

Certificate of Analysis

Certificate No.: 19369

Product: Procopen 300mg/ml inj 100ml RO Manufacturing date: 12-02-19
 Product-No.: 85203 Expiry date: 31-01-23
 Batch-No.: 19004301
 Split: 0
 Quantity: 1.008 Unit(s)

Parameter	Specification	Result
Extractable volume	Min. 100,5 ml	101,0 ml
Batch packaging record	batch packaging record complies	Corresponds to
Appearance	White to yellow white suspension, easily to resuspendable	White to yellow white suspension, easily to resuspendable
Odour	Characteristic	Characteristic
Homogeneity	Easily to homogenise in 30 sec.	6 sec
Particle size	100 % < 40 µm Min. 95 % < 30 µm	complies
pH-value	6,5 ... 7,0	6,8
Relative density	1,082 ... 1,102	1,095
Identity Procain-Benzylpenicilline (HPLC)	Retention time of reference and sample complies	Corresponds to
Identity Methyl-4-hydroxybenzoate (HPLC)	Retention time of reference and sample complies	Corresponds to
Identity Propyl-4-hydroxybenzoate (HPLC)	Retention time of reference and sample complies	Corresponds to
Identity Propylene glycole (GC) (every 5th batch)	Retention time of reference and sample complies	Periodic test, no result
Identity Sodium thiosulphate	Decolourisation of iodine	Corresponds to
Assay Procaine Benzylpenicilline 1 H2O (HPLC)	285,0 ... 315,0 mg/ml	304,3 mg/ml
Assay Procaine (HPLC)	114,0 ... 126,0 mg/ml	119,7 mg/ml
Assay Methyl-4-hydroxybenzoate (HPLC)	2,698 ... 2,982 mg/ml	2,785 mg/ml
Assay Propyl-4-hydroxybenzoate (HPLC)	0,304 ... 0,336 mg/ml	0,313 mg/ml
Assay Propylene glycole (every 5th batch)	147,25 ... 162,75 mg/ml	Periodic test, no result
Assay Sodium thiosulphate 5H2O	0,9 ... 1,1 mg/ml	1,0 mg/ml
Impurity, single	Max. 0,5 %	< 0,1 %
Impurity, total	Max. 1,0 %	0,2 %
4-Hydroxybenzoic acid (DC)	Max. 10,0 %	Corresponds to
Sterility	Sterile	Corresponds to

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

Hereby it is confirmed for the named batch, that the above information is authentic and accurate. The batch was manufactured and tested in accordance to the GMP requirements and the current authorized procedures for manufacturing and testing.

During the manufacture and testing

- ☐ no deviations/irregularities have been observed.
☒ the following deviations/irregularities have been observed:

ADN 2.18-45 sum of API-containers used

These deviations/irregularities do not affect the quality of the product, because

sum of API-containers within manufacturing company complies

The named batch has the required quality and is released

- ☐ for dispatch
☒ for the market

Comments:

/ / / /

12.04.18

Date, Signature Qualified Person

[Signature]