

M₁₉₋₁₀**Certificate of Analysis**
Secondary Reference StandardName: Metformin Hydrochloride
Material No: 10000475Batch No: 0000044688
Insp. Lot No: 10000048254

Test	Specification	Result
Description	White or almost white crystals, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method	Conform
Loss on drying	NMT 0.50%	0.27%
Related substances	Impurity A: NMT 0.02%	0.003%
	Any other impurity: NMT 0.10%	0.02%
Assay	NLT 98.50% and NMT 101.0% of 1, 1-dimethylbiguanide hydrochloride, calculated with reference to the dried substance.	99.14% (as is basis)
		99.41% (on dried basis)

Standardization date: 27/09/2015

Standardized by: Shankar

Exp. date: 09/2016

Weight per vial: 500mg

Checked by: Pensee Mohamed, B. S. Pharm
Quality Control Deputy ManagerHead of Quality Control Department
Sheikha Khams