

WHO Prequalification of Vector Control Products

Phys/Chem tests for ITNs: Verification of denier and tensile strength

1. Purpose

For each fabric used in the construction of a proposed ITN, the applicant must submit data to characterize its integral components, e.g. yarn.

The integral components of the fabric, e.g. yarn, contribute to the physical/chemical characteristics of the fabric and finished ITN. As part of the manufacturer's QMS governing the production of the product, special attention must be given to the integral components and the consistency of their characteristics. In cases where the manufacturer is responsible for the production of the integral components as part of the manufacturing process, appropriate controls and tests should be implemented to ensure consistency. Whereas in cases where the integral components are purchased from a third party, quality checks should be included for verification prior to intake and use of the source materials.

In the generation of pre-market data for an ITN prequalification dossier, the applicant is required to include data on the denier and tensile strength of the yarns used in each fabric for at least three of the five batches which are fully characterized and used for further data generation.

2. Verification of denier

The reference method for verification of yarn denier is ISO 2060:1994 (1).

If yarns are extruded as part of the manufacturing process, representative data from 3 batches must be provided to characterize the denier of the yarn and inter-/intra-batch variability.

If yarns or pre-knitted fabric are purchased from a third party, supporting certificates of analysis must be provided validating the declared denier. The applicant must declare the quality criteria applied for acceptance of yarn/knitted fabric.

3. Tensile strength

The reference method for the determination of yarn tensile strength is ISO 2062:2009 (2) /ASTM D2256/D2256M-21 (3).

If yarns are extruded as part of the manufacturing process, representative data from 3 batches must be provided to characterize the tensile strength of the yarn and inter-/intra-batch variability.

If yarns or pre-knitted fabric are purchased from a third party, supporting certificates of analysis must be provided validating the tensile strength. The applicant must declare the related quality criteria applied for acceptance of yarn/knitted fabric.

4. Related documents

- WHO PQT/VCP Implementation Guidance - Data Requirements Table – Module 3
- WHO PQT/VCP Declaration of product formulation for incorporated ITN fabric – Template
- WHO PQT/VCP Declaration of product formulation for incorporated ITN fabric – Example (Single AI)
- WHO PQT/VCP Declaration of product formulation for incorporated ITN fabric – Example (Dual AI)
- WHO PQT/VCP Declaration of product formulation for coated ITN fabric – Template
- WHO PQT/VCP Declaration of product formulation for coated ITN fabric – Example (Single AI)
- WHO PQT/VCP Implementation guidance – Product manufacturing details

5. References

When using the normative references for physical tests, the updated version of the standard should always be used when available.

1. International Organization for Standardization. ISO 2060:1994. *Textiles - Yarn from packages - Determination of linear density (mass per unit length) by the skein method*. Geneva: ISO; 1994.
2. International Organization for Standardization. ISO 2062:2009. *Textiles - Yarns from packages - Determination of single-end breaking force and elongation at break using constant rate of extension (CRE) tester*. Geneva: ISO; 2009.
3. ASTM International. ASTM D2256/D2256M-21. *Standard test method for tensile properties of yarns by the single-strand method*. Pennsylvania: ASTM; 2008.