

WRS  
P29-3

METROChem

3

WORKING STANDARD CERTIFICATE OF ANALYSIS  
PANTOPRAZOLE SODIUM BP

Batch No.:	PAS/1504073
Quantity:	1.0 gm
Date of Manufacture:	APR-2015
Date of Expiry:	MAR-2020



Sr.No	Test	Result	Specification
01.	Appearance	White powder.	White or almost white powder.
02.	Solubility	Complies	Freely soluble in water and in ethanol (96 per cent), practically insoluble in hexane.
03.	Identification:		
	A). By IR	Complies	Spectrum of sample must be concordant with Pantoprazole sodium working standard.
	B).	Positive	No precipitate is formed
04.	Appearance of solution	The solution is clear and not more intensely colored than reference solution B <sub>6</sub> .	The solution is clear and not more intensely colored than reference solution B <sub>6</sub> .
05.	Optical rotation	+ 0.28°.	- 0.4° to + 0.4°.
06.	Related Substances: (By HPLC)		
	Impurity A	0.04%	Not more than 0.2%
	Sum of impurities D and F	0.02%	Not more than 0.2%
	Impurities B, C, E	Not detected	Not more than 0.1%
	Unspecified impurities	Not detected	Not more than 0.1%
	Total impurities	0.22%	Not more than 0.5%
07.	Heavy metals	Less than 20 ppm	Not more than 20 ppm
08.	Water content by KF	6.24%	5.9 % to 6.9 %
09.	Assay (on anhydrous basis)	99.0% to 101.00% w/w	99.84%

Assay On As Is Basis  
Conclusion: The material as above complies with the BP Specification.

93.6%

	Prepared By (QC)	Checked By (QC)	Approved By (QA)
Designation	Chemist	Chemist	Asst Manager
Sign/Date	<i>Am</i> 11/11/2015	<i>Jim</i> 11/11/2015	<i>Am</i> 11/11/2015

