

This form details the Test and Control (when applicable) Article Characterization Definitions which will assist you in entering the proper information under the Test and Control Article Strength, Purity, and Composition sections of NAMSA's GLP Sample Submission form(s). If you have any questions, please contact a NAMSA Client Care Specialist at 419.666.9455 or email info@namsa.com.

Test and Control Article Characterization Definitions

The sponsor assures the test and control (when applicable) articles have been characterized for identity, strength, purity, and composition as required by FDA Good Laboratory Practice Regulations of 21 CFR Part 58.105. Stability testing is the responsibility of the sponsor and is subject to FDA audit.

The information you provide to NAMSA should be detailed enough to meet the requirements of 21 CFR 58.105(a). This information is necessary in order to allow test(s) to be performed. The information provided by the Sponsor needs to provide the NAMSA Study Director details regarding the composition of the test and control (when applicable) articles which will ensure that testing is conducted properly according to the GLP regulations. A thorough description of the test and control articles is required in the final report.

Batch/Code/Lot ID provides a unique means of identification for relating a specific test or control article with a specified production and/or manufacturing run or process. This information allows identification of a specific test or control article with specified testing.

Physical Description provides information as to what a test or control article looks like, ie, its visual appearance.

Stability is the property of a test or control article to remain in the same state without degrading or losing its effectiveness. Shelf life is a common stability test.

Mixture analysis is required for test or control articles that are mixed with carriers or solvents. Analysis is required by the FDA to demonstrate proper concentration, homogeneity, and stability. If the test or control article does not need to be mixed with a carrier or solvent in order to be used, analysis is not necessary.

Strength is the concentration or amount of active ingredients in the device. If there is no active ingredient, this will not apply (check the second box).

Purity is typically described as the percentage of a specific material, chemical component, or active pharmaceutical ingredient with respect to impurities. Impurities can arise during the manufacture, storage, and/or handling of the specified material. When a test or control article consists of more than one material or component (eg, multi-component device), purity may not be applicable (check the second box).

Composition is the list of ingredients or materials used to make up the test or control article.