



**Chirogate International Inc.**  
**佳和桂科技股份有限公司**



**K Alchem International, Inc.**  
 Compounding Chemicals You Can Trust

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### Certificate of Analysis

**Product: Misoprostol 1% HPMC Dispersion**

**Batch No.:** K-26-6836

**Released Date:** Dec. 21, 2020

**Manufacturing Date:** Dec. 17, 2020

**Re-test Date:** Dec. 16, 2023


**Batch Size:** 50 Kg

Tests	Specifications	Results
<b>Description</b>	White to off-white powder.	Complies
<b>Identification (HPLC)</b>	Identical retention time as that of the reference standard.	Complies
<b>Solubility</b>	The solution is clear.(1.0g in 100mL boiling water, when cooling from 100°C to 20°C)	Complies
<b>Water Content</b>	Not more than 1.50%	0.80%
<b>Residue on Ignition</b>	Not more than 1.50%	0.69%
<b>Heavy metals</b>	Max. 20 ppm	Complies
<b>Limit of Related Substances (HPLC)</b>		
— Epimers	Not more than 1.0%	0.32%
— Misoprostol B	Not more than 0.10%	Not detected
— Misoprostol A	Not more than 0.50%	0.12%
— Specified unidentified impurity	Not more than 0.30%	Not detected
— Total other impurities	Not more than 0.50%	Not detected
— Sum of all impurities	Not more than 2.0%	0.44%
<b>Residual Solvent: Ethanol (GC)</b>	Not more than 3,500 ppm	40 ppm
<b>Assay (w/w of Misoprostol by HPLC)</b>	0.90%~1.10%	1.00%

Remark: Store in airtight and light-resistant packages. Keep refrigerated at temperature of 2~8°C for long-term storage.

Testing Standard: QT-F-M001E.E11

Checked by

  
 Dec. 21, 2020  
 QC Supervisor

Approved by

  
 Dec. 21, 2020  
 Authorized Signature