



连云港市丰恒生物制药有限公司

LIANYUNGANG FENGHENG BIOPHARM CO., LTD

分析报告单
CERTIFICATE OF ANALYSIS

PRODUCT NAME	Mesalazine	BATCH NO.	20200614
PRODUCTION DATE	Jun. 14, 2020	TOTAL QUANTITY	2000kg
EXPIRATION DATE	Jun. 13, 2023	REPORT DATE	Jun. 17, 2020
SPECIFICATION	EP 8.4		

Test	Specification	Result
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 Absorbance ≤ 0.15 (440nm) ≤ 0.10 (650nm)	Clear 0.042 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 $\leq 0.1\%$ Impurity E,G,L,M,R $\leq 0.05\%$ Impurity H $\leq 0.3\%$ Any other impurity $\leq 0.05\%$ Total impurity $\leq 0.5\%$	Nf 0.01 Nf 0.03% 0.04%
Impurity A&C (HPLC)	Impurity A ≤ 200 ppm Impurity C ≤ 200 ppm	Nf Nf
Impurity K	≤ 10 ppm	Nf
Chlorides	$\leq 0.1\%$	Nf
Bulk density	0.2~0.3g/ml	0.21g/ml
Tapped density	0.4~0.6g/ml	0.46g/ml
Sulfates	≤ 200 ppm	<200 ppm
Heavy metals	≤ 10 ppm	<10 ppm
Loss on drying	$\leq 0.5\%$ (1.000g, 105°C)	0.24%
Sulfated ash	$\leq 0.2\%$	0.03%
Assay	98.5%~101.5% (Anhydrous)	99.6%

Conclusion: Corresponding to the requirement of EP8.4

化验员: 刘恒
Analyst:



质检科长: 张军
Head of QC dept: