



08/04/2024

浙江天宇药业股份有限公司
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CERTIFICATE OF ANALYSIS

ORIGINAL

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No.:E10130202403031

Product Name	Losartan Potassium		
Batch NO.	10130-240118	CAS	124750-99-8
Packaging Size	25kg/Drum	Manufacturing Date	2024.01.18
Batch Quantity	937.27kg	Re-test Date	2027.01.17
Analysis Basis	Ph.Eur.11.0	Report Date	2024.03.04
Storage Condition	Preserve in well-closed containers		

Analysis Items	Acceptance criteria	Analysis results
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Infrared absorption	Complies with the spectrum obtained with the reference standard	Conforms
Test for potassium	Positive	Positive
Related substances	Impurity D: NMT 0.15%	Not detected(LOD:0.015%)
	Impurity J: NMT 0.15%	Not detected(LOD:0.004%)
	Impurity K: NMT 0.15%	<LOQ:0.015%
	Impurity L: NMT 0.15%	<LOQ:0.013%
	Impurity M: NMT 0.15%	0.02%
	Any unspecified impurity: NMT 0.10%	0.01%
	Total impurities: NMT 0.3%	0.04%
MB-X	NMT 10.0ppm	Not detected(LOD:1.0ppm)
Loss on drying	NMT 0.5%	0.09%
Residual solvents	Cyclohexane: NMT 1000ppm	12ppm
	2-Propanol: NMT 2000ppm	111ppm
Assay(Titration,calculated on dried substance)	98.5~101.5%	99.7%
Conclusion:The analysis results show that this batch of losartan potassium conforms to Ph.Eur.11.0.		

Prepared by/Date:

2024.03.13

Checked by QC/Date:

2024.03.13

Checked by QA/Date:

2024.03.13

R1-CEP 2009-227-Rev 06

Shipment Quantity

KG

Signature/Date

