



Office : 314, T. V. Indl. Estate, S.K. Ahire Marg, Worli, Mumbai - 400 030. India
 Mfg. Unit : K-56, M. I. D. C., Tarapur, Dist. Thane, Maharashtra - 401 506. India
 Tel. : (91 22) 6663 5456 Fax : (91 22) 6663 5460 E-mail : auro@aurolabs.com Web : www.aurolabs.com

15/09/2022

CERTIFICATE OF ANALYSIS

FQA 09/02/27.03.2014

Product Name	METFORMIN HYDROCHLORIDE Ph. EUR		
Batch No.	2021MPC0455	Mfg. Date	September 2021
Batch Quantity	2000 kg	Exp. Date	August 2026
Qty supplied	250 kg	Date of Analysis	06.10.2021
A. R. No.	AMPC/21/0455	Released Date	06.10.2021
S.No	TEST	SPECIFICATION	RESULT
1.	Characters Appearance	White or Almost white crystals	White crystals
	Solubility	Freely soluble in water, slightly soluble in ethanol (96%), practically insoluble in acetone and in methylene chloride.	Freely soluble in water, slightly soluble in ethanol, practically insoluble in acetone and in methylene chloride.
2.	Identification:		
a.	Melting Point	222° C – 226° C	224° C
b.	By Infra Red Spectroscopy	IR Spectra of sample is concordance with working std	Complies
c.	Thin Layer Chromatography	Conforms to standards	Confirms
d.	Colouration with α -naphthol	A Pink colour develops.	Complies
e.	Reaction of chloride	Positive	Positive
3.	Appearance of solution	Solution S (2 gm in 20 ml water) should be clear and colourless.	Complies
4.	Impurity F (By HPLC)	Not more than 0.05 %	0.030 %
5.	Related substances (By HPLC)		
a)	Impurity A	Not more than 0.015 %	0.004 %
b)	Unspecified impurity	Not more than 0.05 %	0.038 %
c)	Total impurities	Not more than 0.2 %	0.073 %
6.	Loss on drying (At 105 °C for 5 hrs)	Not more than 0.3 %	0.18 %
7.	Sulphated ash	Not more than 0.1 %	0.04 %
8.	Assay on dried basis (By Potentiometer)	Not less than 99.0 % and not more than 101.0 %	100.02 %
Additional test :			
1.	Particle size	100 % particles passing through 100 mesh	Complies
2.	Residual solvents Methanol	Not more than 1000 ppm	26 ppm
3.	Nitrosodimethylamine (NDMA)	Not more than 30 ppb	8.50 ppb
REMARKS: The sample complies with prescribed standards Ph Eur & CEP: R-1 CEP 2005-123 Rev 03. Product is free from animal derived material & manufactured from synthetic source only.			
	Analysed by	Checked by	Approved by
Name	Zarina Churi	P.B.Galave	K.S.Kulkarni
Sign			
Date	06.10.2021	06.10.2021	06.10.2021