



amMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No. 20376

Product	Dexafast 2mg/ml inj. 100ml EP RO	Manufacturing date	19-02-19
Product-No	00100357	Expiry date	31-07-21
Batch-No	19020503		
Split	0		
Quantity	2.000 Units		

Parameter	Specification	Result
Appearance	Clear, colourless solution, essentially free from visible particles	Complies
Batch packaging record	batch packaging record complies	Corresponds to
pH-value	7.0 ... 8.0	7.4
Filling quantity	Min. 100.0 %	100.7 %
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	2.70 mg/ml
Assay: Benzyl alcohol	14.0 ... 17.2 mg/ml	15.7 mg/ml
Purity: Specified impurity (Dexamethasone)	Max. 1.0 %	0.0 %
Purity: Any unspecified impurity	Max. 1.0 %	0.2 %
Purity: Total impurities	Max. 5.0 %	0.6 %
Microbiology: sterility	Sterile	Corresponds to



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Parameter	Specification	Result
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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

deviation no: 50-2019 / 51-2019 / 56-2019

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

no direct impact on packed product

The named batch has the required quality and is released

- ☒ for dispatch *the market*
☐ for the market

Comments

Date Signature Qualified Person

Amtsgericht Goesfeld
HRB-Nr. 10339
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