

## WHO Prequalification of Vector Control Products

# Number of batches required for testing of physical/chemical properties

## PURPOSE

Quality assessment of each product is primarily intended to ensure that the product is fully defined and that there are robust supporting data for the validation of physical/chemical parameters of the product. This information becomes the baseline for defining what the product is intended to be, and enables the analysis of potential impacts of future changes to the product. It also serves as baseline information for investigating any complaints about the product, including out of specification findings.

This document describes the expected number of batches and replicates to be analyzed in the generation of supporting data for Module 3: Quality.

This information is applicable to all submissions to WHO for the purpose of prequalification assessment of vector control products.

## ADVICE

The purpose of these data requirements is to ensure that inter and intra batch variability can be analyzed.

An applicant of a new vector control product application must include an analysis of a minimum of three batches in the supporting GLP complaint studies to ensure sufficient physical/chemical data are provided. A minimum of five replicates from each batch must be tested.

It is important to ensure that sampling is representative of the batch, capturing the characteristics of the complete batch, meaning that samples should be taken from different points across the production of the batch, rather than all from one part of the batch production.

## EXCEPTIONS TO ADVICE

The manufacturing process for formulations which are designed to have a slow or controlled release of active ingredient – independent from the manner/equipment by which it is applied – can have a significant impact on the intended release characteristics of the product(s). For the formulations listed below, a minimum of five batches, with five replicates per batch, is required to adequately analyze the inter/intra batch variability and potential variations in release rates over time.

- Capsule suspension (includes any mixed formulations with a capsule suspension formulation component)
- [Insecticide-treated nets \(ITN\)\\*](#)
- Slow release granules (GR)
- Matrix release (MR)
- Vapour releasing product (VP)
- Vaporizing mats (MV)

\* For ITNs, please refer to the current [WHO guideline for prequalification assessment of ITNs and the relevant implementation guidance documents](#)