

Certification of Analysis

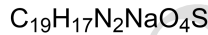
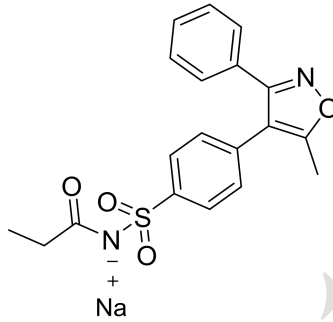
Product Information :

CAS: 198470-85-8

Name: PARECOXIB SODIUM,

N-[4-(5-METHYL-3-PHENYLISOXAZOL-4-YL)PHENYLSULFONYL]PROPIONAMIDE

Structural Formula:



Batch No.: 20180826

Mfg. Date: 20180826

Items	Specification of Standard	Result of Analysis
Appearance	White crystal or crystalline powder; Highly hygroscopicity	Passed
Solubility	It is soluble in DMF, water and methanol. Dissolve in glacial acetic acid and ethanol; Slightly soluble in acetonitrile.	Passed
Identification	IR	Passed
	Sodium salt	Positive
	Alkalinity	pH=7.5~9.0
	Clarity of Solution	Should be clarified; If turbidity, turbidity should be less more than 1 standard liquid
	Chloride	≤0.02%
	Sulfate	≤0.02%
	Related Substances	4-(5-methyl-3-phenyl-4-isoxazolyl) ≤0.15%

Inspections	benzenesulfonamide			
	N-[3-(5-methyl-3-phenyl-4-isoxazolyl) benzenesulfonyl] propylamide		≤0.10%	
	N-[3-[5-methyl-4-[4-(N-propylamide sulfonyl) phenyl]-3-isoxazolyl] benzenesulfonyl] Propionamide		≤0.10%	
	N-[[4-(5-methyl-3-phenyl-4-isoxazolyl) phenyl] sulfonyl] acetamide		≤0.10%	
	Maximum Single Impurity		≤0.10%	
	Total Impurities		≤0.50%	
	Residual Solvent	Ethyl acetate		≤0.50%
		Dichloromethane		≤0.50%
		Acetone		≤0.50%
		Ethanol		≤0.50%
	Sodium		5.60%~6.20%	
	Water		≤1.00%	
	Heavy Metal		≤20.00%	
	Bacterial Endotoxin:		Endotoxin amount per 1 mg Parecoxib Sodium should be less than 2.9 EU	
	Microbial Limits	Microbial limit		Acrobic bacterial count per 1g should be not more than 1600 cfu
		Mould and Yeast		count per 1g should be not more than 160 cfu
		Escherichia coli		not detect Escherichia coli per 1 kg
Particle Size Distribution		d90 should be within 10 micron.		
Assay		C ₁₉ H ₁₇ N ₂ O ₄ SNa: 98.00%~102.00%		

Checker: Hongna Pei

