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Annex 3: Statement regarding Elemental Impurities


Name of Product	Cyclosporine
Name of Manufacturer	North China Pharmaceutical Huasheng Co., Ltd.
Address of manufacturing site	No. 8 Yangzi Road, Shijiazhuang Economic & Technological Development Zone, Hebei 052160, China

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	NO	NO	
Cadmium	Cd	1	NO	NO	
Mercury (inorganic)	Hg	1	NO	NO	
Lead	Pb	1	NO	NO	
Cobalt	Co	2A	NO	NO	
Nickel	Ni	2A	NO	NO	
Vanadium	V	2A	NO	NO	
Silver	Ag	2B	NO	NO	
Gold	Au	2B	NO	NO	
Iridium	Ir	2B	NO	NO	
Osmium	Os	2B	NO	NO	
Palladium	Pd	2B	NO	NO	
Platinum	Pt	2B	NO	NO	
Rhodium	Rh	2B	NO	NO	
Ruthenium	Ru	2B	NO	NO	
Selenium	Se	2B	NO	NO	
Thallium	Tl	2B	NO	NO	
Barium	Ba	3	NO	NO	
Chromium	Cr	3	NO	NO	
Copper	Cu	3	NO	NO	
Lithium	Li	3	NO	NO	
Molybdenum	Mo	3	NO	NO	
Antimony	Sb	3	NO	NO	
Tin	Sn	3	NO	NO	

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- 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	July 15, 2020
Name	Wang Dongyan
Function	QA Manager
Signature	