



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

Previous Ultrapure Assay Method (Potentiometric Titration)		
Lot Number	Specification	Result
TRIS-0223-00033 (Initial Results)	≥ 99.9%	100.0%
Current Ultrapure Assay Method (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.

Signature Manifest**Document Number:** BSI-MEM-1165**Revision:** 1.0**Title:** Batch Result Equivalency for Tris Assay Method Update**Effective Date:** 20 Apr 2023

All dates and times are in US/Eastern.

BSI-MEM-1165 Batch Result Equivalency for Tris Assay Method Update**Change Request**

Name/Signature	Title	Date	Meaning/Reason
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	18 Apr 2023, 04:33:21 PM	Approved
Catherine Smith (CATHERINE.SMITH)	Document Control Technician I	18 Apr 2023, 05:08:41 PM	Approved

Originator and Peer Review Collaboration Workspace

Name/Signature	Title	Date	Meaning/Reason
James Piper (JAMES.PIPER)	Director, Laboratory Testing	19 Apr 2023, 11:46:53 AM	Complete & Quit
Krista Rehrig (KRISTA.REHRIG)	Laboratory Manager	19 Apr 2023, 12:03:21 PM	Complete & Quit
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	19 Apr 2023, 12:08:34 PM	Complete

Departmental Approval

Name/Signature	Title	Date	Meaning/Reason
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	19 Apr 2023, 02:53:54 PM	Approved

Author Approval

Name/Signature	Title	Date	Meaning/Reason
Amy Yencho (AMY.YENCHO)	Vice President, Laboratory Services	19 Apr 2023, 02:53:37 PM	Approved

Quality Approval

Name/Signature	Title	Date	Meaning/Reason
Carissa Albert (CARISSA.ALBERT)	Associate Director of Quality	20 Apr 2023, 07:46:34 AM	Approved

Set Date

Name/Signature	Title	Date	Meaning/Reason
Meghan Skeehan (MEGHAN.SKEEHAN)	Document Control Technician II	20 Apr 2023, 09:07:39 AM	Approved