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SC Bistri-Vet SRL

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RO 420155 RUMÄNIEN

CERTIFICATE OF ANALYSIS

Product:	Genestran 20ml RO	Batch No.:	6450419
Dosage form:	Solution for injection	PV-No.:	P.012.11
Manufac. Date:	03/2019	Expiry Date:	02/2022

Parameter	Specification	Result
Appearance:	clear, odour- and colourless solution free from particulate mater	conforms
Extractable Volume	≥ 20 ml	> 20 ml
pH value	5,5 - 6,5	5,8
rel. density	1,005 – 1,015	1,009
Identity		
(+)-Cloprostenol	positive	positive
Chlorocresol	positive	positive
Assay		
(+)-Cloprostenol	71,2 – 78,8 µg/ml	75,8 µg/ml
Chlorocresol	0,9 – 1, 1 mg/ml	1,0 mg/ml
Purity		
Impurities:		
3-chlorophenol	≤ 1,0%	n.d.
15S-(+)-chlorprostenol	≤ 1,0%	n.d.
clorostenol:		
Impurities unknown, single	≤ 1,0%	< LOQ
Impurities unknown, sum	≤ 1,0%	< LOQ
chlorocresol:		
Impurities unknown, single	≤ 0,1%	< LOQ
Impurities unknown, sum	≤ 0,5%	< LOQ
Sterility	sterile	sterile

The batch complies with the agreed specification and has been released for the market.

We confirm that the above mentioned batch was produced and tested in accordance with the relevant GMP regulations.

Date: 2019-05-28


- Qualified Person -