



Certificate of Analysis

Product Name: Sodium Starch Glycolate
Material Description: White and odourless powder
Lot Number: 24070406
Quantity Supplied: 3100kgs

Compliance Statement: This produce meets all agreed upon specifications.

Test	Specification	RESULT
Character	White and odourless powder	Conform →
Identification	Conform	Conform →
pH	5.5-7.5 ✓	5.7
Loss on Drying	Not More Than 10.0% ✓	4.5%
Sodium Chloride	Not More Than 6.0% ✗	5.2%
Sodium glycolate	Not More Than 2.0% ✓	< 2.0%
Iron	Not More Than 0.002% ✓	< 0.002%
Heavy Metal	Not More Than 0.002% ✓	< 0.002%
Content of Sodium	2.8%-4.2% ✓	2.9%
Microbial Limit:		
Total amount of aerobe	Not More Than 1000cfu/g	Conform
Molds and Yeast	Not More Than 100cfu/g	Conform
Eachenichia Coli	Not detectable	Conform
Salmonella	Not detectable	Conform

(-) Melarutan

Other Statements:

This material meets all requirements of the USP

Supplied By: Tianjin ILE International Pharma Co., Ltd.
Address: Building B, No.9 Rongyuan Road, Huayuan
Industrial Park,
Tianjin 300384, China.

Date of Manufacture: 04 Jul., 2024
Expiry Date: 03 Jul., 2026
Approved Date: 15 Jul., 2024

Approver: [Signature]

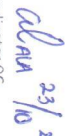
Reviewer: [Signature]

Inspector: [Signature]

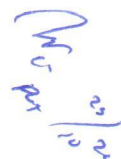
STANDARISASI CERTIFICATE OF ANALYSIS BAHAN BAKU PRODUK

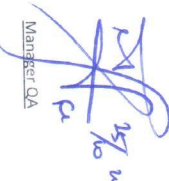
No	Nama Bahan	Manufaktur	Referensi pada CoA Manufacturer saat ini	Referensi pada CoA yang diusulkan	Penyesuaian Parameter			Nomor SPBB	Keterangan
					Parameter yang Dihilangkan	Parameter yang Ditambah	Parameter yang direvisi		
1	Sodium Starch Glycolate	Tianjin Ite	USP	USP47/ F1 VI					
					Identifikasi E (nanoram)	Logam berat : ≤ 20 bpi			

Disetujui Oleh,


23/10/24
Koordinator QC


23/10/24
Koordinator TS


23/10/24
Koordinator QA


23/10/24
Manager QA