

**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/10051548	AR Number	:	2020/QCG/RMR/00300
GRN No	:	RM-00037	Received Qty.	:	2000.000 Kg
Manufacture Name	:	Aarti Drugs Ltd.	Received Date	:	24/05/2020
Supplier Name	:	Sneha Medicare Pvt.Ltd	Sample Qty.	:	0.040 Kg
Mfg. Date	:	May-2020	Sampling Date	:	24/05/2020
Exp Date	:	Apr-2025	Rejected Qty.	:	0.000 Kg
Retest Date	:	30/05/2021	Released Date	:	30/05/2020

SR. No.	Test	Specification	Observation
1	Description	White or almost white crystals.	White crystals.
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 Identification B 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	Impurity F	Not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.05 per cent).	0.0015%
6	Related Substance Impurity A Unspecified impurities Total impurities	Not more than 0.02% Not more than 0.05% maximum 0.2 %	0.0031% 0.0163% 0.0477%
7	Loss on drying (at 105°C)	Not more than 0.5%	0.1%
8	Sulfated ash	Not more than 0.1%	0.07%
9	Assay :	Between 98.5% to 101.0% (on dried substance).	99.8%

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 30/05/2020	Date 30/05/2020	Date 30/05/2020

QUALITY CONTROL CERTIFICATE OF ANALYSIS

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PRODUCT NAME: METFORMIN HYDROCHLORIDE IP	BATCH SIZE : 2000 Kgs
BATCH NO. : MEF/10051548	A. R. NO. : FP/201620
MFG. DATE : MAY - 2020	ANALYSIS DATE: 15/05/2020
EXP. DATE : APR - 2025	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 curdy white precipitate is formed which is insoluble in nitric acid but soluble after being well washed with water in dilute ammonia solution, from which it is re-precipitated by the addition of dilute nitric acid.	Complies
4.	Related substances Dicyandiamide:	Not more than 0.02%.	0.003%
	Any Other Max.Impurity:	Not more than 0.1 %.	0.015%
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 %.	0.20%
8.	Assay	Not less than 98.5 % and Not more than 101.0 % of $C_4H_{11}N_5.HCl$ calculated on the dried basis.	100.28%
9.	*Particle Size (By Malvern Analyser)	NLT 90% Particle below 150µm/ 90% Particle below 100 mesh	Complies

Remark: The Batch of product sample is Complies as per the prescribed standard of Quality pharmacopoeia specification IP-2018. *Additional test.

Prepared By:

Date:

Date
15/05/2020
Pravin Patel
QC-Executive

Checked By:

Date:

15/05/2020
Sandip Gargav.
QC-Executive

Approved By:

Date:

Signature
16/05/2020
Mahendrabhai Bhargava
Executive
(QCP/005/F/1/04)