



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

<b>PRODUCT NAME</b>	Mesalazine	<b>BATCH NO.</b>	20200614
<b>PRODUCTION DATE</b>	Jun. 14, 2020	<b>TOTAL QUANTITY</b>	2000kg
<b>EXPIRATION DATE</b>	Jun. 13, 2023	<b>REPORT DATE</b>	Jun. 17, 2020
<b>SPECIFICATION</b>	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 $\leq 0.15$ (440nm) $\leq 0.10$ (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 $\mu$ 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 $\leq 200$ ppm Impurity C $\leq 200$ ppm	Nf Nf
Impurity K	$\leq 10$ 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	$\leq 200$ ppm	<200 ppm
Heavy metals	$\leq 10$ 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: