

Certificate of Analysis

Certificate No.: 61399

Product:	Procapen 300mg/ml inj 100ml RO		
Article number:	85203	Dosage form:	Suspension for injection
Batch:	24005001 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	04.03.2024	Registration number:	090134 150264
Expiry date:	29.02.2028	Distributor / Importer:	RO - BistriVet Rumänien

correction
23.04.2024 Sph B

Parameter	Specification	Result
Appearance	White to yellowish suspension	White to yellowish suspension
Resuspendability	Easily to homogenise in 30 sec	10 sec
Odour	Characteristic	Characteristic
Relative density	1,082 ... 1,099	1,095
pH	6,5 ... 7,0	6,9
Particle size, <40µm	100% < 40µm	100% < 40µm
Particle size, <30µm	Min 95% < 30µm	100% < 30µm
Extractable volume	Min. 100,5 ml	102,7 ml
Identity: benzylpenicillin-procaine 1H2O	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: methyl-4-hydroxybenzoate	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: propyl-4-hydroxybenzoate	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: propylene glycol	Retention time of standard and sample must correspond	Corresponds to
Identity: sodium thiosulphate 5H2O	Decolouration of iodine	Corresponds to
Assay: benzylpenicillin-procaine 1H2O	285,0 ... 315,0 mg/ml	295,0 mg/ml
Assay: procaine	114,0 ... 126,0 mg/ml	117,3 mg/ml
Assay: methyl-4-hydroxybenzoate	2,698 ... 2,982 mg/ml	2,803 mg/ml
Assay: propyl-4-hydroxybenzoate	0,304 ... 0,336 mg/ml	0,310 mg/ml
Assay: propylene glycol	147,25 ... 162,75 mg/ml	155,11 mg/ml
Assay: sodium thiosulphate 5H2O	0,9 ... 1,1 mg/ml	1,0 mg/ml
Any single impurity	Max. 0,5 %	< 0,1 %
Total impurities	Max. 1,0 %	0,1 %
Impurity: 4-hydroxybenzoic acid	Max. 10,0%	Corresponds to
Sterility	Sterile	Corresponds to



aniMedica GmbH
a LIVISTO company

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Product:	Procopen 300mg/ml inj 100ml RO		
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Batch:	24005001 Split: 0	Package size:	100ml
Quantity:	1,008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	04.03.2024	Registration number:	090134
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Parameter	Specification	Result
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Template: 1884

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

27 APR. 2024
Date, Signature Head of Quality Control