

Elemental Impurities Statement

Thyroid USP

Thyroid USP complies with the ICH Q3D guidelines and USP <232>/<233> requirements. The results of three (3) commercial size batches of Thyroid USP tested were below the 30% oral PDE limits. No class 1, 2a, 2b and 3 elements are likely to be present in Thyroid USP.

Elemental Impurity		Class	Likely to be Present			Oral PDE (IJ) (ug/g)	Detection Limit (0.3J) (ug/g)	Typically Observed Value (ug/g)	Method Used
Arsenic	As	1	Yes ☐	No ☒	Unknown ☐	1.5	0.45	< 0.45	ICP-MS
Cadmium	Cd	1	Yes ☐	No ☒	Unknown ☐	0.5	0.15	< 0.15	ICP-MS
Mercury	Hg	1	Yes ☐	No ☒	Unknown ☐	3	0.9	< 0.9	ICP-MS
Lead	Pb	1	Yes ☐	No ☒	Unknown ☐	0.5	0.15	< 0.15	ICP-MS
Cobalt	Co	2A	Yes ☐	No ☒	Unknown ☐	5	1.5	< 1.5	ICP-MS
Nickel	Ni	2A	Yes ☐	No ☒	Unknown ☐	20	6.0	< 6.0	ICP-MS
Vanadium	V	2A	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Silver	Ag	2B	Yes ☐	No ☒	Unknown ☐	15	4.5	< 4.5	ICP-MS
Gold	Au	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Iridium	Ir	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Osmium	Os	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Palladium	Pd	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Platinum	Pt	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Rhodium	Rh	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Ruthenium	Ru	2B	Yes ☐	No ☒	Unknown ☐	10	3.0	< 3.0	ICP-MS
Selenium	Se	2B	Yes ☐	No ☒	Unknown ☐	15	4.5	< 4.5	ICP-MS
Thallium	Tl	2B	Yes ☐	No ☒	Unknown ☐	0.8	0.24	< 0.24	ICP-MS
Barium	Ba	3	Yes ☐	No ☒	Unknown ☐	140	42	< 42	ICP-MS
Chromium	Cr	3	Yes ☐	No ☒	Unknown ☐	1100	330	< 330	ICP-MS
Copper	Cu	3	Yes ☐	No ☒	Unknown ☐	300	90	< 90	ICP-MS
Lithium	Li	3	Yes ☐	No ☒	Unknown ☐	55	16.5	< 16.5	ICP-MS
Molybdenum	Mo	3	Yes ☐	No ☒	Unknown ☐	300	90	< 90	ICP-MS
Antimony	Sb	3	Yes ☐	No ☒	Unknown ☐	120	36	< 36	ICP-MS
Tin	Sn	3	Yes ☐	No ☒	Unknown ☐	600	180	< 180	ICP-MS