GULF PHARMACEUTICAL INDUSTRIES

Ras Al Khaimah, Post Box No. 997 Tel.: +9717-2461461, Fax: +9717-2462462 United Arab Emirates

Julphar

Quality Control Department

arial celel and as

رأس الخيمة - ص.ب. ۹۹۷ تليفون : ۴۹۷۱۷–۲۲۹۱۲ فاكس : ۲۴۹۲۶۱۷–۹۷۱۷ لامارات المرد فالتحرة

M19-10

<u>Certificate of Analysis</u> Secondary Reference Standard

Name: Metformin Hydrochloride Material No: 10000475 Batch 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)
		# A

Standardization date: 27/09/2015

Exp. date: 09/2016

Standardized by: Shankar

Weight per vial: 500mg

Checked by: Pensee Mohamed, B. S. Pharm Quality Control Deputy Manager

Head of Quality Control Department Shelkha Khamis

17 DEC 2015