

CERTIFICATE OF ANALYSIS

Product Name	Azelaic acid		
Batch Number	20230122	Manufacture Date	20230122
Report Date	20230122	Expiry Date	20250121

Item of Analysis	Specification	Results	Test Methods
Assay (by HPLC)	≥99%	99.25%	HPLC
Organoleptic			
Appearance	Powder	Conforms	Organoleptic
Color	White or off-white crystalline powder	Conforms	Organoleptic
Odor	Characteristic	Conforms	CP2010
Taste	Characteristic	Conforms	CP2010
Physical Characteristics			
Loss on drying	0.5%NMT (%)	0.2%	USP<731>
Residue on ignition	≤0.1%	0.08%	USP<731>
Melting point	106-108°C	106.5°C	Titration
Chlorides (AgNO3)	≤0.005%	0.005MAX	USP<731>
SULFATES(BaCl2)	≤0.0025%	0.0025MAX	USP<731>
Heavy metals			
Total Heavy Metals	10ppm Max	Conform	USP<231>method II
Lead (Pb)	2ppm NMT	Conform	ICP-MS
Arsenic (As)	2ppm NMT	Conform	ICP-MS
Cadmium (Cd)	2ppm NMT	Conform	ICP-MS
Mercury (Hg)	0.5ppm NMT	Conform	ICP-MS
Microbiological Tests			
Total Plate Count	1000cfu/g Max	Conform	USP<61>
Yeast & Mold	100cfu/g Max	Conform	USP<61>
E. Coli.	Negative	Conform	USP<61>
Salmonella	Negative	Conform	USP<61>
Staphylococcus	Negative	Conform	USP<61>

Storage: Store in tight, light-resistant containers, avoid exposure to direct sunlight, moisture and excessive heat.

Shelf Life: 24 months if store under the conditions above and stay in original packaging.

