



VASUDHA PHARMA CHEM LIMITED

Unit-I : Plot No. 39 A & B, Phase-I, I.D.A., Jeedimetla, Hyderabad-500055, Telangana, INDIA.

Phone: +91-40-44754545

Fax : +91-40-44754555

E-mail: mwu1@vasudhapharma.com

Website: www.vasudhapharma.com

DECLARATION FOR RESIDUE OF METAL CATALYST OR METAL REAGENTS/ ELEMENTAL IMPURITIES CONSIDERED IN THE RISK ASSESSMENT FOR API AS PER ICH Q3D

We, M/s Vasudha Pharma Chem Limited, hereby confirm that CISAPRIDE MONOHYDRATE is evaluated according to current guideline for Elemental Impurities (ICH Q3D).

Elemental Impurity		Class	Intentionally added in the process as Catalyst/ Reagent/ /Material/from manufacturing Equipment/ Container Closure systems etc.		Metals to be assessed as per ICH Q3D, Even though, it's not intentionally added	ICH limit (ppm) for Oral dosage form	Analytical Method Used for Detection (e.g. ICP MS, ICP-OES. etc)	LOQ (µg/g)	Specification limits (ppm)
Cadmium	Cd	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	0.5	ICP-OES	0.60	200
Lead	Pb	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	0.5	ICP-OES	0.60	200
Arsenic (inorganic)	As	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	1.5	ICP-OES	0.60	200
Mercury (inorganic)	Hg	1	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	3	ICP-OES	0.60	200
Cobalt	Co	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	5	ICP-OES	0.60	200
Vanadium	V	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	10	ICP-OES	0.60	200
Nickel	Ni	2A	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	Yes	20	ICP-OES	0.60	200
Thallium	Tl	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	0.8	Not Applicable		
Gold	Au	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Palladium	Pd	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Iridium	Ir	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Osmium	Os	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Rhodium	Rh	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Ruthenium	Ru	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Selenium	Se	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	15			
Silver	Ag	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	15			
Platinum	Pt	2B	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	10			
Lithium	Li	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	55			
Antimony	Sb	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	120			
Barium	Ba	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	140			
Molybdenum	Mo	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	300			
Copper	Cu	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	300			
Tin	Sn	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	600			
Chromium	Cr	3	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	No	1100			

DECLARATION

The information shared is accurate and true according to best of our knowledge. In future, we will be informed of any changes to the manufacturing process which may lead to changes in these data. The information will be given before changes are established.

Name: M. Ramesh

Date: 26/05/18

Signature:

