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Julphar
Quality Control Department

شركة الخليج للصناعات الدوائية
رأس الخيمة - ص.ب. ٩٩٧
تلفون: ٢٤٦١٤٦١-٩٧١٧+ فاكس: ٢٤٦٢٤٦٢-٩٧١٧+
الإمارات العربية المتحدة

Noel
WRS
G2-8

Certificate of Analysis
Secondary Reference Standard

Name: Glimepiride
Material No: 10000353

Batch No: 0000033[illegible]11
Insp. Lot No: 100000[illegible]2008

Test	Specification	Result
Description	White to almost white powder, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method.	Conform
Water content	NMT 0.50%	0.34%
Limit of cis-isomer (related compound A)	NMT 0.80%	0.01%
Related compounds	Related compound B: NMT 0.40%	0.13%
	Related compound C: NMT 0.10%	0.00%
	Related compound D: NMT 0.20%	0.00%
	Any unspecified individual impurity: NMT 0.10%	0.00%
	Total impurities excluding related compound B: NMT 0.50%	0.00%
Assay	NLT 98.0% and NMT 102.0%, calculated on the anhydrous basis.	99.56% (as is basis) 99.90% (on anhydrous basis)

Standardization date: 16/11/2015 — Standardized by: Shaima

Exp. date: 11/2016 — Weight per vial: 500mg

Standardized against: Glimepiride USP Reference Standard (Lot No: G0K135)

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

QUALITY CONTROL DEPARTMENT Julphar

Head of Quality Control Department
Sheikha Khamis