Medicap Laboratories

CERTIFICATE OF ANALYSIS

Product Name: Biogenique Melatonin

Batch/Lot No: PK240514

Man. Date: May.2024 **Expiry Date:** Apr.2027

Each Tablet Contains: Melatonin-5.50mg.

Other Ingredients: Dibasic Calcium phosphate, Croscarmellose Sodium, Magnesium Stearate, Microcrystalline cellulose, Silicon Dioxide, Povidone K-30.

Test	Method	Specifications	Result
Description	In-House	Round shape white color uncoated tablet	Complies
Weight variation	USP <2091>	225.00 mg ± 5% (213.75 mg - 236.25 mg)	226.00 mg
Friability	USP <1216>	< 1 %	0.16%
Thickness	USP <1217>	4.00 mm – 5.00 mm	4.52mm
Hardness	USP <1217>	NLT 12 kgf	14 kgf
Disintegration time	USP <701>	NMT 30 minutes	02 minutes
Microbial Test			
Total Plate count	USP<2021>	N.M.T 100,000 CFU/G	<10 CFU/G
Yeast & Mold	USP<2021>	N.M.T 1000 CFU/G	<10 CFU/G
E.coli	USP<2022>	Negative	Negative
Salmonella	USP<2022>	Negative	Negative
S.aureus	USP<2022>	Negative	Negative
Pseudomonas aeruginosa	USP<62>	Negative	Negative
Heavy Metal			
Arsenic	ICP-MS at Finished Product Stage	<0.14 µg/kg b.w./ day	<0.001 µg/kg b.w./ day
Cadmium		<0.09 µg/kg b.w./ day	<0.001 µg/kg b.w./ day
Lead		<0.14 µg/kg b.w./ day	<0.001 µg/kg b.w./ day
Mercury		<0.29 µg/kg b.w./ day	<0.001 µg/kg b.w./ day

Quality Approved: Foram Patel **Date:** Oct.25, 2024

This is to certify that Medicap Laboratories products are manufactured under strict GMP conditions