



Certificate of analysis

Product:	ADRENALINE HYDROGEN TARTRATE		
Batch number:	2006047.1866	Manuf. Batch number:	C38-200401
Manufacturing date:	Apr-2020	Expiry date:	Mar-2023
Quality:	EP 10.0		

Test	Requirement	Result	Unit	Standard remark	Control by
Characters					
Appearance	White or greyish-white, crystalline powder	Complies			AL
Identification					
A. Specific optical rotation	-53.5 - -50.0	-51.7	°	Average of ID samples Sample 01: -51.4 ° Sample 02: -51.9 °	AL
B. IR spectrum	Complies	Complies			AL
C. Tartrates	Complies	Complies			AL
Tests					
Appearance of solution	≤ Reference suspension II	Complies		Clarity of the solution	AL
	≤ Reference solution BY5	Complies		Colour of the solution	AL
Loss on drying	≤ 0.5	0.0	%		AL
Sulfated ash	≤ 0.1	Complies	%		AL
Related Substances					
Impurity A	≤ 0.3	< 0.05	%		AL
Impurity B	≤ 0.2	< 0.05	%		AL
Impurity C	≤ 0.2	< 0.05	%		AL
Impurity D	≤ 0.1	< 0.05	%		AL
Impurity E	≤ 0.1	< 0.05	%		AL
Unspecified impurities	≤ 0.10	< 0.05	%		AL
Total	≤ 0.6	< 0.05	%		AL
Assay					
Titration	98.5 – 101.0	100.3	% w/w	Adrenaline tartrate; dried	AL

AC Man = Analysis performed by Manufacturer AL = Analysis performed by authorized Laboratory Guaranteed traceability available at Ofipharma					
Heembadweg 5, 9561 CZ, Ter Apel, The Netherlands		T: +31 599 745 390	F: +31 599 582 734	E: info@ofipharma.com	
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Other data	Requirement	Result	Standard remark
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform	Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform	Data producer

Production, expiry/retest date conform primary packaging. I hereby confirm that the above mentioned results are in compliance with the referred Pharmacopoeia and are authentic and accurate.

Conclusion: Approved

Quality Assurance

R.B. Lantink, MSc

28 AUG 2020

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