

Certificate of Analysis

Certificate No.: 29521

Product: Procopen 300mg/ml inj 100ml RO

Dosage form:

Package size: 100ml

Product: 85203

Marketing authorisation holder:

Batch: 20002302 Split: 0

Registration number: 150264

Quantity: 1.000 Units

Manufacturing date: 16.03.2020

Expiry date: 29.02.2024

Parameter	Specification	Result
Appearance	White to yellowish suspension	White suspension
Resuspendability	Easily to homogenise in 30 sec	Easily to homogenise in 30 sec
Odour	Characteristic	Characteristic
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	103,8 ml
Identity: benzylpenicillin-procaine 1H2O	Retention time of standard and sample must correspond	Corresponds to
Identity: methyl-4-hydroxybenzoate	Retention time of standard and sample must correspond	Corresponds to
Identity: propyl-4-hydroxybenzoate	Retention time 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: benzylpenicilline-procaine 1H2O	285,0 ... 315,0 mg/ml	299,5 mg/ml
Assay: procaine	114,0 ... 126,0 mg/ml	120,1 mg/ml
Assay: methyl-4-hydroxybenzoate	2,698 ... 2,982 mg/ml	2,790 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	Periodic test, no result
Assay: sodium thiosulphate 5H2O	0,9 ... 1,1 mg/ml	1,1 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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Template: 1884

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

08. MAI 2020

Date, Signature Head of Quality Control

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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:

12.5.26 
Date, Signature Qualified Person

☒ Dr. Hans-Jörg Lange☐ Gudrun Pruß☐ Dr. Jürgen Schlüter☐