Medicap Laboratories

# CERTIFICATE OF ANALYSIS

**PRODUCT NAME:** Biogenique 5-HTP

**Batch/Lot No:** 240545

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

**Each unit dose contains**: 5-Hydroxy-L-Tryptophan (5-HTP): 100.00mg.

**Non-Medicinal Ingredient**: Magnesium Stearate, Hypromellose.

| Test | Method | Specifications | Result |
|---|---|---|---|
| Description | In-House | Clear-Clear size "0" vegi. Capsule filled with white color Powder. | Complies |
| Weight variation | USP <2091> | 580.00 mg± 7.5% (536.50mg/cap to 623.50mg/cap) | 589.12 mg |
| Lock Length | In house | 21.30 mm –21.90mm | Complies |
| Disintegration time | USP | NMT 30 minutes | 12 minutes |
| **Microbial Test** | | | |
| Total Plate count | USP<2021> | NMT 100,000 CFU/g | <10 CFU/g |
| *Yeast & Mold* | USP<2021> | NMT 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. | | | |