

山东科汇药业有限公司
Shandong Kehui Pharmaceutical Co.,Ltd

Address: No.1,Block A, Tianheng Road, Changjia Town, Gaoqing County, Zibo City, Shandong Province, China.

Certificate of Analysis

Product Name	Nepafenac		
Batch Number	210726	Expiry Date	Jul. 25 th ,2023
Manufacturing Date	Jul. 26 th ,2021	Report Date	Aug. 05 th ,2021
Quantity Standard	Enterprise Standard		
ANALYTICAL ITEMS	SPECIFICATION		RESULTS
Characteristics	A yellow or light yellow crystalline powder		light yellow crystalline powder
Solubility	Freely soluble in dimethyl sulfoxide, insoluble in water, sparingly soluble in Tetrahydrofuran, slightly soluble in methanol and acetonitrile.		Conforms
Related Substance	Impurity A≤0.1%		N.D
	Individual impurity≤0.1%		0.01%
	Total impurity≤0.5%		0.02%
Residual solvent	Acetonitrile≤0.041%		N.D
	Isopropanol≤0.5%		0.07%
	Tetrahydrofuran≤0.072%		N.D
	Dichloromethane≤0.06%		N.D
Loss on drying	≤0.5%		0.13%
Sulphated ash	≤0.1%		0.02%
Heavy metals	≤0.002%		<0.002%
Sterility test	Should meets the requirements		Conforms
Microbial Limit:	Total Aerobic Microbial Count: NMT 1000 cfu/g		Conforms
	Total Yeasts and Moulds: NMT 100 cfu/g		Conforms
	E.coli: Absent		Conforms
Assay (on dried base)	98.0%~101.5%		99.7%
Conclusion:The product conforms to the Enterprise Standard.			
Reporter: Lu hanxia	Checker: Du yadong	Reviewer: Liu mulin	

