

Certificate of Analysis

Certificate No.: 16527

Product:	Procapen 300mg/ml inj 100ml RO	Manufacturing date:	24-09-18
Product-No.:	85203	Expiry date:	31-08-22
Batch-No.:	18194004		
Split	0		
Quantity:	1.008 Unit(s)		

Parameter	Specification	Result
Filling quantity	Min. 100,5 ml	101,7 ml
Batch packaging record	batch packaging record complies	Corresponds to
Appearance	white to yellow white suspension	white to yellow white suspension
Ease of resuspendability	easy shakeable	easy shakeable
Odour	specific	specific
Homogeneity	easy shakeable in 30 sec.	5s
Grain size	100 % < 40 µm min. 95 % < 30 µm	100% < 30 µm
pH	6,5 ... 7,0	6,7
rel. Density	1,082 ... 1,102	1,096
Identity (active pharmaceutical ingredient)	conforms	Corresponds to
Assay Procain-Benzylpenicillin 1 H2O	285000 ... 315000	305940 I.E./mL
Assay Procain-Benzylpenicillin 1 H2O	285,0 ... 315,0 mg/ml	305,9 mg/ml
Assay Procain	114,0 ... 126,0 mg/ml	121,1 mg/ml
Assay Methyl-4-hydroxybenzoate	2,698 ... 2,982 mg/ml	2,753 mg/ml
Assay Propyl-4-hydroxybenzoate	0,304 ... 0,336 mg/ml	0,307 mg/ml
Assay Propylenglycol	147,25 ... 162,75 mg/ml	154,02 mg/ml
Assay Sodiumthiosulfate	0,9 ... 1,1 mg/ml	0,9 mg/ml
Impurity, single	Max. 0,5 %	< 0,1 %
Impurity, total	Max. 1,0 %	0,2 %
4-Hydroxybenzoic acid (TCL)	Max. 10,0 %	Corresponds to
Sterility	sterile	Corresponds to

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Parameter	Specification	Result
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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:

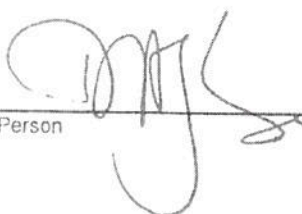
ABU 218-433 deviation in container calculation
 These deviations/irregularities do not affect the quality of the product, because

total amount copies on API cd held
 The named batch has the required quality and is released

- ☐ for dispatch
☒ for the market

Comments:

/ / / /

17.02.18 
 Date, Signature Qualified Person