



# VASUDHA PHARMA CHEM LIMITED

Unit-I, Plot No. 37/A, 38, 39 A & B, Phase-I, IDA, Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

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## DECLARATION ON METAL TEST RESULTS

We, M/s Vasudha Pharma Chem Limited are manufacturing **CYCLOBENZAPRINE HCl** API at our current location. As per USP general chapter <232> & ICH Q3D requirement, three batches were tested by considering the necessary metals [ Lead (Pb), Arsenic (As), Cadmium (Cd), Mercury (Hg), Vanadium(V), Cobalt(Co) and Nickel (Ni) ] and found that all these metal are being controlled at below Option 2a limits. No metals are used in the manufacturing process right from starting material manufacturing process.

The details of executed test results of Cyclobenzaprine HCl are appended below.

Name of class as per ICH Q3D	Name of Elemental Impurity	Limit (Based on PDE limit)	LOD (ppm)	LOQ (ppm)	Results (ppm)		
					CBP/1701001	CBP/1701002	CBP/1703003
Class-1	Arsenic (As)	500	11.36	37.5	BDL	ND	ND
	Lead (Pb)	167	11.36	37.5	ND	ND	ND
	Mercury(Hg)	1000	11.36	37.5	ND	ND	ND
	Cadmium(Cd)	167	11.36	37.5	ND	ND	ND
Class-2A	Cobalt (Co)	1667	11.36	37.5	ND	ND	ND
	Vanadium (V)	3333	11.36	37.5	ND	ND	ND
	Nickel (Ni)	6667	11.36	37.5	BDL	BDL	BDL
Others	Magnesium	---	11.36	37.5	BDL	BDL	BDL

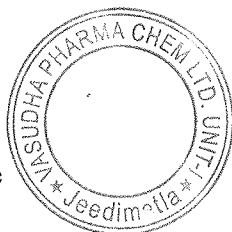
Note: - ND: - Not Detected; BDL: Below Detection Limit

For Vasudha Pharma Chem Limited,

Authorized Signatory,

Sign. & Date : .....  
30/04/2020

Name : M.Ramesh  
Designation : Dy. Manager  
Department : Quality Assurance



Registered Office : 78/A, Vengalrao Nagar, Hyderabad-500038, Telangana State, INDIA. CIN: U24230TG1994PLC019021