

CEFA-CILINAS BIOTICS PVT LTD

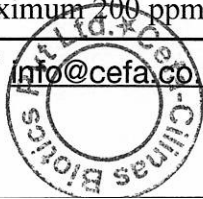
PLOT NO. W-8, CHIKALTHANA MIDC, AURANGABAD -431001, MH INDIA.

15.01.2024

CERTIFICATE OF ANALYSIS

Product Name	Sodium Valproate		
CAS No.	1069-66-5	HS Code	29420090
Batch No.	CEFA-SDVP-20240001		

Sr No	Item	Specifications	Results
1	Appearance	White crystalline, hygroscopic powder	White crystalline, hygroscopic powder
2	Solubility	Very soluble in water, freely soluble in alcohol	Very soluble in water, freely soluble in alcohol
3	Identification		
	A. IR	Comparison sodium valproate RS	Complies test
	B. Chemical test	A dense white precipitate is formed	A dense white precipitate is formed
4	Appearance of solution	The solution is not more opalescent than reference suspension II, and not more intensely coloured than reference solution YS5	Complies
5	Acidity or Alkalinity	Not more than 0.75 ml of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator.	Complies 0.20 ML of 0.1 N solution required
6	Related substances		
	Impurity K	NMT 0.15%	Not detected (Less than 0.15%)
	Unspecified Impurity	NMT 0.05 %	Not detected (less than 0.05%)
	Total Impurities	NMT 0.2%	Not detected (less than 0.2%)
7	Chlorides	Maximum 200 ppm	Less than 200 ppm
8	Sulphate	Maximum 200 ppm	Less than 200 ppm



9	Heavy metals	Maximum 20 ppm	Less than 20 ppm
10	Loss on Drying	Maximum 2.0 %	0.412%
11	Assay	NLT 98.5% to 101% dry substance	100.05%
12	Residual solvent test INH specification	Not applicable because there is no any solvent used in final stage of S. V.	No any other solvent detected in G.C test.

Remark: The results complies with the enterprise standards.




 Mr Sharad R Ahire
 Dept of Quality Control (QC)