

## Enalapril Maleate USP

Batch no Mf date Retest

5112-23-075 Jun 02 2023 Jun 01 2028

Molecular Structure

ОН

Molecular Formula

 $C_{20}H_{28}N_2O_5 \ C_4H_4O_4$ 

Molecular Weight CAS Registry Number

76095-16-4

492.52

Mar 06 2024

<u>Tests</u>	Specifications		Results
Appearance	White or almost white crysta	lline powder	Almost white crystalline powder
Solubility	Freely soluble in methanol, soluble in water, practical in dichloromethane		Conforms
Identification	IR, RRT		Positive
Specific rotation	-41.0 ~ -43.5°		-42. 4°
Loss on drying	≤ 1.0%		< 0.1%
Residue on ignition	≤ 0.2%		< 0.1%
Related substances	Enalaprilat	≤ 0.3%	0. 08%
	Moexipril related compound F		< LOD
	Enalapril related compound D		< L00
	Enalapril cyclohexyl analog		0. 13%
	Any unspecified impurity		< LOD
		≤ 2.0%	0. 21%
Residual solvents (GC)	Ethanol	≤ 5000 ppm	ND
Assay (odb) HPLC	98.0 ~ 102.0%		99.5%

Packaging & storage	Preserve in well-closed containers, and store at controlled room temperature	
Conclusion	Material complies with USP	

