



### Batch Result Equivalency Evaluation For Tris Assay Method Update

A result comparison for the previous method and the current method for USP Assay and Ultrapure Assay was performed on Tris Lot #TRIS-0223-00033. Refer to the table below for the result comparison.

| Previous USP Assay Method<br>(Potentiometric Titration) |               |        |
|---|---------------|--------|
| Lot Number  | Specification | Result |
| TRIS-0223-00033<br>(Initial Results)                    | 99.0 – 101.0% | 99.9%  |
| Current USP Assay Method<br>(Manual Titration)          |               |        |
| TRIS-0223-00033   | 99.0 – 101.0% | 100.0% |
| % RSD between methods = 0.06%                           |               |        |

| Previous Ultrapure Assay Method<br>(Potentiometric Titration) |               |        |
|---|---------------|--------|
| Lot Number  | Specification | Result |
| TRIS-0223-00033<br>(Initial Results)                          | ≥ 99.9%       | 100.0% |
| Current Ultrapure Assay Method<br>(Potentiometric Titration)  |               |        |
| TRIS-0223-00033   | ≥ 99.9%       | 100.1% |
| % RSD between methods = 0.08%                                 |               |        |

In conclusion, the methods are deemed equivalent in accordance with the change control, SCC23-05.