

## Appendix 2: Example – Proficiency Samples

### I. Proficiency Training Samples for new hires:

The following is designed to show proficiency in 7 technologies commonly used in drug analysis. An analyst should demonstrate the ability to successfully analyze these as a minimum requirement.

Each analyst will complete the following tests to demonstrate proficiency for each of the techniques outlined below with the identified sample.

1. **Acetaminophen API** – ID by FT-IR & TLC, ID/Assay by UV/Vis, and Water (Karl Fischer Titration). (Item 1, Part II Training Samples below for specific information)
2. **Acetaminophen & Caffeine Tablets** – Assay by HPLC and Dissolution with HPLC detection. (Item 4, Part II Training Samples below for specific information. Quantify for both acetaminophen & caffeine.
3. **Saccharin** – Assay by Titration. (Item 7, Part II Training Samples below for specific information)
4. **Glycerin** – Organic Impurities by GC (Item 10, Part II Training Samples below for specific information).

#### Technology, Product and Method

Test Technology	Examples of Product Used	Test Method
<b>Spectroscopy</b>		
FTIR	Acetaminophen (API)	USP (Identification) USP <197K>
UV-Vis	Acetaminophen (API)	USP (Assay) USP <197U>
<b>Separation</b>		
HPLC	Acetaminophen & Caffeine Tablets	USP (Assay) USP <621>
GC	Glycerin (API)	USP (Organic Impurities Procedure 1: Related Compounds) USP <621>
TLC	Acetaminophen (API)	USP (Identification)
<b>Misc.</b>		
Titration	Saccharin (API)	NF (Assay) USP <541>
Water (Karl Fischer)	Acetaminophen (API)	USP (Water – Method 1) USP <921>
Dissolution	Acetaminophen & Caffeine Tablets	USP (Dissolution – App. 2) USP <711>

USP and NF ( ) refers to the Test in the Official Monographs for the listed product.

**II. Additional Proficiency Samples as needed:**

Additional proficiency samples may be added or substituted. The products need to include the above 'Test Type' and show proficiency in those techniques.