

# CEFA-CILINAS BIOTICS PVT LTD

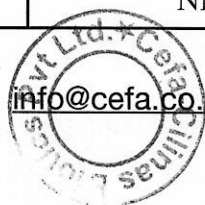
PLOT NO. W-8, CHIKALTHANA MIDC, AURANGABAD -431001, MH INDIA.

11.01.2024

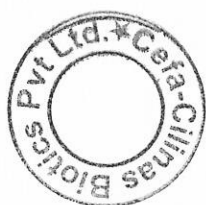
## CERTIFICATE OF ANALYSIS

Product Name	Azelaic Acid (Micronised)		
CAS No.	123-99-9	HS Code	29171300
Batch No.	CEFA-AA-20240001		

Sr No	Item	Specifications	Results
1	Description	White or off white Powder	White Powder
2	Identification by IR	Infrared absorption spectrum of the sample should be concordant with the spectrum of the working standard	Complies
3	Appearance of solution	The solution is clear and colourless	Complies
4	Heavy Metals	NMT 20 ppm	Complies
5	Acid Content	585.0 - 610.0 mg KOH/g	Complies
6	Residue on Ignition	NMT 0.1%	0.04%
7	Water Content	NMT 0.5%	0.28%
8	Loss on Drying	NMT 0.5%	0.22%
9	Assay by GC	NLT 98.00%	99.37%
10	<b>Related Substance by GC :</b>		
A	Azelaic Acid	NLT 98.00%	Complies
B	Sebacic Acid	NMT 0.5%	Not Detected
C	Any unknown impurity	NMT 0.1%	Complies
D	Total Impurities	NMT 0.8%	Complies
11	<b>Residual Solvents by GC</b>		
A	Methanol	NMT 3000 ppm	Complies
B	Ethyl Acetate	NMT 5000 ppm	Complies



13	Melting Point	109°C to 111°C	110.5°C
<b>13</b>	<b>Microbial Test</b>		
A	Total Aerobic Count (TAMC)	NMT 100 cfu/g	Complies
B	Total yeast and mould (TYMC)	NMT 10 cfu/g	Complies
C	Enterobacteria	Should be Absent	Absent
D	Pseudomonas	Should be Absent	Absent
E	Staphylococcus	Should be Absent	Absent
F	Escherichia	Should be Absent	Absent
<b>14</b>	<b>Color and clarify of solution</b>		
A	Transmission 440 nm	NLT 90.0%	Complies
B	Transmission 550 nm	NLT 98.0%	Complies
C	1% w/v solution in Methanol	Should be clear	Complies
15	Storage Condition	Store protected from light, at 8°C to 25°C.	
<b>16</b>	Particle Size	D90 Less than 40µ	Complies



*Sharad R Ahire*

Mr Sharad R Ahire  
Dept of Quality Control (QC)