Title: Sampling Plan for Microbial Testing of Natural Origin Products

Author/s: Ensoy-Musoro, Chellafe

Affiliation: Manufacturing and Applied Statistics, Johnson & Johnson Innovative Medicine, Beerse, Belgium

Chellafe Ensoy-Musoro joined the manufacturing and applied statistics unit of Janssen Pharmaceutica in 2021. Before her current role, she served as a postdoctoral fellow in statistics at Hasselt University, Belgium specializing in analysis of spatio-temporal data and clustered data of non-Gaussian type.

Abstract

In the pharmaceutical industry, natural origin products (such as pre-gelatinized starch, cellulose, etc.) can be commonly used as excipients in tablet production. When a shipment of this natural origin product is received by a manufacturing site, microbial testing of this product before formal acceptance/use is done based on a set of guidelines (e.g. WHO Technical Report Series TRS 929 – Annex 4).

The current sampling plan under consideration is based on the WHO n-plan wherein samples are combined into one composite sample for microbial testing. However, in the case of sampling a large number of bags (e.g. >10), mixing the samples into one composite sample increases the risk of dilution and not being able to correctly detect the presence of microbial contamination (measured in colony-forming unit per gram (CFU/g)).

We present a case study where we assess the performance of the current sampling plan on the data coming from microbial testing of pre-gelatinized starch, commonly used as a binder. A simulation study evaluating the effectiveness of composite sampling for microbial testing is also presented. A recommendation on the sampling plan for microbial testing of natural origin product based on levels of consumer's and producer's risks is provided.

Keywords: microbial test, count data, sampling plan, composite sampling

References:

- TRS 929 - Annex 4: WHO guidelines for sampling of pharmaceutical products and related materials. WHO Technical Report Series, No.929, 2005.
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