

Certificate of Analysis
Secondary Reference Standard

WRS-P29-2

Name: Pantoprazole Sodium
Material No: 10000567Batch No: 0000000903/II
Insp. Lot No: 10000001435

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%	6.50%
Related Compounds	1- Related Compound A: NMT 0.20%	0.089%
	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%	0.00%
	5-Related Compound E: NMT 0.10%	0.064%
	6-Any other individual impurity: NMT 0.10%	0.052%
	7-Total impurities: NMT 0.50%	0.205%
Assay	NLT 98.0% and NMT 102.0% of $C_{16}H_{14}F_2N_3NaO_4S$, calculated with reference to the anhydrous basis.	93.04% (as is basis) 99.51% (anhydrous basis)

Standardization date: 16-12-2014

Standardized by: Anas

Exp. date: 12/2015

Weight per vial: 500mg

Standardized against: Pantoprazole Sodium USP Reference Standard (Lot No: H0L207)

Pensee
Checked by: Pensee Mohamed, B. S. Pharm
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Sheikha Khamis

