

WRS

M42-1



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ACME FORMULATION PVT. LTD.
Ropar Road, Nalagarh, Distt. Solan (H.P.)-174101

WORKING STANDARD CERTIFICATE OF ANALYSIS

Product	Misoprostol 1% HPMC dispersion	Prepared on	22/02/2016
Working Standard No.	AF/HQ/WS/001/16-17	Effective Date	22/02/2016
Batch No.	B12968	Valid Up to	21/02/2017
Ref. Standard	Lot No. 3	Valid Up to	Up to next lot

RESULT OF ANALYSIS

Sr. No.	Test performed	Specification	Observation
1.	Description	A white to light yellow powder.	A white powder.
2.	Identification		
	By UV	A) Test solution exhibits no maximum near 280 nm. B) Test solution exhibits a maximum near 280 nm.	Complies.
	By HPLC	Retention time of Misoprostol in test solution should correspond to the retention time of Misoprostol in standard solution, as obtained in assay and impurity test.	Complies.
3.	Water content	Not more than 1.0 % w/w	0.53%
4.	Related substances (By HPLC)		
	8-Epi Misoprostol	Not more than 0.50 %	0.04 %
	A-form Misoprostol	Not more than 0.50 %	0.10 %
	B-form Misoprostol	Not more than 0.30 %	Not detected
	Individual unknowns	Not more than 0.10 %	0.06 %
	Total unknowns	Not more than 0.50 %	0.06 %
	Total impurities	Not more than 1.80 %	0.26 %
5.	Assay as such basis		0.98 % w/w
	Assay dried basis	Not less than 0.950% and not more than 1.04% w/w.	0.99% w/w

Conclusion: The above material is qualified for working standard.

Sign & Date	Prepared By	Checked By	Approved By
	<i>[Signature]</i> 22-02-2016	<i>[Signature]</i> 22-02-2016	<i>[Signature]</i> 22-02-2016