

Declaration of product sampling

1. Introduction

As part of Module 3, the applicant must submit information about the sampling plan used for generation of physical/chemical characterization data for submission in the prequalification dossier and for validation of product quality when released (quality control [QC] testing of attributes in the manufacturing release specifications).

Given that spatial emanators may include a variety of different product designs, this sampling guidance is presented in a wide manner for covering as many potential product designs as possible. It is important that applicants provide information and schematics (if applicable) to justify the tested samples as representative of their specific product. If the construction or specific characteristics of the product dictate that an augmented approach be proposed, the proposed sampling scheme should be justified and may be submitted as part of a PQ200 (Protocol Review) application for further guidance.

2. Guidance for submission of the sampling plan used for generation of premarket data

Manufacturers should declare the sampling plan used for the physical/chemical tests required in Module 3 (and submit a figure or set of figures, if applicable).

Samples for use in pre-market studies (especially phys/chem characterisation) should capture the characteristics of the complete batch, meaning that they should be taken from different points across the production of the batch, rather than all from one part of the batch production.

The sampling procedure for generating premarket data is dependent upon the study and the product.

Samples must be of the appropriate size to conduct the tests as described in the guidance documents and established methods.

For each of the required physical/chemical tests characterizing the product, a minimum of five batches with five replicates per batch is required to adequately analyse the inter/intra batch variability and potential variations. In general, for the variety of spatial emanator products, a replicate (or sample) is a unit product.

3. Guidance for submission of the sampling plan used for the manufacturing release specifications

Manufacturers should declare the sampling plan used for the QC testing of attributes in the manufacturing release specifications (and submit a figure or set of figures, if applicable).

Normally, the sampling plan used for the QC testing of attributes in the manufacturing release specifications should be the same as the sampling plan used for generation of premarket data. Manufacturers should provide justification and explanation if this is not the case.

- [WHO PQT/VCP Implementation guidance – Module 3. Data requirements table](#)
- [WHO PQT/VCP Implementation guidance – Declaration of Product Formulation \(DPF\) for spatial emanators](#)
- [WHO PQT/VCP Implementation guidance – DPF for spatial emanators – Template](#)
- [WHO PQT/VCP Implementation guidance – Storage stability](#)
- [WHO PQT/VCP Implementation guidance – Manufacturing release specifications](#)
- [WHO PQT/VCP Manufacturing release specifications – Template](#)
- [WHO PQT/VCP Implementation guidance – Product manufacturing details - spatial emanators](#)