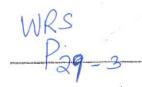
METROChem



WORKING STANDARD CERTIFICATE OF ANALYSIS
PANTOPRAZOLE SODIUM BP

***	PANTOPRAZOLE SODIUM BP			
Batch No.:	PAS/1504073			
Quantity:	1.0 gm			
Date of Manufacture:	APR-2015 Date of Analysis 11/11/2015			
Date of Expiry;	MAR-2020 Igsa Before 10/11/2016			
Tr. 20,000 4 20 T-22 T-22 T-22 T-22 T-22 T-22 T-22 T	Land Philipping			

Sr.No	Test	Result 9. Box 29725 - 0020	Specification		
)].	Appearance	White powder.	White or almost white powder.		
)2.	Solubility	Complies	Freely soluble in water and in ethanol (96 per cent), practically insoluble in hexane.		
)3.	Identification:				
	A). By IR	Complies	Spectrum of sample must be		
B).	(A). Dy He		concordant with Pantoprazole sodium working standard.		
		Positive	No precipitate is formed		
		The solution is clear and not more	The solution is clear and not		
04.	Appearance of solution	intensely colored than reference solution	more intensely colored than reference solution B ₆ .		
		B _{6.}	-0.4° to $+0.4^{\circ}$.		
05.	Optical rotation	+ 0.28°,			
)6.	Related Substances: (By F	Not more than 0.2%			
	Impurity A	0.04%	Not more than 0.2%		
	Sum of impurities D and	0.02%	Not like to		
	F		Not more than 0.1%		
	Impurities B, C, E	Not detected	Not more than 0.1%		
	Unspecified impurities	Not detected	Not more than 0.5%		
	Total impurities	0.22%	Not more than 20 ppm		
07.	Heavy metals	Less than 20 ppm	5.9 % to 6.9 %		
08.	Water content by KF	6.24%	99.84%		
09.	Assay (on anhydrous	99.0% to 101.00% w/w			
	basis)	0 AS IS BASIS	93.6 %		

Conclusion: The material as above complies with the BP Specification.

Conclusion: The II	laterial as doors		(0.1)
00000000000000000000000000000000000000	·	Checked By (QC)	Approved By (QA)
	Prepared By (QC)	Checker	
1		c hemist	Asit Managel
Designation	<u>Chemist</u>	(New Hall	0
	·Atm	Sections	pany 11/1/2000
Sign/Date	75 Mulis	0 1/1/12/15	
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