



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 24011

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

Manufacturing date: 09-09-19

Product-No.: 00100357

Expiry date: 28-02-22

Batch-No.: 19052202

Split: 0

Quantity: 2.000 Unit(s)

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	7,5
Filling quantity	Min. 100,0 %	101,8 %
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	15,6 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



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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:

Released to the market

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Date: Signature Qualified Person