NQAC
Nestlé Quality Assurance Center
Dublin

USP PREPARATORY TESTING

HOW WOULD DETERMINE IF I SHOULD USE A USP METHOD FOR TESTING?

If your product contains complex active ingredients, for example dietary supplements and supplement ingredients, these can present challenges for microbiology methods due to antimicrobial action or competitive inhibition. In this case, USP methods are most appropriate and can be validated to demonstrate that the method can recover the organism of interest if it were present.

If your product is considered a conventional food or food ingredient, our other method options would be best suited to your sample.

WHY DOES PREPARATORY TESTING NEED TO BE PERFORMED?

The FDA requires that all product formulations undergo a preparatory or suitability test to ensure that the method can recover the target organism and provide accurate results for USP methods. This testing allows our laboratory to confirm that the sample is not inhibitory for the target organisms and reduces the likelihood of false negatives or method interference.

WHAT HAPPENS WHEN PREPARATORY TESTING IS NEEDED?

Our laboratory will perform the preparatory testing starting at a 1:10 dilution and can be plated up to a 1:100 dilution to confirm the proper dilution for testing for quantitative methods. Qualitative methods will start at the 1:10 dilution and can be performed up to the 1:500 dilution.

To help with this process, please provide your product specification or requirements prior to testing so that the laboratory can set testing up at the correct dilution. Certain ingredients, such

Turnaround Time	Sample Weight Required
10 calendar days per dilution (dilutions can be run in tandem)	150 g

NOTE: Charges will apply per dilution plated and will be assessed even if the material fails testing at a 1:100 dilution.

HOW DOES NQAC DUBLIN TRACK WHICH SAMPLES HAVE UNDERGONE PREPARATORY TESTING?

NQAC Dublin maintains databases for USP methods and our other method options. Once the preparatory testing is completed, you will be notified of the lowest dilution that the product will be tested at via email. For future submissions of the same material, our team will reference the appropriate database and proceed at the approved dilution.

WHAT INFORMATION IS NEEDED WHEN SUBMITTING A SAMPLE?

To ensure that redundant preparatory testing is not completed, please include the following information on your sample submission so the sample registration team can pull up your information.

1. Full product name
2. Unique Identifier (product SKU, SAP number, etc.)
3. Preparatory results from previous submissions (if applicable)

NOTE: if a sample is sent in under different description/unique identifier the preparatory testing will be repeated. Please keep the descriptions/unique identifiers consistent to prevent this from occurring.