



ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: WATER FOR INJECTION
PROCESS VALIDATION 2026

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TABLE 1: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0097 WFI Batch Record: WAFI-BGR-L05 WFI Process Validation Protocol: BSI-PRL-0988 Parenteral Specifications: 1,000 g/day MDD		
Element	Class	Method Limit of Quantitation ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0005-PV Composite ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0005-PV Drum 1 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0005-PV Drum 2 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0005-PV Drum 3 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0005-PV Drum 4 ppm (µg/g)
As	1	0.0045	<0.0045	<0.0045	<0.0045	<0.0045	<0.0045
Cd	1	0.0006	<0.0006	<0.0006	<0.0006	<0.0006	<0.0006
Hg	1	0.0009	<0.0009	<0.0009	<0.0009	<0.0009	<0.0009
Pb	1	0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015
Co	2A	0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015
Ni	2A	0.006	<0.006	<0.006	<0.006	<0.006	<0.006
V	2A	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Tl	2B	0.0024	<0.0024	<0.0024	<0.0024	<0.0024	<0.0024
Se	2B	0.024	<0.024	<0.024	<0.024	<0.024	<0.024
Ag	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Au	2B	0.030	<0.030	<0.030	<0.030	<0.030	<0.030
Pd	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Ir	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Os	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Pt	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Rh	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003

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Ru	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Ba	3	0.210	<0.210	<0.210	<0.210	<0.210	<0.210
Sb	3	0.027	<0.027	<0.027	<0.027	<0.027	<0.027
Li	3	0.075	<0.075	<0.075	<0.075	<0.075	<0.075
Mo	3	0.450	<0.450	<0.450	<0.450	<0.450	<0.450
Cu	3	0.090	<0.090	<0.090	<0.090	<0.090	<0.090
Sn	3	0.180	<0.180	<0.180	<0.180	<0.180	<0.180
Cr	3	0.330	<0.330	<0.330	<0.330	<0.330	<0.330
Al	4	0.0075	<0.0075	<0.0075	<0.0075	<0.0075	<0.0075
Ca	4	0.225	<0.225	<0.225	<0.225	<0.225	<0.225
Fe	4	0.060	<0.060	<0.060	<0.060	<0.060	<0.060
K	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Mg	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Na	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Zn	4	0.060	<0.060	<0.060	<0.060	<0.060	<0.060

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Analytical Method: BSI-ATM-0097 WFI Batch Record: WAFI-BGR-L05 WFI Process Validation Protocol: BSI-PRL-0988 Parenteral Specifications: 1,000 g/day MDD		
Element	Class	Method Limit of Quantitation ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0006-PV Composite ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0006-PV Drum 1 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0006-PV Drum 2 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0006-PV Drum 3 ppm (µg/g)	FG Result Lot: WAFI-L05-0826-0006-PV Drum 4 ppm (µg/g)
As	1	0.0045	<0.0045	<0.0045	<0.0045	<0.0045	<0.0045
Cd	1	0.0006	<0.0006	<0.0006	<0.0006	<0.0006	<0.0006
Hg	1	0.0009	<0.0009	<0.0009	<0.0009	<0.0009	<0.0009
Pb	1	0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015
Co	2A	0.0015	<0.0015	<0.0015	<0.0015	<0.0015	<0.0015
Ni	2A	0.006	<0.006	<0.006	<0.006	<0.006	<0.006
V	2A	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Tl	2B	0.0024	<0.0024	<0.0024	<0.0024	<0.0024	<0.0024
Se	2B	0.024	<0.024	<0.024	<0.024	<0.024	<0.024
Ag	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Au	2B	0.030	<0.030	<0.030	<0.030	<0.030	<0.030
Pd	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Ir	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Os	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Pt	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003
Rh	2B	0.003	<0.003	<0.003	<0.003	<0.003	<0.003

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Ba	3	0.210	<0.210	<0.210	<0.210	<0.210	<0.210
Sb	3	0.027	<0.027	<0.027	<0.027	<0.027	<0.027
Li	3	0.075	<0.075	<0.075	<0.075	<0.075	<0.075
Mo	3	0.450	<0.450	<0.450	<0.450	<0.450	<0.450
Cu	3	0.090	<0.090	<0.090	<0.090	<0.090	<0.090
Sn	3	0.180	<0.180	<0.180	<0.180	<0.180	<0.180
Cr	3	0.330	<0.330	<0.330	<0.330	<0.330	<0.330
Al	4	0.0075	<0.0075	<0.0075	<0.0075	<0.0075	<0.0075
Ca	4	0.225	<0.225	<0.225	<0.225	<0.225	<0.225
Fe	4	0.060	<0.060	<0.060	<0.060	<0.060	<0.060
K	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Mg	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Na	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Zn	4	0.060	<0.060	<0.060	<0.060	<0.060	<0.060

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Hg	1	0.0009	<0.0009	<0.0009	<0.0009	<0.0009	<0.0009
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Mg	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
Na	4	0.150	<0.150	<0.150	<0.150	<0.150	<0.150
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