

WUHAN WUYAO PHARMACEUTICAL CO.,LTD



CERTIFICATE OF ANALYSIS

METAPHARMACEUTICAL

REC-QC-00235-04

N DE LOTE:

0074122

Report Number: J15-220004

Product Name: **Adrenaline Tartrate** Batch No: C38-220501
 Test Standard: EP10.0/BP2018 Manufacturing Date: 2022.05.12
 Packing: / Report Date: 2022.05.19
 Quantity: 15.38kg Retest Date: 2025.04

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10/11/2022

Item	Requirements	Result
【Characters】		
Appearance	White or greyish-white, crystalline powder	White crystalline powder
Solubility	freely soluble in water, slightly soluble in ethanol (96 per cent)	Conforms
【Identification】		
A. Specific optical rotation	-53.5° to -50°	-51.5°
B. IR	The sample spectrum complies with the reference standard spectrum	Conforms
C. Tartrates reaction	Should be comply	Conforms
【Tests】		
Appearance of solution	Not more than II Not more than BY5	Less than II Less than BY5
Related substances (HPLC)		
Impurity A	Not more than 0.3%	Less than 0.05%
Impurity B	Not more than 0.2%	Not detected
Impurity C	Not more than 0.2%	Not detected
Impurity D	Not more than 0.1%	Not detected
Impurity E	Not more than 0.1%	Not detected
Unspecified Impurities	Not more than 0.10%	Less than 0.05%
Total impurities	Not more than 0.6%	Less than 0.05%
Loss on drying	Not more than 0.5%	0.1%
Sulfated ash	Not more than 0.1%	0.04%
【Assay】		
(dried substance)	98.5% to 101.0%	99.5%

Conclusion: The above product complies with the standard EP10.0/BP2018

Approved by: *章子忠 2022.05.19* Checked by: *李伟 2022.05.19* Prepared by: *王强 2022.05.19*

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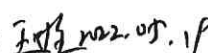
Product Name:	Adrenaline Tartrate	Batch No:	C38-220501
Test Standard:	Customer Standard	Manufacturing Date:	2022.05.12
Packing:	/	Report Date:	2022.05.19
Quantity:	15.38kg	Retest Date:	2025.04

<u>Item</u>	<u>Requirements</u>	<u>Result</u>
【Microbial test】		
Total aerobic microbial count	Not more than 100 CFU/g	Less than 1CFU/g
Total yeasts and mould count	Not more than 50 CFU/g	Less than 1CFU/g
【Bacterial endotoxins】	Not more than 12.6 EU/mg	Less than 12.6 EU/mg
【Residual solvent】		
Methanol	Not more than 3000 ppm	417ppm
Ethanol	Not more than 5000 ppm	Not detected
Palladium	Not more than 1ppm	Less than LOD

Conclusion: The above product complies with the standard Customer Standard

Approved by: 
2022.05.19

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