

## NITROSAMINE STATEMENT

Tris GMP

BioSpectra can state that a Nitrosamine Risk Evaluation prepared in accordance with European Medicines Agency (EMA) requirements and US FDA Control of Nitrosamine Impurities in Human Drugs Guidance for Industry is available upon request for Tris, Bio Excipient Grade, and Bio Pharma Grade manufactured by BioSpectra.

| Current Product Number | Historic Product Number |
|------------------------|-------------------------|
| TRIS-3201              | TR3201                  |
| TRIS-3220              | TR3220                  |
| TRIS-3221              | TR3221                  |
| TRIS-3251              | TR3251                  |
| TRIS-3252              | TR3252                  |
| TRIS-3254              | TR3254                  |
| TRIS-3255              | TR3255                  |
| TRIS-3256              | TR3256                  |
| TRIS-3257              | TR3257                  |
| TRIS-4220              | TR4220                  |
| TRIS-4221              | TR4221                  |

For further information, please contact [info@biospectra.us](mailto:info@biospectra.us)

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