



Shelys Pharmaceuticals Limited

P.O. Box 32781, Dar es Salaam, Tanzania

Certificate of Analysis

Working Standard

Name of CRS used: Clotrimazole

Lot/Batch: 2025

Source: BP

Purity/Potency: 99.7%

ExpDate: Depending on website information

Name of working standard: Clotrimazole W/S No: 28/14

Raw Material Bno: 20130813 Mfg Date: 03/2013 Expiry Date: 03/2017

Manufacturer: Jintan Zhongxing Pharmaceuticals

Supplier: Essential Drugs Ltd

Date of Analysis: 13 August 2014

No	Test	Limits	Observations
1	Description	Yellowish – white, fine crystalline powder, needles	Yellowish -White crystalline powder
2	Identification: IR Spectrum	IR spectrum of Clotrimazole test material is concordant to the IR spectrum of Clotrimazole CRS	IR spectrum of Clotrimazole test material is concordant to the IR spectrum of Clotrimazole CRS
	Melting Point	141.0°C - 145.0°C	142.5°C
3	Loss on Drying	NMT 0.5%	0.16%
4	Assay: (on dried basis)	98.0% - 100.5%	99.85%

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

Remarks: Working standard complies

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

Clotrimazole - Bno 20130813 - Assay – 99.84%

Date received: 12 August 2014 (1 Batch)

	Analysed by	Checked by	Approved by
Signature			
Name	Munira S. M	Mwakatumbuli	Codere Obwaro
Date	13 August 2014	13/08/2014	13/08/2014
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control

