瑾 岚 医 药 技 术 开 发 有 限 公 司

Hangzhou Jinlan Pharm-Drugs Technology CO., Ltd.

Certificate of Analysis

Name of product	Pemafibrate CAS848259-27-8		
Batch No.	RY20220307	QTY	0.89kg
Manufacture date	2022-03-07	Test Date	2022-03-016
Report Date	2022-03-17	Retest date	2025-03-06

Item	Specification		Results
Appearance	White to off-white powder		White powder
Solubility	Freely soluble in Dimethyl Sulfoxide or N,N-Dimethylformamide;Soluble in Methanol or Ethyl acetate;Sparingly soluble in Acetonitrile or Ethanol (99.5%);Practically insoluble in Hexane or Water		Complies
Melting point	96.0~105.0℃		98~101℃
Specific rotation	+14°~+20°		+16.3°
Identification	HPLC: In chromatograms recorded under relevant substances, the retention time of the main peak of the test product solution should be consistent with that of the system applicable solution (The deviation shall not exceed 5%)		Complies
	IR: The infrared absorption spectrum of this product should be consistent with that of the reference product		Complies
	UV: Maximum absorption occurs at 250nm and 283nm wavelengths (Deviation shall not exceed ±2nm)		Complies
Chloride and Bromide	≤0.1%		Complies
Related Substances	Impurity A407S-Z7	≤0.15%	N.D.
	Impurity A407(M-2)S	≤0.15%	N.D.
	Other largest single impurities	≤0.10%	N.D.
	Total impurity	≤1.0%	N.D.
	Impurity A407S-ZI	≤0.15%	0.01%
Water Determination	≤0.5%		0.01%
Residue on Ignition	≤0.1%		0.02%
Heavy Metals	≤20ppm		Complies
	Trifluoromethanesulfonic acid	≤0.10%	N.D.
	Methyl chloride	≤0.15%	N.D.
	Methanol	≤0.3%	N.D.
	Ethanol	≤0.5%	N.D.
	Acetonitrile	≤0.041%	N.D.

Residual Solvents	Dichloromethane	≤0.06%	N.D.
	Tert-Butyl methyl ether	≤0.5%	N.D.
	Ethyl acetate	≤0.5%	N.D.
	Cyclochexane	≤0.388%	N.D.
	Heptane	≤0.5%	N.D.
	1-Butanol	≤0.5%	N.D.
	Toluene	≤0.089%	N.D.
	2,6-Lutidine	≤0.1%	N.D.
	N,N- Dimethylacetamide	≤0.109%	N.D.
Microbial Limit	Total number of aerobic bacteria	$<10^3$cfu/g	1 cfu/g
	Total number of molds and yeast	$<10^2$ cfu/g	<50cfu/g
	E.coli should not be detected every lg	Absent	N.D.
Assay	Calculated as dry product, the assay of $C_{28}H_{30}N_2O_6$ should≥98.5%		100.4%
Conclusion	The test results conform to above standard.		

Tested by: Meng Xiao Checked by: Shen Junli Approved by: He Youguang