



K alchem International, Inc
Compounding Chemicals You Can Trust

PRODUCT:	MISOPROSTOL 1% HPMC DISPERSION	EXPIRATION DATE:	12/16/23
FINISHED LOT NO:	K-26-6836	MFG DATE:	12/21/20
CAS#	59122-46-2	SPECIFICATIONS:	
MANUFACTURE:	CHIROGATE INTERNATIONAL INC.	COUNTRY OF ORIGIN:	TAIWAN

Certificate of Analysis

TEST CRITERIA	SPECIFICATIONS	RESULTS
DESCRIPTION	White to off- white powder.	Complies
*IDENTIFICATION By Infrared Spectroscopy USP <197>		Complies
IDENTIFICATION By HPLC	Identical retention time as that of the reference standard.	Complies
SOLUBILITY	The solution is clear. (1.0g in 100mL boiling water, when cooling from 100°C to 20°C)	Complies
WATER CONTENT	Not more than 1.50%	0.80%
RESIDUE ON IGNITION	Not more than 1.50%	0.69%
HEAVY METALS	Max 20 ppm	Complies
RELATED SUBSTANCES BY HPLC -Epimers -Misoprostol B	Not more than 1.0% Not more than 0.10%	0.32% Not detected

-Misoprostol A -Specified unidentified impurity -Total other impurities -Sum of all impurities	Not more than 0.50% Not more than 0.30% Not more than 0.50% Not more than 2.0%	0.12% Not detected Not detected 0.44%
ASSAY (w/w of Misoprostol by HPLC)	Between 0.90% ~ 1.10%%	1.00%
*ASSAY	NLT 95.0% and NMT 104.0%	98.6%
Residual Solvents: Ethanol (By GC)	Not more than 3,500 ppm	40ppm
**Remark: Store in airtight and light-resistant packages. Keep refrigerated at temperature of 2~8°C for long term storage.		

*Kalchem International independent testing results

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APPROVED BY/ DATE: _____

Kalyn R Tabor, Quality Control