WHO Prequalification of Vector Control Products

Manufacturing release specifications for ITNs

1. Introduction

The applicant must submit proposed manufacturing release specifications for each ITN to be reviewed as part of the WHO Prequalification Assessment of Vector Control Products and maintained on file by WHO as a reference.

The primary purpose of the manufacturing release specifications is to ensure that key physical and chemical properties of commercial batches of an ITN are controlled to within ranges consistent with a reasonable expectation of acceptable efficacy and durability.

The proposed specifications should indicate the quality control (QC) tests to be performed to assess the quality of the product, the test methods to be used, and the limits to be applied.

> **IMPORTANT NOTE** – The manufacturing release specifications are distinct from the complete ITN product specifications, which include full characterization of the product based on the defined dossier and data requirements. In most cases, not all product specifications are necessary nor appropriate for quality control related product testing activities.

The manufacturing release specification is to be used for testing of commercial batches of the ITN for conformance, whether by the manufacturer of the ITN or by a contract laboratory, prior to release by the manufacturer. (Note - "Release" in this context means a formal process for certifying that the batch conforms to the specification and is suitable for supply to the customer. The batch may leave the manufacturing facility shortly after release or it may be stored by the manufacturer for a period of time.) Member states, procurement agencies, or other organizations may rely on these same attributes, methods, values and tolerances for the purpose of pre- and post-shipment testing as required by their relevant policies.

2. Tests to be included in the specifications

Proposed manufacturing release specifications should include, at a minimum, attributes/tests for: appearance/description, content and wash resistance index for each AI/synergist, content of any relevant impurities, fabric weight, netting mesh size, and bursting strength (fabric and seam).

Proposed manufacturing release specifications must include a figure with a supporting narrative description proposing a recommended sampling plan. This sampling plan should be used for product

testing in order to determine that the product is in compliance with the manufacturing release specifications for the relevant attributes. The Declaration of ITN Construction and Sampling Procedure and Declaration of ITN Construction and Sampling – Template provide guidance on presentation of sampling schemes.

3. Test methods

The proposed manufacturing release specifications should include references to documented methods for each test. These should be methods published in standard references such as ISO or the CIPAC Handbooks.

In some cases, "in-house" or other methods may be referenced. Justification must be provided for the selection of the method(s). The method(s) must be fully described in a separate document in the dossier, including supporting evidence of the method validation, and be permissible for publication as part of the WHO Public Assessment Report.

4. Setting of limits

Limits for tests relevant to the physical durability of the ITN, such as bursting strength, should be proposed and justified based on the available batch data characterization included in the product dossier.

Limits for tests relevant to entomological efficacy and the residuality of insecticidal activity, such as AI content and Wash Resistance Index, should be based on results for the batches used in the storage stability and semi-field studies initially, then either confirmed or amended when results for batches used in operational use studies are available.

IMPORTANT NOTE – Since some of the limits in the manufacturing release specifications will be based on the properties of the batches used in the semi-field and operational use studies, selecting the "best" batches for use in these studies may result in specifications that are difficult for commercial batches to meet. Manufacturers are encouraged to select batches that are representative of typical production for use in the Module 5 studies to ensure that realistic and achievable specifications can be set based on the properties of these batches. Inability of commercial batches to meet the requirements in the specification is not an acceptable justification for widening limits beyond what can be supported by results for the batches used in the Module 5 studies.

5. Related documents

- WHO PQT/VCP Implementation Guidance - Declaration of ITN Construction and Sampling Procedure
- WHO PQT/VCP Implementation Guidance - Declaration of ITN Construction and Sampling – Template
- WHO PQT/VCP Implementation guidance – Determination of wash resistance index for ITN fabric
- WHO PQT/VCP Implementation guidance – Determination of mesh size