Summary - Process Validation Sampling for Non-Sterile Solid Dose Drug Products

This guidance provides Process Validation Sampling guidelines for non-sterile solid dose drug product dosage forms.

There are many concerns regarding blend uniformity sampling, for example:

- Inappropriate sample thief technology;
- Powder segregation of samples may occur after sampling;
- Difficulty in proving that the blender sample plan will be representative of worst-case locations;
- Segregation of blend that can occur during discharge, storage, and transport prior to final processing.

Solid dosage forms typically provide many opportunities for applying appropriate and scientifically sound sampling approaches.

A approach to demonstrating blend uniformity by combining blend testing with in-process dosage unit compendial testing. This approach postulates that the analysis of finished tablets/capsules can support or provide statistical evidence that a failing blend result was due to poor sampling or handling technique.

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