DISOLCEL® MINGTAI

Certificate of Analysis

Compendial name : CROSCARMELLOSE SODIUM NF/USP/EP/BP/JP/IP
Type : Standard
Lot No. : D2102011
Date manufactured : February 18, 2021 Date of analysis : February 26, 2021

Test items	Units	Limits	Results
Characters		White, free-flowing, hygroscopic powder	Conforms
Identification A,B,C		To meet requirement	Conforms
pH		5.0-7.0	6.2
Loss on drying	%	Not more than 10.0	2.8
Na-chloride & Na-glycolate	%	Not more than 0.50	0.25
Heavy metals	ppm	Not more than 10	Conforms
Degree of substitution		0.60-0.85	0.77
Water soluble substances	%	Not more than 10.0	4.1
Settling volume	ml	10-30	10
Particle size, on 200 mesh	%	Not more than 2.0	0.2
Particle size, on 325 mesh	%	Not more than 10.0	3.0
Residue on ignition	%	14.0-28.0	20.5
Residual solvents(Methanol)	ppm	Not more than 3,000	836
Total aerobic microbial count	cfu/g	Not more than 100	Conforms
Total molds and yeasts count	cfu/g	Not more than 20	Conforms
Escherichia coli	/1g	Absence	Conforms
Staphylococcus aureus	/1g	Absence	Conforms
Salmonella species	/10g	Absence	Conforms
Pseudomonas aeruginosa	/1g	Absence	Conforms

[MINGTAI Spec ref.C001]

Additional statement :
The product meets the requirement for Residual Solvents USP<467>

We certify herewith the above mentioned product is in conformity with the specification.

Jack Su
QA Chief
2021.03.16
10:21:10 +08'00'
Jack Su

Note :
Re-evaluation date : February 2024
WE CERTIFY THAT ABOVE-MENTIONED PRODUCT MEETS CURRENT USP/NF,EP,BP,JP
AEO no. : [illegible]