

Certificate of Analysis

Certificate No.: 48956

Product:	Procopen 300mg/ml inj 100ml RO		
Article number:	85203	Dosage form:	Suspension for injection
Batch:	22024402 Split: 0	Package size:	100ml
Quantity:	1.008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	29.03.2022	Registration number:	090134
Expiry date:	28.02.2026	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	White to yellowish suspension	White to yellowish suspension
Resuspendability	Easily to homogenise in 30 sec	<30sec
Odour	Characteristic	Characteristic
Relative density	1,082 ... 1,099	1,097
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	102,5 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	298,7 mg/ml
Assay: procaine	114,0 ... 126,0 mg/ml	118,8 mg/ml
Assay: methyl-4-hydroxybenzoate	2,698 ... 2,982 mg/ml	2,800 mg/ml
Assay: propyl-4-hydroxybenzoate	0,304 ... 0,336 mg/ml	0,309 mg/ml
Assay: propylene glycol	147,25 ... 162,75 mg/ml	154,38 mg/ml
Assay: sodium thiosulphate 5H2O	0,9 ... 1,1 mg/ml	0,9 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

Certificate of Analysis

Certificate No.: 48956

Product: Procopen 300mg/ml inj 100ml RO
Article number: 85203
Batch: 22024402 Split: 0
Quantity: 1.008 Units
Manufacturing date: 29.03.2022
Expiry date: 28.02.2026

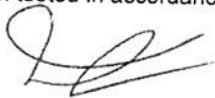
Dosage form: Suspension for injection
Package size: 100ml
Marketing authorisation holder: aniMedica GmbH
Registration number: 090134
Distributor / Importer: RO - BistriVet Rumänien

Parameter	Specification	Result
-----------	---------------	--------

Template: 1884

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

17. MAI 2022



Date, Signature Head of Quality Control



aniMedica GmbH
a LIVISTO company

Batch certificate

Certificate No.: 48956

Product:	Procapen 300mg/ml inj 100ml RO		
Article number:	85203	Dosage form:	Suspension for injection
Batch:	22024402 Split: 0	Package size:	100ml
Quantity:	1.008 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	29.03.2022	Registration number:	090134
Expiry date:	28.02.2026	Distributor / Importer:	RO - BistriVet Rumänien

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:

Four horizontal lines for remarks, each with a diagonal slash through it, indicating no remarks.

18.05.22
Date, Signature Qualified Person

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