



Certificate of Analysis

Product Name	Linaclotide	Catalog No.	
CAS. No.	851199-59-2	Batch No.	
Manufacturing Date		Retest Date	

Sequence: H-Cys-Cys-Glu-Tyr-Cys-Asn-Pro-Ala-Cys-Thr-Gly-Cys-Tyr-OH cyclic(1-6),(2-10),(5-13)-tris (disulfide)

	Test	Specification	Result
1	Appearance	White or almost white powder	white powder
2	Molecular	1526.8±1	1527.35
3	Purity(HPLC)	≥98.0%	Conforms
4	Related substances(HPLC)	Total impurities:≤2.0%	Conforms
		Maximum single impurity:≤1.0%	Conforms
5	Water Content(Karl Fischer)	≤8.0%	Conforms
6	Acetonitrile	NTM 410 ppm	Conforms
7	Acetate (HPLC)	NMT 5.0%	Conforms
8	Host Cell Protein	≤0.01%	Conforms
9	Host Cell DNA	≤10.0 ng/mg	Conforms

Storage in an air tight container, protected from light at a temperature of 2-8°C.