

Certificate of Analysis

Certificate No.: 66096

aniMedica Herstellungs GmbH
a LIVISTO company

Product:	Dexafast 2mg/ml inj 100ml EP RO		
Article number:	00100357	Dosage form:	Solution for injection
Batch:	24029803 Split: 0	Package size:	100ml
Quantity:	2,016 Units	Marketing authorisation holder:	Livisto Int'l
Manufacturing date:	09.09.2024	Registration number:	190002
Expiry date:	31.08.2028	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	Clear, colourless solution essentially free of visible particles	corresponds to
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	2,66 mg/ml
Assay: benzyl alcohol	14,0 ... 17,2 mg/ml	15,7 mg/ml
Impurity: dexamethasone	Max. 1,0 %	0,1 %
Any unspecified impurity	Max. 1,0 %	0,1 %
Total impurities	Max. 5,0 %	0,4 %
Sterility	Sterile	Corresponds to

Template: 2116

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

23. OKT. 2024

Date, Signature Head of Quality Control