



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 26277

Product:	Dexafast 2mg/ml inj 100ml EP RO	Dosage form:	Injektion (Lösung)
		Package size:	100ml
Product:	00100357	Marketing authorisation holder:	Livisto Int'l
Batch:	19052302 Split: 0	Registration number:	
Quantity:	2.000 Piece		
Manufacturing date:	10-09-19		
Expiry date:	28-02-22		

Parameter	Specification	Result
Appearance	Clear, colourless solution, essentially free from visible particles	Clear, colourless solution, essentially free from visible particles
Batch packaging record	batch packaging record complies	Corresponds to
pH-value	7,0 ... 8,0	7,4
Filling quantity	Min. 100,0 %	102,5 %
Density	1,003 ... 1,013	1,010
Identity: Dexamethasone sodium phosphate	Retention times and UV spectra of sample and standard peak must comply	Corresponds to
Identity: Benzyl alcohol	Retention times and UV spectra of standard and sample must comply	Corresponds to
Assay: Dexamethasone sodium phosphate	2,50 ... 2,76 mg/ml	2,64 mg/ml
Assay: Benzyl alcohol	14,0 ... 17,2 mg/ml	15,7 mg/ml
Purity: Specified impurity (Dexamethasone)	Max. 1,0 %	< 0,1 %
Purity: Any unspecified impurity	Max. 1,0 %	0,1 %
Purity: Total impurities	Max. 5,0 %	0,3 %
Microbiology: sterility	Sterile	Corresponds to

Template: 2116

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


31. JAN. 2020
Date/Signature Head of Quality Control



aniMedica Herstellungs GmbH
a LIVISTO company

Batch certificate

Certificate No.: 26277

Product: Dexafast 2mg/ml inj 100ml EP RO

Dosage form: Injektion (Lösung)

Package size: 100ml

Product 00100357

Batch: 19052302 Split: 0

Marketing authorisation holder: Livisto Int'l

Quantity: 2.000 Piece

Registration-No.:

Manufacturing 10-09-19

Expiry date: 28-02-22

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

Annotations:

/

/

/

/

0522 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange

☐ Gudrun Pruß

☐ Dr. Jürgen Schlüter

☐