



Rungs GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 69703

Product: Dexafast 2mg/ml inj 100ml EP RO
Article number: 00100357 Dosage form: Solution for injection
Batch: 25011007 Split: 0 Package size: 100ml
Quantity: 2,016 Units Marketing authorisation holder: Livisto Int'l
Manufacturing date: 23.04.2025 Registration number: ~~490002~~ 240002
Expiry date: 31.03.2029 Distributor / Importer: RO - BistriVet Rumänien

2807.2025

Parameter	Specification	
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	7,4
Relative density	1,003 ... 1,013	1,010
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	
Assay: benzyl alcohol	14,0 ... 17,2 mg/ml	15,6 mg/ml
Impurity: dexamethasone	Max. 1,0 %	0,2 %
Any unspecified impurity	Max. 1,0 %	0,1 %
Total impurities	Max. 5,0 %	0,7 %
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. JULI 2025
Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 10339
Geschäftsführer:
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