

CERTIFICATE OF ANALYSIS
Working Standard

Name of CRS used: Metformin Hydrochloride
Lot/Batch: no. 3.0
Source: EPRS

Purity/Potency: 100%
Exp Date: Website information

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 PHARMACEUTICALS
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DAR ES SALAAM

	Analysed by	Checked by	Approved by
Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
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Date	18/04/2015	18.04.2015	18/04/2015
Title	Analyst	Supervisor	QC Manager
Department	Quality Control	Quality Control	Quality Control