

Miedykol

A brand by IKEM

Mikem (Shandong) Biopharmaceutical Science and Technology Co., Ltd.



Certificate Of Analysis

PRODUCT	Bromfenac Sodium		
BATCH NO.:	202404002	MFG.DATE	Apr.17,2024
QUANTITY	2 kg	EXP.DATE	Apr.16,2026

ITEMS	SPECIFICATION	RESULT
Appearance	Yellow or orange crystalline powder.	Yellow crystalline powder
Solubility	Freely soluble in water, sparingly soluble in methanol, practically insoluble in ethyl acetate.	Conform
Identification	1.UV:Max.absorption exhibited at 268 nm and 379 nm	Conform
	2.The infrared absorption spectrum corresponds to that of reference standard	Conform
	3.The identification of sodium salt is positive reaction	Conform
pH	8.3 to 9.5	9.2
Chlorides	$\leq 0.05\%$	$< 0.05\%$
Loss on drying	6.5% to 7.5%	6.8%
Moisture content	6.5% to 8.5%	7.5%
Heavy metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
Related Substances	Max other single impurity $\leq 0.2\%$	0.02%
	Total impurities $\leq 0.50\%$	0.02%
	Purity: NLT 99.5%	99.98%
Residual solvents	2-methoxyethanol $\leq 0.005\%$	N.D
	Acetone $\leq 0.5\%$	0.02%
Assay	$\geq 98.5\%$	99.9%

Conclusion: it conform to the factory's standard

QC Checker: 王建

Analysis: 刘超