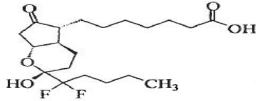


上海京河医药科技有限公司  
Shanghai Genriver Pharmaceutical Co., Ltd.

**CERTIFICATE OF ANALYSIS**

Product Name	Lubiprostone	Batch No.	190101
Structure			
Molecular Formula	C <sub>20</sub> H <sub>32</sub> F <sub>2</sub> O <sub>5</sub>	CAS No.	333963-40-9/ 136790-76-6
Manufacturing Date	2019.01.22	Retest Date	2021.01.21
Storage	Store a temperature below 0 °C		
Quality Specification	Enterprise Standard		
Tests	Specifications	Results	
Appearance	white or off white crystalline powder	Conforms	
Solubility	Insoluble in water and n-hexane, soluble in methanol, acetone, alcohol, ethyl acetate and dichloromethane	Conforms	
Identification (HPLC)	Retention time matches with the reference	Complies	
Optical rotation	$[\alpha]_D^{20}$ : - 42.0° ~ - 48.0° (10mg/ml, in methanol, 100mm)	-45.4°	
Water	N.M.T.0.5 %	0.12%	
Residual solvents	Ethyl Acetate: N.M.T. 0.5%	0.21%	
	n-Heptane : N.M.T. 0.5%	0.18%	
Heavy metals	N.M.T.0.002 %	Conforms	
Purity (HPLC)	Related impurity(except tautomer): N.M.T. 0.5%	0.04%	
	Total impurity N.M.T. 0.5%	0.08%	
Assay	99.0%-101.0%	99.4%	
<b>Conclusion</b>	<b>Conform to Enterprise Standard</b>		

Date of Report: 2019-01-22

Date of Audit: 2019-01-22

Approved by QA:Jun Yang