

Specification Report

Specification No	RMS/0044	Effective Date	2025-06-19
Supersedes No	RMS/0044-00	Item Code	RMA0012
CAS No.	69388-84-7	Molecular Formula	C8H10NNaO5S
Molecular Weight	255.2 g/mol	Storage Conditions	Store protected form moisture
Chemical Sample Qty	0 gm	Micro Sample Qty	2 gm
Control Sample Qty(g) :	24 gm		
Sampling precautions and warning	Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed.		

Pharmacopoeial Tests:

Test Type	Test	Sub Test	Reference Type	Limit Type	Description/Limits	Retest
Physcial	Description	NA	IP	Description	A white or almost white, hygroscopic, crystalline powder.	Applicable
Identification	Identification	BY IR	IP	Compliances	The IR spectrum of the substance to be examined should be identical with that of the reference standard.	Applicable
Identification	Identification	By Sodium Test (A)	IP	Compliances	No precipitate is formed.	Applicable
Physcial	Solubility	NA	IP	Compliances	Freely soluble in water, sparingly soluble in ethyl acetate, very slightly soluble in ethanol (95 %). It is freely soluble in dilute acids.	Applicable
Instrumental	Water content by KF	NA	IP	Not MoreThan	NMT 1.0%	Applicable
Instrumental	Light absorption	NA	IP	Compliances	Absorbance of 1.0 per cent w/v solution at 430 nm is not more than 0.1.	Applicable
Physcial	Apperance of solution	NA	IP	Compliances	A 10 per cent w/v solution is.clear.	Applicable

Ver

Instrumental	pH	NA	IP	Range	5.2 to 7.2	Applicable
Instrumental	2-Ethylhexanoic acid	NA	IP	Not MoreThan	NMT 0.5%	Applicable
Instrumental	Specific Optical Rotation	NA	IP	Range	219.0 DEGREE to 233.0 DEGREE	Applicable
Instrumental	Related Substances by HPLC	Sulbactam related compound A	IP	Not MoreThan	NMT 0.5%	Applicable
Instrumental	Related Substances by HPLC	Amoxicillin related compound A	IP	Not MoreThan	NMT 0.1%	Applicable
Instrumental	Related Substances by HPLC	6-Bromopenicillanic acid sulfone	IP	Not MoreThan	NMT 0.2%	Applicable
Instrumental	Related Substances by HPLC	Sulbactam related compound D	IP	Not MoreThan	NMT 0.1%	Applicable
Instrumental	Related Substances by HPLC	Sulbactam related compound E	IP	Not MoreThan	NMT 0.2%	Applicable
Instrumental	Related Substances by HPLC	Sulbactam related compound F	IP	Not MoreThan	NMT 0.1%	Applicable
Instrumental	Related Substances by HPLC	Any individual unspecified impurity	IP	Not MoreThan	NMT 0.1%	Applicable
Instrumental	Related Substances by HPLC	Total unspecified impurities	IP	Not MoreThan	NMT 1.0%	Applicable
Instrumental	Assay by HPLC (on anhydrous basis)	NA	IP	Range	97.0% to 102.0%	Applicable
Microbiology	Bacterial Endotoxin Test	NA	IP	Compliances	Not more than 0.17 EU/mg of sulbactam sodium.	Applicable
Microbiology	Sterility Test	NA	IP	Compliances	Should be sterile.	Applicable

Client Tests:

Test Type	Test	Sub Test	Reference Type	Limit Type	Description/Limits	Retest
-----------	------	----------	----------------	------------	--------------------	--------

Revision History:

Sr	Revision No	Version No	Change Mode	Reason for change	Effective Date
1	00		NA	New specification prepared in software using IP 2022 and Vendor COA of Hebei Union Pharmaceutical Co. Ltd.	19-06-2025

DOWNLOAD MANUAL PDF

DOWNLOAD DIGITAL PDF

CLOSE