



# Nootan Pharmaceuticals

Village Tipra , Barotiwala - Kalka Road , Barotiwala , Tehsil Baddi , Distt. Solan , H.P. 174103.

## RAW MATERIAL SPECIFICATION

Name of Material	Sulbactam Sodium		
Reference	IP	Spec/STP No.	RMS/0044
Supersede No.	RMS/0044-00	Revision no.	0
Effective Date	2025-06-19	Review Date	

Sr.No	Test	Specification
1.	Description	A white or almost white, hygroscopic, crystalline powder.
2.	Identification	The IR spectrum of the substance to be examined should be identical with that of the reference standard.
3.	Identification	No precipitate is formed.
4.	Solubility	Freely soluble in water, sparingly soluble in ethyl acetate, very slightly soluble in ethanol (95 %). It is freely soluble in dilute acids.
5.	Water content by KF	NMT 1.0%
6.	Light absorption	Absorbance of 1.0 per cent w/v solution at 430 nm is not more than 0.1.
7.	Apperance of solution	A 10 per cent w/v solution is.clear.
8.	pH	5.2 to 7.2
9.	2-Ethylhexanoic acid	NMT 0.5%
10.	Specific Optical Rotation	219.0 DEGREE to 233.0 DEGREE
11.	Related Substances by HPLC	NMT 0.5%
12.	Related Substances by HPLC	NMT 0.1%
13.	Related Substances by HPLC	NMT 0.2%
14.	Related Substances by HPLC	NMT 0.1%
15.	Related Substances by HPLC	NMT 0.2%
16.	Related Substances by HPLC	NMT 0.1%
17.	Related Substances by HPLC	NMT 0.1%
18.	Related Substances by HPLC	NMT 1.0%
19.	Assay by HPLC (on anhydrous basis)	97.0% to 102.0%
20.	Bacterial Endotoxin Test	Not more than 0.17 EU/mg of sulbactam sodium.
21.	Sterility Test	Should be sterile.

## REVISION HISTORY

Revision No.	Change Control No	Reasons for Revision
	NA	New specification prepared in software using IP 2022 and Vendor COA of Hebei Union Pharmaceutical Co. Ltd.