Apharma

Sudeep Pharma Pvt. Ltd.

CERTIFICATE OF ANALYSIS

LUBRI-PREZ ™

Product	Magnesium Stearate
Grade	Harmonised
Product Code	MS/H/001 (LUBRI-PREZ-2)

Report No.	Batch No.	Mfg. Date	Exp. Date	Quantity	Drug Licence No.
F/MS/0031	20E/MS/031	MAY.2020	APR.2025	3000 Kg	G-975

General Characteristics		
Appearance	A white very fine, light powder, greasy to the touch	Complies
Solubility	Practically insoluble in water and in ethanol	Complies

Chemical Analysis

Properties	Method	Specification Values			Result
		Unit	Min.	Max.	
Identification					
Test A	EP	---	NLT 53°C		55
Test A	USP		Passes the test		Complies
Test-B	USP		The retention time of the principal peak obtained in the in the chromatogram of the test solution approximately same as those of the principal peak obtained in the chromatogram with the reference solution		Complies
Acidity or Alkalinity	USP	ml	Not More than 0.05 ml of 0.1 M HCl or 0.1 M NaOH is required to change the colour of solution		0.03
Chloride	IH	ppm	---	100	< 100
Sulphate	USP	%	---	0.5	< 0.5
Cadmium	ICP-MS	ppm	---	3	<3
Lead	ICP-MS	ppm	---	5.0	<5
Nickel	ICP-MS	ppm	---	5	<5
Specific surface area	IH	m^2/g	6	10	8.01
Magnesium content	IH	%	4.2	4.8	4.79
Free fatty acid	FCC	%	---	2.0	1.48
Residual Solvent	USP	---	Meet the requirement < 467 >		Complies
Heavy Metal as Lead	JP	ppm	---	20	<20
Acid Value of the fatty acids	EP	mg KOH/g	195	210	200.4
Fatty Acid Composition The fatty acid fraction contains of stearic acid	EP	%	60.0	70	65.55
The sum of stearic acid & Palmitic acid and palmitic acid	EP	%	95.0	100	98.60
Loss on drying	USP	%	---	4.0	3.36

Physical Analysis

Fineness (In-house Test)	IH	Max. 1.0% retained on 200#			0.6
Particle size	Malvern	D10<5.0µ D50- Between 7.0µm to 11.0µm D90 <35.0			2.10 7.57 20.2
Tapped Density	IH	g/cc	0.27	0.37	0.34

Microbiological Analysis

Total aerobic microbial count	IH	cfu/gm	---	1000	Complies
Total combined molds & yeast count		cfu/gm	---	100	Complies
Escheria Coli		Negative/gm	---	Negative/gm	Complies
Salmonella		Negative/10gm	---	Negative/10gm	Complies

Note: The manufacturing process & facility do not contain any of the solvent listed in residual solvent (USP < 467 >). "Elements listed in ICH Q3D Guideline for elemental impurities are not used in manufacturing and not analysed per batch; detailed information is available on request."

OPINION: The above product is declared as standard / ~~non-standard~~ quality as specified in EP/NF.

Analyzed by :		Checked by :		Approved by :	
Date:	28/05/2020	Date:	28/05/2020	Date:	29/05/2020

C/COA-2020/Yigitoglu-neutec/003

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