

ELEMENTAL IMPURITY STATEMENT

Guanidine Hydrochloride GMP

BioSpectra's Guanidine Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade material was profiled for elemental impurity via ICP-MS utilizing USP <232> and <233> in accordance with ICH Q3D with reference to parenteral application and associated limits. The results comply with the limits as per USP <232>, USP <233>, and ICH Q3D.

Current Product Number	Historic Product Number
GHCL-3201	GH3201
GHCL-3202	GH3202
GHCL-3220	GH3220
GHCL-3221	GH3221
GHCL-3222	GH3222
GHCL-3223	N/A
GHCL-3224	GH3224
GHCL-3250	GH3250
GHCL-3251	N/A
GHCL-3252	GH3252
GHCL-3253	GH3253
GHCL-4201	GH4201
GHCL-4220	GH4220
GHCL-4250	GH4250

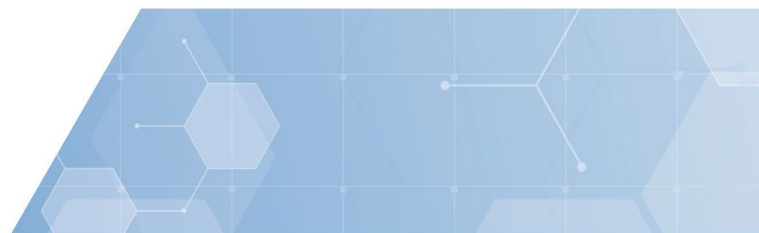


Table 1. Parenteral limits as per USP <232> and <233>

Element	Class	Impurity Limit (µg/g)	Result:
Cadmium (Cd)	1	0.2	<0.2 µg/g
Lead (Pb)	1	0.5	<0.5 µg/g
Arsenic (As)	1	1.5	<1.5 µg/g
Mercury (Hg)	1	0.3	<0.3 µg/g
Cobalt (Co)	2A	0.5	<0.5 µg/g
Vanadium (V)	2A	1	<1 µg/g
Nickel (Ni)	2A	2	<2 µg/g
Thallium (Tl)	2B	0.8	<0.8 µg/g
Gold (Au)	2B	10	<10 µg/g
Palladium (Pd)	2B	1	<1 µg/g
Iridium (Ir)	2B	1	<1 µg/g
Rhodium (Rh)	2B	1	<1 µg/g
Ruthenium (Ru)	2B	1	<1 µg/g
Selenium (Se)	2B	8	<8 µg/g
Silver (Ag)	2B	1	<1 µg/g
Platinum (Pt)	2B	1	<1 µg/g
Lithium (Li)	3	25	<25 µg/g
Antimony (Sb)	3	9	<9 µg/g
Barium (Ba)	3	70	<70 µg/g
Molybdenum (Mo)	3	150	<150 µg/g
Copper (Cu)	3	30	<30 µg/g
Tin (Sn)	3	60	<60 µg/g
Chromium (Cr)	3	110	<110 µg/g

For further information, please contact info@biospectra.us



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