

Risk Assessment Questionnaire – Elemental Impurities

Dear valued supplier, please complete the short form below to aid us in our efforts to meet ICH Q3D, USFDA, and USP <232>, <233> elemental impurities requirements. Please avoid potential ambiguity by adequately addressing every single impurity listed below. Please send your completed response to technicalservices@spectrumchemical.com.

Spectrum Product Number: CA 131F, CA 131E, CA131D, CA131B, CA130D, CA130F, CA130E

Spectrum Product Description: Calcium Carbonate

Supplier / Manufacturer Company Name: Sudeep nPharma Pvt Ltd

Supplier Product Number / Description: Calcium Carbonate

Elemental Impurity		Class	Likely to be Present? (Y/N)	If Yes, Expected Concentration (ppm)
Cadmium	Cd	1	Y	<1.0 ppm
Lead	Pb	1	Y	<1.0 ppm
Arsenic	As	1	Y	<1.0 ppm
Mercury	Hg	1	Y	<0.1 ppm
Cobalt	Co	2A	N	
Vanadium	V	2A	N	
Nickel	Ni	2A	N	
Thallium	Tl	2B	N	
Gold	Au	2B	N	
Palladium	Pd	2B	N	
Iridium	Ir	2B	N	
Osmium	Os	2B	N	
Rhodium	Rh	2B	N	
Ruthenium	Ru	2B	N	
Selenium	Se	2B	N	
Silver	Ag	2B	N	
Platinum	Pt	2B	N	
Lithium	Li	3	N	
Antimony	Sb	3	N	
Barium	Ba	3	N	
Molybdenum	Mo	3	N	
Copper	Cu	3	N	
Tin	Sn	3	N	
Chromium	Cr	3	N	

Reference: ICH Q3D Industry Guideline for Elemental Impurities. September 2015.

Supplier respondent name and title: Krishnaraj A M, Sr. QA Manager

Supplier respondent signature:  Date: 20.01.2018