

CERTIFICATE OF ANALYSIS

No: 30150072

Product name	Enalapril Maleate	According to	SOP-03938-08
Source	Workshop I	Batch No.	3015-2110-072
Package	Fibre drum	Manufacturing date	2021.10.27
Package size	25kg/drum	Report date	2021.11.01
Quantity	325.3kg	Retest date	2025.10.26
Items	Specification		Results
Description	Off-white ,crystalline powder		Complies
Identification	A	IR Spectrum accordance with that of CRS	Complies
	B	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the assay.	Complies
Specific rotation	-41.0° ~ -43.5°		-41.9°
Loss on drying	Not more than 1.0 %		0.04%
Residue on ignition	Not more than 0.2%		0.03%
Related substances	Enalaprilat: not more than 0.3%		0.06%
	Moexipril related compound F: not more than 0.3%		<0.05%
	Enalapril cyclohexyl analog: not more than 0.3%		0.15%
	Enalapril related compound D: not more than 0.3%		<0.05%
	Any unspecified impurity: not more than 0.10%		<0.05%
	Total impurities: not more than 2.0%		0.34%
* Residual solvents	Ethanol: not more than 5000ppm		130ppm
	Acetone: not more than 5000ppm		No detectable
	Dichloromethane: not more than 600ppm		No detectable
	n-Hexane: not more than 290ppm		No detectable
Assay (Calculated on the dried basis)	98.0% ~ 102.0%		100.1%
Conclusion: Complies with USP-NF 2021			

QC: 陈仁通

2022.02.16

QA:



2022.02.16