Reference Method: **Preparation of Buffer A and Buffer B using 2 M TEAA - SOPU-058 rev 2**

1.0 Purpose

The purpose of this standard operating procedure is to describe the preparation of HPLC Buffer A and Buffer B from 2 M Triethylammonium Acetate.

2.0 Scope

This scope of this procedure is limited to the Irvington Manufacturing facility.

3.0 Responsibility

It is the responsibility of the QC and Liquid Production Group to carry out this procedure as described.

4.0 Health and Safety

Wear appropriate laboratory attire and PPE. Acetonitrile should be used in a chemical fume hood.

5.0 Materials and Equipment

5.1 2 M TEAA (553300)
5.2 Acetonitrile, HPLC grade
5.3 50 mL class A volumetric pipette
5.4 250, 1000 mL class A volumetric flasks
5.5 18.2 MΩ water, HPLC grade
5.6 1 L amber bottle for HPLC

6.0 Procedure

6.1 Preparation of Buffer A – 0.1 M TEAA in solution

6.1.1 Using the 50 mL volumetric pipette, deliver 50 mL TEAA into a clean 1 L volumetric flask, add 900 mL HPLC grade water to the flask.

6.1.2 Cover with parafilm and invert several times to mix.

6.1.3 Bring to 1 L final volume with HPLC grade water. Cover with parafilm and mix well by inversion.

6.1.4 Transfer the Buffer A to 1 L amber bottle. Mix well.

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6.2 Preparation of Buffer B – 0.1 M TEAA in 25% MeCN

6.2.1 Using a 50 mL class A volumetric pipette, deliver 50 mL TEAA into a clean 1 L volumetric flask, add 500 mL HPLC grade water to the flask.

6.2.2 Using a 250 mL class A volumetric flask, fill to mark with HPLC grade acetonitrile. Carefully transfer to the 1 L flask.

6.2.3 Bring volume to approximately 950 mL HPLC grade water. Cover with parafilm and invert several times to mix. Allow to settle.

6.2.4 Bring to final volume of 1 L with HPLC grade water, cover with parafilm and invert several times to mix.

6.2.5 Place solution 1 L amber bottle. Mix well.

TGHowe — Signature

25 MAY 2022 — Date

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