



WRS - E27 - 1

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CERTIFICATE OF ANALYSIS Working Standard

Name of CRS used: Enalapril Maleate
Lot/Batch: no. JIC267
Source: USP

Purity/Potency: 0.992mg/mg
Exp Date: Website information

Name of Working Standard: Enalapril Maleate
Raw Material Bno, used: EPFP 10005
Manufacturer: Sri Krishna
Date of Analysis: 15/05/2015
Validity of use: Use within one month after opening, valid up to 09/2015, when sealed.
Quantity: 2.0g

EWS No: 13/15

Mfg Date: 10/2010, Exp Date: 09/2015

RESULTS:

Sr. No.	Test Parameters	Limits	Observation
1	Description	A white or almost white powder	A white crystalline powder
2	Identification: A. Infra red absorption	The IR spectrum of test sample is concordant to the IR spectrum of Enalapril Maleate working standard	The IR spectrum of test sample is concordant to the IR spectrum of Enalapril Maleate working standard
3	Loss on drying	NMT 1.0 %	0.51%
4	Assay (On anhydrous basis)	98.5% - 101.5%	100.4%

Additional Remarks:

Storage conditions:

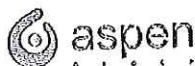
- Store in refrigerator at 2°C- 8°C, when not in use
- Use within 30 days after opening, kept at a temperature of below 25 °C
- Keep tightly closed and protect from light

Justification of the selection of raw material for qualification:

- The Enalapril Maleate Raw material was taken from the current lot.

QUALITY CONTROL
SHELYS PHARMACEUTICALS
P. O. BOX 3016
DAR ES SALAAM

	Analysed by	Checked by	Approved by
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Name	Richard M.	Mwagathi M. Sule	Codene Obwagira
Date	15/05/2015	15/05/2015	15/05/2015
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control



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