

Lithium Orotate

Certificate of Analysis · CAS 5266-20-6 · CPh / USP Methods

1. Header Data

Product Name	Lithium Orotate
Molecular Formula	C ₅ H ₃ LiN ₂ O ₄ ·H ₂ O
CAS Number	5266-20-6
Batch Number	MLP-LOE-20250922
Quantity	600 kg
Manufacturing Date	22/09/2025
Report Date	30/09/2025
Retest Date	21/09/2027

Data based on the manufacturer's certificate of analysis.

2. Identification

Parameter	Specification	Result	Method	Status
Identification (1H NMR)	Confirms to structure	Conforms	CPh	Pass

3. Active Ingredients

Parameter	Specification	Result	Method	Status
Assay (dried basis)	98.0–102.0%	99.94%	CPh	Pass
Lithium ion content	3.5–4.3%	3.8%	USP	Pass

4. Physical Control

Parameter	Specification	Result	Method	Status
Appearance	Fine powder	Conforms	Visual	Pass
Colour	White to off-white	Conforms	Visual	Pass
State of solution	Clear and colourless	Conforms	Visual	Pass
Odour	Characteristic	Conforms	Organoleptic	Pass
Taste	Characteristic	Conforms	Organoleptic	Pass
Particle size	60% pass 60 mesh	Conforms	CPh	Pass
Loss on drying	$\leq 1.0\%$	0.23%	CPh	Pass

5. Chemical Control

Parameter	Specification	Result	Method	Status
Heavy metals	≤ 20 ppm	< 10 ppm	USP	Pass
Lead (Pb)	≤ 0.5 ppm	< 0.05 ppm	ICP-MS	Pass
Arsenic (As)	≤ 1.5 ppm	< 0.005 ppm	ICP-MS	Pass
Cadmium (Cd)	≤ 0.5 ppm	< 0.005 ppm	ICP-MS	Pass
Mercury (Hg)	≤ 3.0 ppm	Not detected	ICP-MS	Pass
Chloride (Cl)	$\leq 0.1\%$	Conforms	GB 5009.44	Pass
Sulfate (SO ₄)	$\leq 0.1\%$	Conforms	CPh	Pass
pH	5.5–7.5	6.04	CPh	Pass

6. Microbiological Control

Parameter	Specification	Result	Method	Status
Total Plate Count	$\leq 1,000$ CFU/g	$< 1,000$ CFU/g	ISO 4833-1	Pass

Parameter	Specification	Result	Method	Status
Yeast	≤ 50 CFU/g	< 50 CFU/g	ISO 21527-2	Pass
Moulds	≤ 50 CFU/g	< 50 CFU/g	ISO 21527-2	Pass
E. coli	Negative	Negative	ISO 16649-3	Pass
Salmonella sp.	Negative	Negative	GB 4789.4	Pass

7. Conclusion

Specification compliant – all parameters within limits. Assay 99.94% (dried basis), lithium ion 3.8%.

8. Storage

Shelf Life	2 years (until 21/09/2027)
Packaging	Paper drums with two plastic bags inside
Storage	Well-closed container, away from moisture and direct sunlight