



# Certificate of analysis

Productname: Misoprostol HPMC (1% dispersion)

Cas number: 59122-46-2

Molecular Formula:  $C_{22}H_{38}O_5$

Molecular Weight: 382.54

Date of production: Apr. 01, 2019

Batch NO: 20190401

Exp Date: Mar. 31, 2021

| ITEMS                 | SPECIFICATIONS   | RESULTS  |
|-----------------------|--|--|
| Description           | White or off-white powder  | off-white powder   |
| Identification        | HPLC<br>UV(No maximum near 280nm until KOH is added)   | Complies   |
| Water                 | $\leq 5.0\%$   | 2.26%  |
| Solubility            | The solution is clear(1.0g in 100ml boiling water, when cooling from 100°C to 20°C)  | Complies   |
| Individual impurities | A-type misoprostol $\leq 0.5\%$<br>B-type misoprostol $\leq 0.3\%$<br>Norprostaglandin $\leq 0.1\%$<br>8-epimisoprostol $\leq 0.3\%$<br>12-epimisoprostol $\leq 1.0\%$<br>Any other individual impurity $\leq 0.5\%$ | 0.16%<br>Not detectable<br>Not detectable<br>0.24%<br>0.11%<br>0.13% |
| Total impurities      | $\leq 2.0\%$   | 0.53%  |
| Residue on Ignition   | $\leq 1.5\%$   | 0.87%  |
| Heavy Metals          | $\leq 10\text{ppm}$  | Complies   |
| Assay                 | 0.9%~1.1%  | 1.07%  |

**Conclusion: It complies with the Enterprise Standard.**

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F