



Shelys Pharmaceuticals Limited

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

Certificate of Analysis

Working Standard

Name of CRS used: Lumefantrine

Lot/Batch: FOH108

Source: USP

Purity/Potency: 99.8%

ExpDate: Depending on website information

Name of working standard: Lumefantrine

W/S No: 25/14

Raw Material Bno: 3011LU7JM

Mfg Date: 08/2013

Expiry Date: 07/2018

Manufacturer: Ipca laboratories Ltd

Supplier: Ipca laboratories Ltd

Date of Analysis: 09 June 2014

No	Test	Limits	Observations
1	Description	Yellow crystalline powder	Yellow crystalline powder
2	Identification: IR Spectrum	IR spectrum of Lumefantrine test material is concordant to the IR spectrum of Lumefantrine CRS	IR spectrum of Lumefantrine test material is concordant to the IR spectrum of Lumefantrine CRS
3	Loss on Drying	NMT 5.0mg/g	1.6mg/g
4	Assay: (on dried basis)	97.0% - 102.0%	100.46%

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

Remarks: Working standard complies

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

Lumefantrine - Bno 3011LU7JM - Assay - 99.10%

Date received: 18 November 2013 (1 Batch)

	Analysed by	Checked by	Approved by
Signature			
Name	Munira S. M	Mwalitumbulo	Codene Oboro
Date	09 JUNE 2014	09 JUNE 2014	09/06/2014
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control