



## Certificate of Analysis

<b>Product Name</b>	Lubiprostone	<b>Manufacture Date</b>	Sep.13.2023
<b>Batch Number</b>	SW230913	<b>Analysis Date</b>	Sep.14.2023
<b>Batch Quantity</b>	8.5kg	<b>Expiry Date</b>	Sep.13.2025

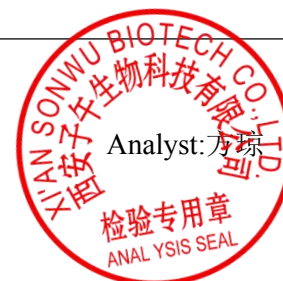
ANALYSIS	SPECIFICATION	RESULT
<b>Appearance</b>	White or off-white solid powder	Complies
<b>Identification</b>	By IR	Complies
	By HPLC	Complies
<b>Solubility</b>	Soluble in DMF, sparingly soluble in THF, slightly soluble in methanol and acetonitrile, very slightly soluble in ethanol and dichloromethane, insoluble in water	Complies
<b>Polymorphic Form</b>	Polymorphic form 1	Complies
<b>Melting Point</b>	211°C~216°C	212.8°C~214.9°C
<b>Water Content</b>	≤ 0.50%	0.10%
<b>Heavy Metals</b>	≤ 20ppm	Complies
<b>Residue on Ignition</b>	≤ 0.20%	0.09%
<b>Related Substance</b>	Any single impurity: ≤0.10%	0.06%
	Total Impurities: ≤1.00%	0.16%
<b>Assay (on the anhydrous basis)</b>	98.0%~102.0%	99.94%
<b>Particle Size</b>	D90: ≤100μm	Complies

<b>Packing description</b>	Sealed export grade drum & double of sealed plastic bag
<b>Storage</b>	Store in a cool and dry place, stay away from strong light and heat
<b>Shelf life</b>	2 years when properly stored

Quality Assurance Officer: 李强

Corrector: 佟丽华

Analyst: 方琼





Appearance	White or off-white solid powder	Complies
Identification	By IR	Complies
	By HPLC	Complies
Solubility	Soluble in DMF, sparingly soluble in THF, slightly soluble in methanol and acetonitrile, very slightly soluble in ethanol and dichloromethane, insoluble in water	Complies
Polymorphic Form	Polymorphic form 1	Complies
Melting Point	211°C~216°C	212.8°C~214.9°C
Water Content	≤ 0.50%	0.10%
Heavy Metals	≤ 20ppm	Complies
Residue on Ignition	≤ 0.20%	0.09%
Related Substance	Any single impurity: ≤0.10%	0.06%
	Total Impurities: ≤1.00%	0.16%
Assay (on the anhydrous basis)	98.0%~102.0%	99.94%
Particle Size	D90: ≤100μm	Complies