

# CERTIFICATE OF ANALYSIS



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Product: **Cepect 25 mg/ml (100 ml) (HU/RO)**  
 Art. Nr.: 75858  
 Batch number: KPZZZ6J  
 Manufacturing date: 18.02.14  
 Expiry date: 02/2016  
 Container: bottle of 100 ml

Parameter	Specification	Result
<b>Analyses</b>		
properties	complies	complies
imprint (batch number and date of expiry) is correct	complies	complies
text, layout and product insert	complies	complies
<b>Parameter</b>	<b>Specification</b>	<b>Result</b>
<b>Analyses</b>		
<b>properties</b>		
appearance and consistency	white - light yellow suspension.	complies
particle size <= 30 µm (EP 7.0, chapter 2.9.37)	99.5 %	complies
relative density (EP 7.0, chapter 2.2.5)	0.860 - 0.900 g/ml	0.882 g/ml
sedimentation (4h / Ho after 24 hours)	<= 0.50	0.22
withdrawable volume	>= 100 ml	100 ml
syringeability (10 ml syringe, 40 mm needle, Ø 1.2 mm)	< 10 sec	3 sec
resuspendability	homogeneous in less than 60 sec. (handshaking)	complies
<b>Identity</b>		
cefquinome	HPLC: t(R) sample and reference are comparable	complies

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Parameter	Specification	Result
cefquinome (UV spectrum)	complies	complies
Assay		
cefquinome	23.75 - 26.25 mg/ml	24.72 mg/ml
<b>Purity</b>		
7-ACA (ref. to cefquinome)	≤ 1.0 %	<0.3 %
7-CHP (ref. to cefquinome)	≤ 1.0 %	<0.3 %
desacetyl/cefquinome (ref. to cefquinome)	≤ 1.0 %	0.4 %
desacetoxy/cefquinome (ref. to cefquinome)	≤ 1.0 %	<0.3 %
desacetyl/cefquinome lactone (ref. to cefquinome)	≤ 1.0 %	<0.3 %
delta 2 cefquinome (ref. to cefquinome)	≤ 1.0 %	<0.3 %
cefotaxime (ref. to cefquinome)	≤ 1.0 %	0.3 %
THQ (ref. to cefquinome sulfate)	≤ 1.0 %	<0.3 %
unknown impurity (ref. to cefquinome)	≤ 1.0 %	<0.3 %
impurities, total (ref. to cefquinome)	≤ 3.0 %	<0.7 %
<b>Microbiology</b>		
<b>General</b>		
Sterility	sterile according to EP 7.0, chapter 2.6.1	complies



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The batch has been manufactured and checked in accordance with the requirements of its marketing authorisation and the principles and guidelines of EC Good Manufacturing Practice.

Electronical approval on 14.3.14-11:20 by Dr. Andreas Benen

## Finished product

- complies to all specifications
- is released for market

  
Dr. Andreas Benen  
Qualified Person

Garbsen, 14.3.2014