Yunpeng Pharmaceutical Group Co., Ltd.

(Former Name: Shanxi Yunpeng Pharmaceutical Co., Ltd.)

Certificate of Analysis

Product Name	Mexiletine Hydrochloride	**Batch No.**	210802
Specification	20kg/drum	**Quantity**	198.5 kg
Date of Manufacture	May 19, 2021	**Date of Report**	August 23,2021
Standard	EP 10.3	**Date of Retest**	May 18,2023
Test Items	**Specification**		**Result**
Description	White or almost white ,crystalline powder		White, crystalline powder
Solubility	Freely soluble in water and in methanol, sparingly soluble in methylene chloride		Complies
Identification	a) IR. Mexiletine hydrochloride RS		Complies
	b) Reaction of chloride		Complies
Appearance of solution	Clear and colourless		Clear and colourless
Melting Point	200-204℃		201-203℃
PH	4.0~5.5		4.8
Residue Solvent	Ethyl acetate≤0.5%		Not detected
Impurity D	≤0.1%		Not detected
Related substances	Impurity A≤0.1%		Not detected
	Impurity C≤0.1%		0.06%
	Any single impurity≤0.1%		0.09%
	Total impurities≤0.5%		0.15%
Sulfated ash	≤0.1%		0.1%
Loss on drying	≤1.0%		0.5%
Microbial Limits	Aerobic bacteria per 1g must not exceed the total number of 10^3 cfu		<10^3cfu
	Fungi and yeast per 1g must not exceed 10^2 cfu		<10^2cfu
	Escherichia coli per 1g must not be detected		Not detected
Assay (HPLC)	99.0%~101.0%		100.7 %
Conclusion	The product was tested as per EP 10.3, the results meet the requirements.		

QA Manager：Liang Xiaoli **Reviewed by: Hua Shuwen** **Test by: Zhang Xiaoyang**