

Dear Valued Customer,

The following Elemental Impurity Profile for Tris Excipient is applicable to the following BioSpectra product codes:

Current Product Number
TRIS-3201
TRIS-3220
TRIS-3221
TRIS-3251
TRIS-3252
TRIS-3254
TRIS-3255
TRIS-3256
TRIS-3257
TRIS-4220
TRIS-4221
TRIS-4223

Respectfully submitted,



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ELEMENTAL IMPURITY ASSESSMENT
MATERIAL NAME: TRIS
2021

TABLE 1: ELEMENTAL IMPURITY RISK ASSESSMENT				Manufacturing Process: BSI-MPR-0009 Parenteral Specifications 100 g/day MDD			
Element	Class	Intentionally Added?	Potential Sources?	Manufacturing Equipment Risk?	Method LOQ ppm (µg/g)	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Cd	1	No	No	No	0.002	0.20	0.06
Pb	1	No	No	No	0.005	0.50	0.15
As	1	No	No	No	0.015	1.5	0.45
Hg	1	No	No	No	0.003	0.30	0.09
Co	2A	No	No	No	0.005	0.50	0.15
V	2A	No	No	No	0.01	1.0	0.30
Ni	2A	No	Yes	No	0.02	2.0	0.60
Tl	2B	No	No	No	0.008	0.80	0.24
Au	2B	No	No	No	0.10	10	3.0
Pd	2B	No	No	No	0.01	1.0	0.30
Ir	2B	No	No	No	0.01	1.0	0.30
Os	2B	No	No	No	0.01	1.0	0.30
Rh	2B	No	No	No	0.01	1.0	0.30
Ru	2B	No	No	No	0.01	1.0	0.30
¹ Se	2B	No	No	No	0.05	5.0	1.5
Ag	2B	No	No	No	0.01	1.0	0.30

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Element	Class	Intentionally Added?	Potential Sources?	Manufacturing Equipment Risk?	Method LOQ ppm (µg/g)	Limits 1.0J Target ppm(µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)
Pt	2B	No	No	No	0.01	1.0	0.30
Li	3	No	No	No	0.25	25	7.5
Sb	3	No	No	No	0.09	9.0	2.7
Ba	3	No	No	No	0.70	70	21
¹ Mo	3	No	No	No	0.05	5.0	1.5
¹ Cu	3	No	No	No	0.025	2.5	0.75
Sn	3	No	No	No	0.60	60	18
¹ Cr	3	No	No	No	0.05	5.0	1.5
² Additional Elements							
Al	4	No	Yes	No	0.40	40	12
Fe	4	No	No	No	0.20	20	6.0
Mn	4	No	No	No	0.025	2.5	0.75
Zn	4	No	No	No	0.20	20	6.0
¹ Specification calculated based on lower internal specification.							
² Additional Elements Specifications and Results are For Informational Purposes only.							

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Manufacturing Process: BSI-MPR-0009 Parenteral Specifications: 100 g/day MDD		
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: TR3200-660-0121 ppm (µg/g)	Result Batch 2 Lot: TR3200-661-0121 ppm (µg/g)	Result Batch 3 Lot: TR3200-662-0121 ppm (µg/g)	Meets Control Threshold (Yes or No)
Cd	1	0.20	0.06	<0.06	<0.06	<0.06	Yes
Pb	1	0.50	0.15	<0.15	<0.15	<0.15	Yes
As	1	1.5	0.45	<0.45	<0.45	<0.45	Yes
Hg	1	0.30	0.09	<0.09	<0.09	<0.09	Yes
Co	2A	0.50	0.15	<0.15	<0.15	<0.15	Yes
V	2A	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ni	2A	2.0	0.60	<0.60	<0.60	<0.60	Yes
Tl	2B	0.80	0.24	<0.24	<0.24	<0.24	Yes
Au	2B	10	3.0	<3.0	<3.0	<3.0	Yes
Pd	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ir	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Os	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Rh	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Ru	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
¹ Se	2B	5.0	1.5	<1.5	<1.5	<1.5	Yes
Ag	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes

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TABLE 2: ELEMENTAL IMPURITY ASSESSMENT					Manufacturing Process: BSI-MPR-0009 Parenteral Specifications: 100 g/day MDD		
Element	Class	Limits 1.0J Target ppm (µg/g)	Control Threshold Limits 0.3J Target ppm (µg/g)	Result Batch 1 Lot: TR3200-660-0121 ppm (µg/g)	Result Batch 2 Lot: TR3200-661-0121 ppm (µg/g)	Result Batch 3 Lot: TR3200-662-0121 ppm (µg/g)	Meets Control Threshold (Yes or No)
Pt	2B	1.0	0.30	<0.30	<0.30	<0.30	Yes
Li	3	25	7.5	<7.5	<7.5	<7.5	Yes
Sb	3	9.0	2.7	<2.7	<2.7	<2.7	Yes
Ba	3	70	21	<21	<21	<21	Yes
¹ Mo	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
¹ Cu	3	2.5	0.75	<0.75	<0.75	<0.75	Yes
Sn	3	60	18	<18	<18	<18	Yes
¹ Cr	3	5.0	1.5	<1.5	<1.5	<1.5	Yes
² Additional Elements							
Al	4	40	12	1.462	1.510	0.709	Yes
Fe	4	20	6.0	<6.0	<6.0	<6.0	Yes
Mn	4	2.5	0.75	<0.75	<0.75	<0.75	Yes
Zn	4	20	6.0	<6.0	<6.0	<6.0	Yes
¹ Specification calculated based on lower internal specification.							
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