WRS MIG -8

Shelys
An Aspon Group Company

shelys pharmaceuticals itd an aspen group company

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CERTIFICATE OF ANALYSIS Working Standard

Name of CRS used: Metformin Hydrochloride

Purity/Potency: 100%

Lot/Batch: no. 3.0

Exp Date: Website information

Source: EPRS

Name of Working Standard: Metformin Hydrochloride

EWS No: 15/15

Raw Material Bno, used: 4110062

Mfg Date: 09/2013, Exp Date: 08/2017

Manufacturer: Granules India Date of Analysis: 18 /04/2015

Validity of use: Use within one month after opening, valid up to 08/2017, when sealed.

Quantity: 5.0g

RESULTS:

Sr. No.	Test Parameters	Limits	Observation
1	Description	A white crystalline powder	A white crystalline powder
2	Identification: A. Infra red absorption	The IR spectrum of working standard sample is concordant to the IR spectrum of Reference standard	The IR spectrum of working standard sample is concordant to the IR spectrum of Reference standard
3	Loss on drying	NMT 0.5%	0.42%
4	Assay (on dried basis)	92.5% - 97.5%	94.49%

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 Metformin Hydrochloride Raw material used was taken from the current lot.

QUALITY CONTROL MANAGER

SHELYS PHARMACEL.

P. O. BOX 3016

	DAKES SALAAN		
	Analysed by	Checked by	Approved by
Signature	Margahared	D.L.	alisto
Name	Viterburel M	Wwalst Sub	Coollie Chiggo
Date	18/04/2015	18.04.2015	13/04/2014
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control
		Landing	

