

Certificate of Analysis

Certificate No.: 40457

Product:	Procapen 300mg/ml inj 100ml RO		
Article number:	85203	Dosage form:	Suspension for injection
Batch:	21022503 Split: 0	Package size:	100ml
Quantity:	1.000 Units	Marketing authorisation holder:	aniMedica GmbH
Manufacturing date:	18.05.2021	Registration number:	090134
Expiry date:	30.04.2025	Distributor / Importer:	RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	White to yellowish suspension	complies
Resuspendability	Easily to homogenise in 30 sec	12sec
Odour	Characteristic	complies
Relative density	1,082 ... 1,102	1,094
pH	6,5 ... 7,0	6,9
Particle size	100% < 40µm	100% < 40µm
Particle size	Min 95% < 30µm	100% < 30µm
Extractable volume	Min. 100,5 ml	101,7 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	Periodic test, no result
Identity: sodium thiosulphate 5H2O	Decolouration of iodine	Corresponds to
Assay: benzylpenicillin-procaine 1H2O	285,0 ... 315,0 mg/ml	305,0 mg/ml
Assay: procaine	114,0 ... 126,0 mg/ml	121,6 mg/ml
Assay: methyl-4-hydroxybenzoate	2,698 ... 2,982 mg/ml	2,825 mg/ml
Assay: propyl-4-hydroxybenzoate	0,304 ... 0,336 mg/ml	0,306 mg/ml
Assay: propylene glycol	147,25 ... 162,75 mg/ml	Periodic test, no result
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

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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.

16. JUNI 2021

Date, Signature Head of Quality Control

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.

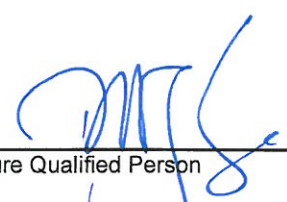
This batch has the required quality and

☐ is released for delivery

☒ is released for the market

Remarks:

/ / / /

16.06.21 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange ☐ Gudrun Prußeit

☐ Dr. Jürgen Schlüter

☐ Dr. Bernd Manfred Müller ☐