F&A PHARMA

COPY QA APPROVED Date 29.07.24 Signature

01/08/2024

METAPHARMACEUTICAL

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浙江天宇药业股份有限公司
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CERTIFICATE OF ANALYSIS

ORIGINAL

No.:E10131202407011

Product Name	Losartan Potassium		
Batch NO.	10131-240501	CAS	124750-99-8
Packaging Size	25kg/Drum	Manufacturing Date	2024.05.17
Batch Quantity	940.28kg	Re-test Date	2027.05.16
Analysis Basis	Ph.Eur.11.0	Report Date	2024.06.03
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%	Not detected(LOD:0.004%)
	Impurity M: NMT 0.15%	0.01%
	Any unspecified impurity: NMT 0.10%	<RL:0.02%
	Total impurities: NMT 0.3%	0.03%
Loss on drying	NMT 0.5%	0.18%
Residual solvents	Cyclohexane: NMT 1000ppm	52ppm
	2-Propanol: NMT 2000ppm	103ppm
Assay(Titration,calculated on dried substance)	98.5%~101.5%	99.7%
Additional Items		
MB-X	NMT 10.0ppm	Not detected(LOD:1.0ppm)
Conclusion: The analysis results show that this batch of losartan potassium conforms to Ph.Eur.11.0 requirements of additional items.		

Prepared by/Date: 2024.07.05

CEP 2009-227-Rev 07

Checked by QC/Date: 2024.7.6

Checked QA/Date:

Shipment Quantity _____KG Signature/Date

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