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. 0478 *Dated* 22/08/2026

CERTIFICATE OF ANALYSIS

(Finished Product)

Product name	EX1 Inositol for PCOS 3 g - Myo:D-Chiro Inositol (40:1) Tablets	**Batch No.**	BLNT-A0131
Mfg. Date	08-2026	**Exp. Date**	07-2028
Batch size	90,000 tablets	**Market**	Domestic
Sample received	13-08-2026	**Sample quantity**	90 tablets
Report date	21-08-2026	**Analysis period**	13-08-2026 to 20-08-2026
Manufactured by	Bionial Lifesciences, Mohali, Punjab	**Marketed by**	Vynza Pharmaceuticals Pvt. Ltd., Panchkula, Haryana
Mfg. FSSAI Lic. No.	12122999000156	**Sample packing**	Transparent PET jar with golden cap; 90 tablets

1. Identification and physical characteristics

Test	Result	Unit	Specification / Limit
Description	Conforms	-	Red, oval, film-coated tablets; uniform appearance; free from visible defects
Identification - Myo-Inositol	Complies	-	Principal peak corresponds to Myo-Inositol reference standard
Identification - D-Chiro-Inositol	Complies	-	Principal peak corresponds to D-Chiro-Inositol reference standard
Identification - Chromium	Complies	-	Positive for chromium
Average tablet weight	1267	mg	1260 mg ± 5% (1197-1323 mg)
Weight variation (20 tablets)	1234-1296; Complies	mg	Not more than 2 outside ±5%; none outside ±10%
Thickness	7.5	mm	6.8-8.2 mm
Hardness	13.2	kp	10-16 kp
Friability	0.36	% w/w	NMT 1.0% w/w
Disintegration	17 min 20 sec	-	NMT 30 minutes
Loss on drying	2.2	% w/w	NMT 5.0% w/w
Pack content	90 tablets; 114.0 g	-	90 tablets; net weight NLT 113.4 g

	Prepared by	Checked by	Approved by
Sign.			

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2. Assay

Test	Method / Reference	Result	Unit	Specification / Limit
Myo-Inositol	HPLC-RI	3030 (101.0%)	mg/3 tablets	NLT 2700 mg/3 tablets; label claim 3000 mg
D-Chiro-Inositol	HPLC-RI	74.4 (99.2%)	mg/3 tablets	NLT 67.5 mg/3 tablets; label claim 75 mg
Folic Acid	HPLC-UV	130.7 (101.0%)	mcg/3 tablets	NLT 116.5 mcg/3 tablets; label claim 129.41 mcg
Chromium	ICP-MS	25.3 (101.2%)	mcg/3 tablets	NLT 22.5 mcg/3 tablets; label claim 25 mcg

3. Metal contaminants

Test	Method Source	Result	Unit	Limit	LOQ*
Lead (Pb)	ICP-MS	<0.050	mg/kg	NMT 2.5 mg/kg	0.05
Arsenic (As)	ICP-MS	0.060	mg/kg	NMT 1.1 mg/kg	0.05
Cadmium (Cd)	ICP-MS	<0.020	mg/kg	NMT 1.5 mg/kg	0.02
Mercury (Hg)	Cold-vapour AAS	<0.010	mg/kg	NMT 1.0 mg/kg	0.01
Tin (Sn)	ICP-MS	<0.300	mg/kg	NMT 250 mg/kg	0.30
Methyl Mercury	HPLC-ICP-MS	<0.100	mg/kg	NMT 0.25 mg/kg	0.10

Reference basis: applicable FSSAI/FSSR metal-contaminant limits for foods not otherwise specified / all foods, as relevant.

4A. Microbiological examination

Test	Method Source	Result	Unit	Specification / Requirement	LOQ*
Aerobic Plate Count	ISO 4833-1:2013	150	cfu/g	Table 10A: n=5; c=2; m=1×10^4; M=1×10^5	10
Yeast and moulds	ISO 21527-2:2008	<10	cfu/g	Table 10A: n=5; c=2; m=1×10^2; M=1×10^3	10
Enterobacteriaceae	ISO 21528-2:2017	<10	cfu/g	Table 10A: n=5; c=2; m=1×10^2; M=1×10^3	10
Salmonella spp.	IS 5887 (Part 3) (Sec 1):2020	Not Detected	/25 g	Table 10B: n=5; c=0; Absent / 25 g	-
Listeria monocytogenes	IS 14988 (Part 1):2020	Not Detected	/25 g	Table 10B: n=5; c=0; Absent / 25 g	-

Microbiology sampling plan: FSSAI Appendix B Table 10A process-hygiene criteria use n=5, c=2; Table 10B food-safety criteria use n=5, c=0 for direct-consumption health supplements/nutraceuticals.

	Prepared by	Checked by	Approved by
Sign.	Simran	Ravinder	

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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
Escherichia coli	ISO 7251:2005	Absent	/g	Absent / g	-
Staphylococcus aureus	ISO 6888-1:2021	<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: Myo-Inositol 3030 mg/serving (101.0%); D-Chiro-Inositol 74.4 mg/serving (99.2%); folic acid and chromium comply; 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.

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Sign.			