Sri Krishna Pharma
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Elemental Analysis & Metal Residues Evaluation
Manufacturer Questionnaire
(EU marketed products)

As per the methodology stated in the EMA "Guideline on the specification limits for residues of metal catalysts or metal reagents" (EMA/CHMP/SWP/4446/2000) and the general chapter of "Metal residues" in the European pharmacopoeia (5.20),

Manufacturer Name	Address	API/*Excipient name	API/Excipient code #
Sri Krishna Pharmaceuticals Limited	Unit –IV: Survey No.: 296/7/10, IDA Bollaram, Jinnaram Mandal, Medak Dist. – 502 325	FUROSEMIDE	200

	Please answer the following :	YES	NO
1.	Are any **metal catalysts** and /or **metal reagents** are used in the final manufacturing step or earlier manufacturing step?		✓
2.	Are metals used from the 14 metals indicated in the EMEA guide /EP? If yes, indicate identity of metals used and fill in the table:		✓
3.	The following metals are likely to be present (Toxic not part of EP list): (indicate Y/N and level) Lead (Pb) ___/___, Arsenic (As) ____/____, Cadmium (Cd) ___/____, Mercury (Hg) ____/_____. Also are the additional ICH metals are likely to be present Au, Tl, Co, Se, Ag, W, Sb, Ba, Sn, Li, B, Al (indicate Y/N and level)		✓
4.	These metals used in the manufacturing stage are **consistently removed** (by purification process, crystallization, filtration, distillation and /or any other metals removal process) - please specify:		N.A
5.	If not consistently removed, are these metals **likely to be present** in the manufactured API/Excipient?		N.A
6.	Are there production variants used, such as different routes of synthesis and/or variation of raw materials (purchased from multiple suppliers/source)? If yes, do any variants of synthesis include metals which are not consistently removed and likely to be present in the API/Excipient?		✓
7.	Is there any evidence for an adequate removal of metal residues from the final product: ☐ By screening the APIs /Excipients using ICP-OES, ICP-MS, AA, XRF, or other analytical techniques. ☐ Does evidence exist as part of process validation?		N.A
8.	Analytical method for identification and quantification of metal residues exist and fully validated.		N.A
9.	If any elemental impurities known to be present or added are being controlled through a validated process but not reported or monitored regularly (Skip testing) , please list all elemental impurities and provide validation data to support rationale for not reporting or monitoring.		N.A
10.	**Manufacturer Commitment**: ***In the future, we will be notified regarding any changes in the manufacturing process that might change the reported data; the information of the planed change will be reported before change is established.***		

Class	Metals	Presence YES	Presence NO	Typical measured values (ppm)	Comply with EP limits (Y/N)
1A	Pt				
	Pd				
1B	Ir				
	Rh				
	Ru				
	Os				
1C	Mo				
	Ni				
	Cr				
	V				
2	Cu				
	Mn				
3	Fe				
	Zn				

For Sri Krishna Pharmaceuticals Limited, Unit-IV,

VV Raghupathi 05 NOV 2019

R.V.V. Raghupathi Rao, Manager-QA

Sri Krishna Pharmaceuticals Limited
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