	Marketing authorisation holder:	
Quantity:	150 Units	Registration-No.:	
Manufacturing	01.01.2019		
Expiry date:	31.12.2023		

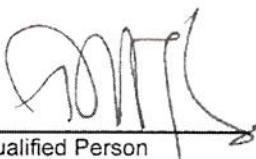
I certify that the above information is authentic and correct. This batch has been manufactured, including packaging and quality control, in full compliance with the GMP requirements of the local regulatory authority and with the information in the marketing authorisation as laid down in the manufacturing and quality control instructions. The batch processing, packaging and analytical documentation has been reviewed and is in full compliance with GMP guidelines. All deviations were evaluated before batch release.

This batch has the required quality and

- ☐ is released for delivery
- ☒ is released for the market

Remarks:

elevated probability value, aesthetical problem
if tablets are thoroughly stable, all other para-
meters within limits

2005 26 

Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Prüßert ☐ Dr. Jürgen Schlüter ☐