GST TIN No. : 03AAZFB3143Q1ZX

# BIONIAL LIFESCIENCES

(A WHO GMP Compliance & ISO 9001:2015 Certified Co.)

**Plot No. 459, Sector 82, JLPL, Mohali (Pb.) - 140308**

*Ref. No.* 0484 *Dated* 24/08/2026

## CERTIFICATE OF ANALYSIS

## (Finished Product)

| | | | |
|---|---|---|---|
| **Product name** | EX1 Ashwagandha 600 mg Root Extract (5%) Capsules | **Batch No.** | BLAC-A0016 |
| **Mfg. Date** | 08-2026 | **Exp. Date** | 07-2029 |
| **Batch size** | 120,000 capsules | **Market** | Domestic |
| **Sample received** | 14-08-2026 | **Sample quantity** | 100 capsules |
| **Report date** | 22-08-2026 | **Analysis period** | 14-08-2026 to 21-08-2026 |
| **Manufactured by** | Bionial Lifesciences, Mohali, Punjab | **Marketed by** | Vynza Pharmaceuticals Pvt. Ltd., Panchkula, Haryana |
| **Mfg. AYUSH Lic. No.** | 909/AY-PB | **Sample packing** | Transparent PET jar with golden cap; 60 vegetarian capsules |

### 1. Identification and physical characteristics

| Test | Result | Unit | Specification / Limit |
|---|---|---|---|
| Description | Conforms | - | Transparent vegetarian hard capsules containing brown to brownish-tan powder; capsules intact, properly locked and free from visible defects |
| Identification - Ashwagandha | Complies | - | Fingerprint corresponds to Withania somnifera root extract reference |
| Identification - Withanolides | Complies | - | Marker peaks correspond to withanolide reference profile |
| Average capsule fill weight | 904 | mg | 900 mg target; average contents mass ≥300 mg |
| Uniformity of fill weight (20 capsules) | 872-931; Complies | mg | Not more than 2 outside ±7.5%; none outside ±15% |
| Capsule integrity | Complies | - | Capsules intact, properly locked and free from leakage/damage |
| Disintegration | 13 min 20 sec | - | NMT 30 minutes |
| Loss on drying | 3.1 | % w/w | NMT 5.0% w/w |
| Pack content | 60 capsules; 54.2 g | - | 60 capsules; net weight NLT 54 g |

| | Prepared by | Checked by | Approved by |
|---|---|---|---|
| Sign. | Simran | Reena | |
| | | | |

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## 2. Assay

| Test | Method / Reference | Result | Unit | Specification / Limit |
|---|---|---|---|---|
| Ashwagandha root extract | RM COA + BMR reconciliation | 600 (BMR input verified) | mg/capsule | Label/BMR input 600 mg/capsule |
| Total Withanolides | HPLC-UV | 30.3 (5.05%; 101.0%) | mg/capsule | NLT 30 mg/capsule; standardized to NLT 5.0% w/w |

## 3. Heavy metals

| Test | Method Source | Result | Unit | Limit | LOQ* |
|---|---|---|---|---|---|
| Lead (Pb) | ICP-MS | 0.42 | mg/kg | NMT 10 mg/kg | 0.05 |
| Arsenic (As) | ICP-MS | 0.18 | mg/kg | NMT 3 mg/kg | 0.05 |
| Cadmium (Cd) | ICP-MS | 0.06 | mg/kg | NMT 0.3 mg/kg | 0.02 |
| Mercury (Hg) | Cold-vapour AAS | <0.010 | mg/kg | NMT 1.0 mg/kg | 0.01 |

Reference basis: Ayurvedic Pharmacopoeia of India (API), Part I, Vol. IX limits for herbal medicines: Pb NMT 10 mg/kg, As NMT 3 mg/kg, Cd NMT 0.3 mg/kg and Hg NMT 1 mg/kg.

## 4A. Microbiological examination

| Test | Method Source | Result | Unit | Specification / Requirement | LOQ* |
|---|---|---|---|---|---|
| Total aerobic microbial count | Pharmacopoeial plate-count method | 420 | cfu/g | NMT $1\times10^5$ cfu/g | 10 |
| Yeast and moulds | Pharmacopoeial fungal-count method | 30 | cfu/g | NMT $1\times10^3$ cfu/g | 10 |
| Escherichia coli | Pharmacopoeial microbial limit test | Absent | /g | Absent / g | - |
| Salmonella spp. | Pharmacopoeial microbial limit test | Absent | /g | Absent / g | - |
| Staphylococcus aureus | Pharmacopoeial microbial limit test | Absent | /g | Absent / g | - |
| Pseudomonas aeruginosa | Pharmacopoeial microbial limit test | Absent | /g | Absent / g | - |

Microbiology basis: API limits for herbal extracts/powders - total aerobic microbial count NMT $1\times10^5$ cfu/g, yeast and moulds NMT $1\times10^3$ cfu/g; E. coli, Salmonella spp., S. aureus and P. aeruginosa absent.

| | Prepared by | Checked by | Approved by |
|---|---|---|---|
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4B. Additional microbiological quality indicators

| Test | Method Source | Result | Unit | Specification | LOQ* |
|---|---|---|---|---|---|
| Coliforms | ISO 4832:2006 | <10 | cfu/g | Less than 10 cfu/g | 10 |

5. Stability status

| Test | Method Source | Result | Specification / Requirement |
|---|---|---|---|
| Accelerated stability (40 °C ± 2 °C / 75% RH ± 5% RH) | As per approved accelerated stability protocol | T0 complies: total withanolides 30.3 mg/capsule (5.05%; 101.0% of 30 mg target); Ashwagandha extract BMR input verified; description and disintegration comply. Study initiated; subsequent scheduled time points pending. | Assay and physical characteristics to conform to the approved stability specification at each scheduled time point |

6. Conclusion

**ASSESSMENT: Based on the illustrative results shown above, the tested parameters comply with the stated product specifications.**

| | Prepared by | Checked by | Approved by |
|---|---|---|---|
| Sign. | Simran | Ravneet | |
| | | | |