



aniMedica GmbH
a LIVISTO company

Certificate of Analysis

Certificate No.: 68021

Product: Procaben 300mg/ml inj 100ml RO
Article number: 85203 Dosage form: Suspension for injection
Batch: 25009304 Split: 0 Package size: 100ml
Quantity: 1,176 Units Marketing authorisation holder: aniMedica GmbH
Manufacturing date: 10.02.2025 Registration number: 150264
Expiry date: 31.01.2029 Distributor / Importer: RO - BistriVet Rumänien

Parameter	Specification	Result
Appearance	White to yellowish suspension	White to yellowish suspension, easily resuspendable
Resuspendability	Easily to homogenise in 30 sec	Easily to homogenise in 30 sec
Relative density	1.082 ... 1.102	1,095
pH	6.5 ... 7.0	6,9
Particle size, <40µm	100% max. 40µm	100% < 40µm
Particle size, <30µm	Min 95% max. 30µm	100% < 30µm
Extractable volume	Min. 100.5 ml	102,5 ml
Identity: benzylpenicillin-procaine 1H ₂ O, Procaben	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: methyl-4-hydroxybenzoate, Procaben	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: propyl-4-hydroxybenzoate, Procaben	Retention time and UV spectrum of standard and sample must correspond	Corresponds to
Identity: sodium thiosulphate 5H ₂ O, Procaben	Decolouration of iodine	Corresponds to
Assay: benzylpenicillin-procaine 1H ₂ O, Procaben	285.0 ... 315.0 mg/ml	301,6 mg/ml
Assay: procaine, Procaben	114.0 ... 126.0 mg/ml	120,8 mg/ml
Assay: methyl-4-hydroxybenzoate, Procaben	2.698 ... 2.982 mg/ml	2,848 mg/ml
Assay: propyl-4-hydroxybenzoate, Procaben	0.304 ... 0.336 mg/ml	0,314 mg/ml
Assay: propylene glycol, Procaben	147.25 ... 162.75 mg/ml	Periodic test, no result
Assay: sodium thiosulphate 5H ₂ O, Procaben	0.9 ... 1.1 mg/ml	0,9 mg/ml
Any single impurity, Procaben	Max. 0.5 %	0,0 %
Total impurities, Procaben	Max. 1.0 %	0,1 %
Impurity: 4-hydroxybenzoic acid, Procaben	Max. 10,0%	Corresponds to
Sterility	Sterile	Corresponds to

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

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Along with you



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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.

11. MRZ. 2025

Date, Signature Head of Quality Control

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