- Sensitive/labile products (light, temperature, time, oxygen, moisture).
- Mixtures prone to segregation/separation.

b) **Number of Samples, Sample Size and Population**: Samples should be representative of the population. Some materials may not homogenous due to segregation that occurs during transport, or handling; variability occurring during the manufacturing process; and a variety of other factors that might impact a representative sample. Samples or sampling plans are often based on statistical criteria and the use of an appropriate statistically-based sampling plan can be important to ensure the sample is representative of the population. Each sampling plan should be developed to consider the specific attributes being measured and the risks associated with accepting a defective lot.

- Samples should relate to evaluation of critical quality attributes and the critical process parameters.
- Use sampling plans designed to obtain a representative sample from the product being evaluated or cite reference to an established sampling plan (e.g. site procedure, or ANSI/ASQ standards for inspection of attributes in packaging validation for example).
- Ensure that an adequate amount of sample is available to complete all tests. The number of tests per sample should be determined in consultation with the laboratory performing the testing and specified in the sampling plan or protocol. One test per sample may be preferable when sample material is inexpensive or there is a risk of cross-contamination when performing multiple tests on the same sample.
- Collect sufficient reserve sample, when possible, (e.g. >2x normal amount) to support potential investigation, except for sterility testing.

c) **Sample collection, handling, and identification**: Proper sample collection, handling and identification are vital to the success of the validation and the guidance provided by Sampling of Production Materials and Finished Goods should be followed.