

CERTIFICATE OF ANALYSIS

Product Name:	Mesalazine		
Batch No.	20200614	Quantity	2000kg
Manufacturing Date	June 14, 2020	Expiry Date	June 13, 2023
Report Date	June 17, 2020	Standard	EP 8.4
Analytical Results			
Items	Specifications		Results
Appearance	Almost white or light grey or light pink powder or crystals		light grey powder
Identification	The IR absorption spectrum conform the reference spectrum		Complies
Appearance of solution	Clarity; Clear		Clear
	Absorbance \leq 0.15 (440nm)		0.042
	Absorbance \leq 0.10 (650nm)		0.009
Reducing substances	The solution turns blue or violet-brown		The solution turns violet-brown
Particle size (4mg/ml HCl solution)	90% NMT 50 μ m after addition of Starch solution & 0.01M iodine		Complies
Related substances(HPLC)	Impurity F,J,O,P. \leq 0.10%		N.D
	Impurity E,G,L,M,R. \leq 0.05%		0.01%
	Impurity H. \leq 0.3%		N.D
	Any other impurity \leq 0.05%		0.03%
	Total impurity \leq 0.5%		0.04%
Impurity A&C(HPLC)	Impurity A. \leq 200 ppm		N.D
	Impurity C. \leq 200 ppm		N.D
Impurity K	\leq 10 ppm		N.D
Chlorides	\leq 0.10%		N.D
Bulk density	0.2~0.3g/ml		0.21g/ml
Tapped density	0.4~0.6g/ml		0.46g/ml
Sulfates	\leq 200 ppm		< 200 ppm
Heavy metals	\leq 10 ppm		<10ppm
Loss on drying	\leq 0.5%(1.000g, 105°C)		0.24%
Sulfated ash	\leq 0.20%		0.03%
Assay	98.5%~101.5% (Anhydrous)		99.60%
Conclusion	Corresponding to the requirement of EP8.4		

Inspector: Carlifor Wu

Verifier: Jack He

