

Certificate of Analysis

Product Name	NAPROXEN	Grade	USP
Batch Quantity	1457.62 Kg	Batch No.	Ks20230510
Manuf. Date	2023.05.10	Report Date	2023.05.10
Items	Standard	Test results	
Description	White to off-white crystalline powder	White crystalline powder	
Solubility			
water	Practically insoluble in water	Insoluble	
Chloroform	Soluble in Chloroform	Soluble	
Dehydrated alcohol	Soluble in Dehydrated alcohol	Soluble	
Alcohol	Soluble in Alcohol	Soluble	
Ether	Sparingly soluble in Ether	Sparingly soluble	
Melting range	Report the result	156C to 157C	
Identification by IR Spectrum	Concordant with WS	Concordant with standard spectrum	
Identification by UV Spectrum	A1% 1cm at 271nm is less than 3% with that of ws	0%	
Specific rotation (on dried basis)	Between +83.0 and +89.5°	87.1	
Loss on drying	Not more than 0.5%w/w	0.1 %w/w	
Chromatographic purity by TLC			
Individual impurity	Not more than 0.5%	<0.1%	
Sum of impurities	Not more than 2.0%	<0.1%	
Residual solvents			
Methanol	Not more than 200 ppm	Not detected	
Toluene	Not more than 250 ppm	97 ppm	
Assay(on dried basis)	Not less than 98.5% and not more than 101.5%w/w	99.7%w/w	
Particle D90	Not more than 10 micron	complied	
6-Methoxy-2-Naphthoic Acid	Not more than 0.07%	Not detected	
2-Acetyl-6-methoxy	Not more than 0.1%	Not detected	
Particle size	60-70	complied	

ANALYST: 王怀明

CHECKER: 吴晗

Q.C. DIRECTOR:

