

Certificate of Analysis

Certificate No.: 40964

Product:	Dexafast 2mg/ml inj 100ml EP RO		
Article number:	00100357	Dosage form:	Solution for injection
Batch:	21007503 Split: 0	Package size:	100ml
Quantity:	2.000 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	27.05.2021	Registration number:	190002
Expiry date:	31.10.2023	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless solution essentially free of visible particles	Clear, colourless solution essentially free of visible particles
Batch packaging record	batch packaging record complies	Corresponds to
pH	7,0 ... 8,0	7,5
Relative density	1,003 ... 1,013	1,010
Extractable volume	Min. 100,0 %	101,8 %
Identity: dexamethasone sodium phosphate	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Identity: benzyl alcohol	Retention times and UV spectrum of standard and sample must correspond	Corresponds to
Assay: dexamethasone sodium phosphate	2,50 ... 2,76 mg/ml	2,65 mg/ml
Assay: benzyl alcohol	14,0 ... 17,2 mg/ml	15,8 mg/ml
Impurity: dexamethasone	Max. 1,0 %	0,0 %
Any unspecified impurity	Max. 1,0 %	0,2 %
Total impurities	Max. 5,0 %	0,6 %
Sterility	Sterile	Corresponds to

Template: 2116

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

24. JUNI 2021

Date, Signature Head of Quality Control

Batch certificate

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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:

240621 

Date, Signature Qualified Person

- ☒ Dr. Hans-Jörg Lange ☐ Gudrun Prußeit ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐