



Certificate of Analysis

Certificate No.: 22467

aniMedica GmbH
a LIVISTO company

Product:	Genestran 75µg/ml inj 20ml RO		
Article number:	49258	Dosage form:	Solution for injection
Batch:	6450123 Split: 0	Package size:	20ml
Quantity:	640 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	01.02.2023	Registration number:	120133
Expiry date:	31.01.2026	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	clear, odour- and colourless solution free from particulate mater	corresponds to
pH	5,5 ... 6,5	5,9
Relative density	1,005 ... 1,015	1,010
Identity: (+)-cloprostenol sodium	positive	Corresponds to
Identity: chlorocresol	positive	Corresponds to
Assay: (+)-cloprostenol	71,2 ... 78,8	74,3 µg/ml
Assay: chlorocresol	0,9 ... 1,1 mg/ml	1,0 mg/ml
Impurity: 3-chlorophenol	Max. 1,0 %	0,0 %
Impurity: 15S-(+)-cloprostenol	Max. 1,0 %	0,0 %
Unknown impurity of (+)-cloprostenol, single	Max. 1,0 %	< 1,0 %
Unknown impurities of (+)-cloprostenol, total	Max. 1,0 %	< 1,0 %
Unknown impurity of chlorocresol, single	Max. 0,1 %	< 0,1 %
Unknown impurities of chlorocresol, total	Max. 0,5 %	< 0,5 %
Sterility	sterile	Corresponds to
Extractable volume	Min. 20 ml	> 20 ml

Template: 1653

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

09. MAY 2023

Date, Signature Head of Quality Control

Amtsgericht Coesfeld
HRB-Nr. 7210
Geschäftsführer:
Dr. Enno Gottschalk

Im Südfeld 9
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Along with you


LIVISTO**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:

Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☒ Stephan Bruns ☐ Dr. Jürgen Schlüter ☐ Dr. Bernd Manfred Müller ☐ Ulrich Kontny

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