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Julphar
Quality Control Department

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

WRS P29-4

Certificate of Analysis
Secondary Reference Standard

WRS P29-4

Name: Pantoprazole Sodium
Material No: 10000586

Batch No: 0000047901
Insp. Lot No: 10000053327

Test	Specification	Result
Description	White to off-white powder, free from extraneous substances like black particles.	Conform
Identification	To pass tests under analytical method	Conform
Water content	5.0% to 8.0%	6.67%
Related Compounds	1- Related Compound A: NMT 0.20%	0.061%
	2-Related Compound B: NMT 0.15%	0.00%
	3-Related Compound C: NMT 0.10%	0.00%
	4-Related Compound D and F: NMT 0.20%	0.074%
	5-Related Compound E: NMT 0.10%	0.00%
	6-Any other individual impurity: NMT 0.10%	0.00%
	7-Total impurities: NMT 0.50%	0.135%
Assay	NLT 98.0% and NMT 102.0% of $C_{16}H_{14}F_2N_3NaO_4S$, calculated with reference to the anhydrous basis.	93.21% (as is basis) 99.87% (anhydrous basis)

NATIONAL QUALITY CONTROL LABORATORY RECEIVED 23 JUN 2016 P.O.Box 29726 – 00202, NAIROBI

Standardization date: 08/12/2015

Standardized by: Anas

Exp. date: 12/2016

Weight per vial: 500mg

Standardized against: Pantoprazole Sodium USP Reference Standard (Lot No: H1M239)

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

QUALITY CONTROL Julphar DEPARTMENT

Head of Quality Control Department
Sheikha Khamis