




CERTIFICATE OF ANALYSIS (COA)

Product name	Isotretinoin	Batch No.	SP-20220710
CAS No.	4759-48-2	Specification	In-house
Quantity	320.28kg	Mfg. Date	2022.07.10
Date of Analysis	2022.07.13	Expiry Date	2025.07.09

Test Items	Specification	Test results
Appearance	Fine yellow Powder	Yellow powder
Assay (HPLC)	97%-102%	98.12%
Odor	Characteristic	Complies
Mesh	100% pass 100 mesh	Complies
Limit of Isotretinoin	MAX5.0%	3.9%
Organic Volatile Impurities	Meet The Requirements	Complies
Microbiology Total Plate Count Yeast & Mold E.Coli Salmonella	<1000cfu/g <100cfu/g Negative Negative	82cfu/g Negative Complies Complies
Loss on drying	MAX0.5%	0.39%
Residue on ignition	MAX0.1%	Complies
Ash%	MAX.1.0%	0.52%
Heavy metal	MAX.0.002%	Complies
Conclusion	The test product complies with the requirements of specification.	

Analyst: 	Checker: 	Q. C. Director: 
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