

August 12th, 2020 Revision 2

AFLATOXIN/MYCOTOXIN STATEMENT

Tris Bio Active Bio Excipient Bio Pharma

TR2220 TR2221 TR2250 TR3220 TR3221 TR3251 TR3252 TR3254 TR3255 TR3256 TR4220 TR4221

Tris, Bio Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes TR2220, TR2221, TR2250, TR3220, TR3221, TR3251, TR3252, TR3254, TR3255, TR3256, TR4220, TR4221 are of synthetic origin. BioSpectra does not specifically test for Aflatoxin/Mycotoxin, as Aflatoxin/Mycotoxin are not directly used in the manufacture of Tris, Bio Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes TR2220, TR2221, TR2250, TR3220, TR3221, TR3251, TR3252, TR3254, TR3255, TR3256, TR4220, TR4221 and are not intentionally added to the manufacturing process. BioSpectra has evaluated the Raw Material Supply through the Supplier Approval Program and can state that Aflatoxin/Mycotoxin are not a concern based on this evaluation.

BioSpectra can state that based on our knowledge of the manufacturing process and the controlled handling and storage of the product, Aflatoxin/Mycotoxin are not expected to be present in Tris, Bio Active Grade, Bio Excipient Grade, and Bio Pharma Grade product codes TR2220, TR2221, TR2250, TR3220, TR3221, TR3251, TR3252, TR3254, TR3255, TR3256, TR4220, TR4221, manufactured by BioSpectra.

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