

Annex 3: Statement regarding Elemental Impurities


Name of Product	KETOPROFEN
Name of Manufacturer	BEC CHEMICALS PVT LTD.
Address of manufacturing site	PLOT NO. 24, MIDC, DHATAV, ROHA, RAIGAD, MAHARASHTRA, INDIA, 402 116.

Reference: ICH Q3D Industry Guideline for Elemental Impurities, September 2015
USFDA
USP <232>, <233> elemental impurities requirements

The product does not contain Elemental Impurities

The following Elemental Impurities are potentially present in the product:

Elemental Impurity	Symbol	Class	Used as metal catalyst (MC) or metal reagent (MR) or NA	Likely to be Present? (YES/NO)	IF YES, CONCENTRATION (ppm) PRESENT
Arsenic (inorganic)	As	1	NA	No	
Cadmium	Cd	1	NA	No	
Mercury (inorganic)	Hg	1	NA	No	
Lead	Pb	1	NA	No	
Cobalt	Co	2A	NA	No	
Nickel	Ni	2A	NA	No	
Vanadium	V	2A	NA	No	
Silver	Ag	2B	NA	No	
Gold	Au	2B	NA	No	
Iridium	Ir	2B	NA	No	
Osmium	Os	2B	NA	No	
Palladium	Pd	2B	NA	No	
Platinum	Pt	2B	NA	No	
Rhodium	Rh	2B	NA	No	
Ruthenium	Ru	2B	NA	No	
Selenium	Se	2B	NA	No	
Thallium	Tl	2B	NA	No	
Barium	Ba	3	NA	No	
Chromium	Cr	3	NA	No	
Copper	Cu	3	NA	No	
Lithium	Li	3	NA	No	
Molybdenum	Mo	3	NA	No	
Antimony	Sb	3	NA	No	
Tin	Sn	3	NA	No	

	API Manufacturer Quality Questionnaire	Doc. No.: WF10-01
		Rev:02
		Page 2 of 2
		Effective date: 11 May 2017

- For all Elemental Impurities potentially present it is demonstrated that they have been adequately removed from the product. Adequate removal is demonstrated if in 3 consecutive industrial scale batches an elemental impurity <30% of the appropriate limit according to ICH Q3D/USP<232>, <233> was found.

Yes
 No
 Not Applicable

- For determination of each elemental impurities, appropriate and validated method according to ICH is used.

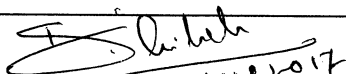
Yes
 No
 Not Applicable

- Methods and method validations are available on request.

Yes
 No
 Not Applicable

We herewith certify that this statement is valid and true for each lot supplied to LGM Pharma.

LGM Pharma will be notified in written form of any change concerning the parameters outlined above.

Signatures	
Date	12.12.2017
Name	P.K.SHIRBHATE
Function	DGM-QA
Signature	 12/12/2017