

## STABILITY STATEMENT

### Tris Hydrochloride GMP

BioSpectra can state that Tris Hydrochloride, Bio Excipient Grade, and Bio Pharma Grade manufactured at BioSpectra undergoes a 36-month stability testing program. A 24-month retest date is currently assigned based on the Long-Term Stability Data with regulated conditions for temperature at 15-30°C and humidity (monitor). The packaging configurations included in this study are Poly/Poly, Poly/Fiber, and Tyvek/Poly.

Current Product Number	Historic Product Number
THCL-3203	TH3203
THCL-3220	TH3220
THCL-3221	TH3221
THCL-3250	TH3250
THCL-3251	TH3251
THCL-3252	TH3252
THCL-3253	TH3253
THCL-3254	TH3254
THCL-3255	TH3255
THCL-3256	TH3256
THCL-3257	TH3257
THCL-3258	TH3258
THCL-3259	TH3259
THCL-3260	N/A
THCL-4220	TH4220
THCL-4221	TH4221

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