

**Pell Tech Health Care Pvt Ltd**

Plot No. 20B, Tansa Farm Estate, Bhiwandi-Wada Road, Wada, Thane, Maharashtra - 421312

CERTIFICATE OF ANALYSIS

Material Name	:	Metformin Hydrochloride B.P.			
Batch No.	:	MEF/18061164	AR Number	:	2018-19/QCG/RMR/00206
GRN No	:	RM-00127	Received Qty.	:	2000.000 Kg
Manufacture Name	:	Aarti Drugs Ltd.	Received Date	:	11/06/2018
Supplier Name	:	Aarti Drugs Ltd.	Sample Qty.	:	0.040 Kg
Mfg. Date	:	Jun-2018	Sampling Date	:	18/06/2018
Exp Date	:	May-2023	Rejected Qty	:	0.000 Kg
Retest Date	:	21/06/2019	Released Date	:	21/06/2018

SR No	Test	Specification	Observation
1	Description	White or almost white crystals.	White crystalline Powder.
2	Solubility	Freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in acetone and in methylene chloride.	Freely soluble in water, slightly soluble in ethanol (96 per cent), practically insoluble in acetone and in methylene chloride.
3	Identification First Identification B First Identification E	The infra red absorption spectrum is concordant with the reference spectrum of Metformin hydrochloride BP. It gives reaction (a) of chlorides - The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.	The infra red absorption spectrum is concordant with the reference spectrum of Metformin hydrochloride BP. It gives reaction (a) of chlorides - The precipitate dissolves easily with the possible exception of a few large particles which dissolve slowly.
4	Appearance of solution	Solution S is clear and colourless.	Solution S is clear and colourless.
5	Related Substance Impurity A Unspecified impurities	Not more than 0.02% Not more than 0.1%	0.002% 0.005%
6	Heavy Metals	Any brown colour in the test solution is not more intense than that in the reference solution. (Not more than 10ppm).	Any brown colour in the test solution is not more intense than that in the reference solution
7	Loss on drying (at 105°C)	Not more than 0.5%	0.35
8	Sulfated ash	Not more than 0.1%	0.04
9	Assay :	Between 98.5% to 101.0% (dried substance).	99.60

Conclusion : The conclusion of the undersigned about the above mentioned Raw Material complies as per British Pharmacopoeia Laid down specification & is of a standard quality mentioned there in.

Prepared By	Checked By	Approved By
Date	Date	Date



Aarti Drugs Limited

Manufacturers of : Bulk Drugs & Chemicals

Corporate Office : Plot No. 109-D, Mahendra Industrial Estate,
Ground Floor, Road No. 29, Sion (East), Mumbai - 400 022, India
Tel.: 022-24072249 / 24019025 (30 Lines) • Fax : 022-24070144 / 24073462
E-mail : admin@aatidrugs.com • Website : www.aatidrugs.com

Regd. Off.: Plot No. N-198, M.I.D.C. Tarapur, Tal. & Dist. Palghar (M.H.)-401506.

Factory : Plot No. 211 & 213, Road No. 2, GIDC, Sarigam,
Tal. Umergaon, Dist. Valsad, Gujarat, (India) - 396155.
Tel.: (0260) 2780269 / +91 9998010751

E-mail : hr211@aatidrugs.com Website : www.aatidrugs.com
CIN No. : L37060MH1984PLC055433

QUALITY CONTROL CERTIFICATE OF ANALYSIS

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PRODUCT NAME: METFORMIN HYDROCHLORIDE IP	BATCH SIZE : 2000 Kgs
BATCH NO. : MEF/18061164	A. R. NO. : FP/181200
MFG. DATE : JUNE - 2018	ANALYSIS DATE: 06/06/2018
EXP. DATE : MAY - 2023	CAS NO. : 1115-70-4

SR. NO.	TESTS	SPECIFICATION	RESULTS
1.	Description	A white or almost white crystalline powder.	White crystalline powder.
2.	Solubility	Freely soluble in water, slightly soluble in ethanol (95%), practically insoluble in acetone, in chloroform, in dichloromethane and in ether.	Complies
3.	Identification A. By IR	The infra-red absorption spectra of sample should be concordant with the spectrum obtained with Metformin Hydrochloride IP working standard.	Concordant
	B. Test B	An orange-red colour should produced which darkens on keeping.	Complies
	C. Test C	A wine red colour should develops within 3 minutes.	Complies
	D. Reaction of chloride	A curdled white precipitate should be formed which should dissolve in Ammonia R easily with the possible exception of a few large particles , which should dissolve slowly.	Complies
4.	Related substances Dicyandiamide:	Not more than 0.02%.	0.003%
	Any Other Max.Impurity:	Not more than 0.1 %.	Not Detected
5.	Heavy metals	Not more than 20 ppm.	Complies
6.	Sulphated Ash	Not more than 0.1 %.	0.03%
7.	Loss on drying	Not more than 0.5 %.	0.25%

(QCP/005/F/1/04)