

苏州华鑫医药科技有限公司 Suzhou Huaxin Pharmaceutical Technology Co., Ltd.

CERTIFICATE OF ANALYSIS

Product Name: Rebamipide Crude	Cas No.: 90098-04-7
Production Batch No.: Rp220813	Quantity: 200kg
Production Date: 2022-08-13	Expiry Date: 2024-08-12

Item	Specification	Results
Appearance	White powder	White powder
Identification		
IR	The infrared absorption spectrum is consistent with the spectrum of Rebamipide reference standard	Conforms
Clarity and color of solution	Clear and colorless	Conforms
Loss on drying	Not more than 3.0%	1.10%
Arsenic	Not more than 2ppm	Conforms
Chloride	Not more than 0.01%	Conforms
Related substances		
Any individual impurity	Not more than 0.1 %	0.030%
Total impurities	Not more than 0.3%	0.09%
Residue on ignition	Not more than 0.1%	0.02%
Heavy metals	Not more than 10ppm	Conforms
Assay	Contains not less than 99.0% of Rebamipide (C ₁₉ H ₁₅ ClN ₂ O ₄),calculated on the dried basis	99.8%
Particle size(D90)	10~50μm PHARMACEUTICAL TECHNO	41μm
Conclusion	The product corresponds to the requirements of the enterprise standard.	

Quality Analysis: Bian Xiaobao

Quality Analysis Manager: Long Zaihua

Certificate Date:2022.08.15