

**Risk Management Summary for Elemental Impurities in Gabapentin**Intended Route of Administration: Oral

Maximum daily dose of Gabapentin = 3600 mg/day = 3.6 g/day

Element	Class	Intentionally Added? (yes/no)	Considered in Risk Management	Is it added in the process?	Oral PDE µg/g*	Acceptable level in API (ppm)	Control			LOD in ppm	LOQ in ppm	Conclusion
							Results (by ICP-OES) in ppm					
							B71010615/004	B71010615/005	B71010615/006			
Cd	1	No	Yes	No	0.5	0.5	ND	0.02	0.01	0.02	0.1	Risk under control
Pb	1	No	Yes	No	0.5	0.5	ND	ND	ND	0.01	0.1	Risk under control
As	1	No	Yes	No	1.5	1.5	ND	ND	ND	0.02	0.1	Risk under control
Hg	1	No	Yes	No	3.0	3.0	ND	ND	ND	0.02	0.1	Risk under control
Co	2A	No	Yes	No	5.0	5.0	0.03	ND	ND	0.02	0.1	Risk under control
V	2A	No	Yes	No	10.0	10.0	0.27	ND	ND	0.01	0.1	Risk under control
Ni	2A	No	Yes	No	20.0	20.0	0.25	ND	ND	0.02	0.1	Risk under control
Tl	2B	No	No	No	0.8	0.8	NA	NA	NA	NA	NA	NA
Au	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Pd	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Ir	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Os	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Rh	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Ru	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Se	2B	No	No	No	15.0	15.0	NA	NA	NA	NA	NA	NA
Ag	2B	No	No	No	15.0	15.0	NA	NA	NA	NA	NA	NA
Pt	2B	No	No	No	10.0	10.0	NA	NA	NA	NA	NA	NA
Li	3	No	No	No	55.0	55.0	NA	NA	NA	NA	NA	NA
Sb	3	No	No	No	120.0	120.0	NA	NA	NA	NA	NA	NA
Ba	3	No	No	No	140.0	140.0	NA	NA	NA	NA	NA	NA
Mo	3	No	No	No	300.0	300.0	NA	NA	NA	NA	NA	NA
Cu	3	No	No	No	300.0	300.0	NA	NA	NA	NA	NA	NA
Sn	3	No	No	No	600.0	600.0	NA	NA	NA	NA	NA	NA
Cr	3	No	No	No	1100.0	1100.0	NA	NA	NA	NA	NA	NA

NA – Not applicable,

LOD – Limit of Detection

LOQ – Limit of Quantification

\* As per ICH Q3D guideline for Elemental impurities, Table A.2.2.

**Note:** Class 1 and 2A elements are considered for risk assessment even if they are not added or generated in the manufacturing process. Class 2B and Class 3 elements are considered only if intentionally added or generated in the manufacturing process. Possible contribution from Manufacturing equipment and packaging materials are also considered in the Risk evaluation.

  
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