



LIVISTO

aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 21433

Product: Dolocarp flavour 100mg 100tab RO Manufacturing date: 01-04-19
Product-No.: 87321 Expiry date: 31-03-24
Batch-No.: 19A3604
Split: 0
Quantity: 108 Unit(s)

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	19,0 +/- 0,3mm	19,0 mm
Height	7,8 +/- 0,3mm	7,8 mm
Average mass	3020,0 mg / tablet +/- 5,0% (2869,0 - 3171,0 mg / tablet)	3014,0 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	138 N
Break test	breakable	breakable
Friability	Max. 1,0 %	1,6 %
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	95,0 ... 105,0	99,8 mg/Tabl.
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 %
Unkown impurity, total	Max. 1,0 %	< 0,1 %



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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:

ABU 2619-85 increased friability values
These deviations/irregularities do not affect the quality of the product because

aesthetical problem i.e. tablets are broken vigorously,
The named batch has the required quality and is released

- ☐ for dispatch
☒ for the market
all other physico-chemical parameters within limits
6/260715

Comments:

260715
Date, Signature Qualified Person