



aniMedica Herstellungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 60755

Product:	Dexafast 2mg/ml inj 100ml EP RO	Dosage form:	Solution for injection
Article number:	00100357	Package size:	100ml
Batch:	24006701 Split: 0	Marketing authorisation holder:	Livisto Int'l
Quantity:	2,016 Units	Registration number:	190002
Manufacturing date:	19.02.2024	Distributor / Importer:	RO - BistriVet Rumänien
Expiry date:	31.01.2028		

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	1,011
Extractable volume	Min. 100,0 %	101,5 %
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 %	< 0,1 %
Any unspecified impurity	Max. 1,0 %	< 0,1 %
Total impurities	Max. 5,0 %	0,1 %
Sterility	Sterile	Corresponds to

Template: 2116

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

25. MRZ. 2024

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
Thomas Höltker

Im Südfeld 9
48308 Senden-Bösensell
Deutschland

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www.livisto.com

Along with you



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Batch certificate

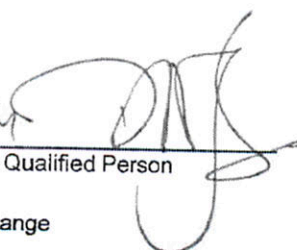
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Certification statement:

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation of the destination country.

Remarks:

Four horizontal lines for remarks, each crossed out with a diagonal slash.

26.02.24 
Date, Signature Qualified Person
Dr. Hans-Jörg Lange

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