



1 vial  
G-1

**Shelys Pharmaceuticals Limited**  
P.O. Box 32781, Dar es Salaam, Tanzania  
**Certificate of Analysis**  
**Working Standard**

Name of CRS used: Cetirizine Dihydrochloride Purity/Potency: 100.0%  
Lot/Batch: 3.1 ExpDate: Depending on website information  
Source: Eur Ph

Name of working standard: Cetirizine Dihydrochloride W/S No: 24/14  
Raw Material Bno: CTZ/033/13 - 14 Mfg Date: 03/2014 Expiry Date: 02/2019  
Manufacturer: Karunesh Remedies  
Supplier: Sanjay Chemicals Ltd  
Date of Analysis: 30 May 2014

No	Test	Limits	Observations
1	Description	White powder	White powder
2	Identification: IR Spectrum	IR spectrum of Cetirizine Dihydrochloride test material is concordant to the IR spectrum of Cetirizine Dihydrochloride CRS	IR spectrum of Cetirizine Dihydrochloride test material is concordant to the IR spectrum of Cetirizine Dihydrochloride CRS
3	Loss on Drying	NMT 0.5 %	0.08%
4	Assay: (on dried basis)	99.0% - 100.5%	99.99%

Storage condition: In refrigerator at: 2°C – 8°C

Remarks: Working standard complies

Justification for selection of this batch for W/S qualification:

Cetirizine Dihydrochloride - Bno CTZ/033/13 - 14 – Assay - 99.69%

Date received: 19 May 2014 (1 Batch)

	Analysed by	Checked by	Approved by
Signature			
Name	Munira S. M	LILIAN MUSEWA	Mwakatubulu
Date	30 MAY 2014	30 MAY 2014	30 MAY 2014
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control