

WHO Prequalification of Vector Control Products

Declaration of ITN construction and sampling

1. Introduction

As part of Module 3, the applicant must submit information about the construction of the insecticide-treated net (ITN) and the sampling plan used for generation of physical/chemical characterization data for submission in the prequalification dossier.

The declaration of ITN construction is needed to clearly convey the intended integration of the same or different fabrics in the finished ITN in order for WHO to appropriately assess the proposed product.

Additionally, it is critical that applicants provide information and schematics to justify the tested samples as representative of the fabric/product.

This document is intended to provide guidance on:

- information to include in the declaration of ITN construction;
- considerations for sampling from constructed ITNs for physical/chemical characterization testing (pre-market); and,
- presentation of the declared sampling plan used for generation of physical/chemical characterization data (pre-market).

It is recommended to follow this guidance for traditional shapes and constructions of ITNs. 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 submitting the declaration of ITN construction

The intended construction of the ITN, including all fabrics used, must be declared.

For each fabric used in the constructed product, an image must be provided indicating the wale-wise and course-wise directionality of the yarns in the fabric.

Figures with supporting descriptions must be provided for each intended shape of the constructed ITN. If there is an intent to interchange fabrics within the construction, separate figures and descriptions must be provided for each possible construction.

All shapes of the construction (e.g. rectangular and/or conical) and available dimensions must be listed.

3. Considerations for sampling for pre-market physical/chemical characterization studies

The sampling procedure for generating pre-market data for ITNs is dependent on the fabric design and construction of the ITN, including the presence of multiple fabrics in the ITN construction. It must ensure that all fabrics in the ITN are adequately represented. The number of samples required is dependent upon the study and the product.

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.

Samples must be of the appropriate size to conduct the tests as described in the guidance documents and established methods. Enlarged swatches may be cut and then sub-divided to support sample preparation for multiple studies/tests.

Except where seams are to be tested, do not cut samples within 10 cm of seams or selvages. Where a final product is made from more than one fabric, each fabric must be sampled and tested separately.

Use sharp scissors, or equivalent, to minimize damage to the fibres and fabric and thus avoid any consequential bias in the results of certain tests. Ensure that the material is not being stretched nor compressed when cutting the samples.

For each of the required physical/chemical tests, information on the method, sampling and number of samples has been compiled in Table 1.

Table 1. Summary of sampling for physical/chemical characterization studies for ITNs required for the data generation of Module 3 dossier.

Attribute	Sample size (area)	Method	Guidance on sampling plan	Number of samples	Notes
Active ingredient content/ isomer ratio and synergist content. Relevant impurities content	The size of samples (e.g. 25 × 25 cm) should be selected to comply with the selected method for AI quantification and to provide results with a relative standard deviation (RSD) ≤ 5% or as applicable in justifiable cases.	The analytical method should be selected based on the active ingredient and applicable validated method. Method(s) of analysis must be CIPAC, AOAC or equivalent. Where methods have not yet been published, full details and appropriate method validation	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	Roll and place cut samples in labelled, new, clean aluminium foil prior to analysis. Samples should be kept cool, avoiding heat sources (including direct sunlight) or freezing, and analysed/tested with minimum delay. Representative portions (sub-samples) for testing

Attribute	Sample size (area)	Method	Guidance on sampling plan	Number of samples	Notes
		data must be submitted.			should be taken as described in each test method (1). Isomer ratio should be measured and reported where the active ingredient is defined as a particular isomer ratio or in situations where isomerization of the AI leads to an inactive form (1).
Wash resistance index (WRI)	25 × 25 cm pieces (as per CIPAC MT 195 (2))	IG – Wash Resistance Index Test for ITN Fabrics CIPAC MT 195 (2)	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	See IG – Wash Resistance Index Test for ITN Fabrics
Fabric weight	See Method	ISO 3801 (3)/ EN 12127(4)	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	
Mesh size	Appropriate template size depends on each fabric	IG – Determination of mesh size	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	2 samples per fabric of the ITN x 2 ITNs per batch x 5 batches	See IG – Determination of mesh size
Dimensional stability to washing	Size of test portions: 500 mm x 500 mm; mark off 350 mm x 350 mm within each test portion.	ISO 6330: 2021 (5)	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	2 sample per fabric of the ITN x 2 ITNs per batch x 5 batches	Method of preparation, marking and measuring: ISO 3759 (6). Method of washing: ISO 6330 (5). Method of calculation: ISO 5077 (7). Test a total of 1 piece x net x 4 ITNs, 2 washed in each of 2 separate loads. Type of washing machine: ISO type A (front loading). Washing programme: 30°C

Attribute	Sample size (area)	Method	Guidance on sampling plan	Number of samples	Notes
					Mild programme. Fill the washer with fabrics and ballast Type III (polyester ballast) up to 2 kg (according to the ISO 6330 standard (5)). Drying: flat drying (1).
Bursting strength	tests of 7.3 cm ² areas of fabric	ISO 13938 part 2: 2019 (8) with conditioning of the fabric as specified in the ISO standard	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	2 samples per fabric of the ITN x 2 ITNs per batch x 5 batches	
Bursting strength – seam	tests of 7.3 cm ² areas of fabric	ISO 13938 part 2: 2019 (8) with conditioning of the fabric as specified in the ISO standard	Samples should be taken in a manner which allows for the seam to be centred on the test head.	For homogeneous ITNs: 2 samples per ITN x 2 ITNs per batch x 5 batches Sample 1: side-side Sample 2: side-roof For mosaic ITNs: 3 samples per ITN x 2 ITNs per batch x 5 batches Sample 1: side-side Sample 2: side-roof Sample 3: side-roof	
Flammability	See Method	EN 1102 (9), using the surface ignition method (position the burner perpendicular to the surface of the sample)	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material.	1 sample per fabric of the ITN x 1 ITNs per batch x 5 batches	See IG - Flammability
Abrasion resistance	The test sample is a circle of at least 140 mm in diameter	IG – Abrasion resistance	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material. When taking the samples for testing it is important to ensure	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	See IG – Abrasion resistance

Attribute	Sample size (area)	Method	Guidance on sampling plan	Number of samples	Notes
			that they do not share wale yarns.		
Snag strength	Samples measure 120 X 100 mm (L x W)	IG –Snag strength	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material. When taking the samples for testing it is important to ensure that they do not share wale yarns.	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	See IG –Snag strength
Resistance to hole formation	The fabric test area is a circular sample of at least 140 mm in diameter. Typically, a square of 200 X 200 mm is utilized for testing	IG -Resistance to hole formation	Samples should be taken for each fabric according to Fig. 1 or on a convenient diagonal across the width of the material. When taking the samples for testing it is important to ensure that they do not share wale yarns.	3 samples per fabric of the ITN x 4 ITNs per batch x 5 batches	See IG -Resistance to hole formation
Accelerated and real time storage stability	See Method	IG – Storage stability CIPAC MT 46.4 (10)	The sampling plan should be the same for samples taken before and after the storage stability test for the physical/chemical properties analyzed. Samples of the formulation taken before and after the accelerated storage stability test may be analysed concurrently after the test in order to reduce the analytical error.	“n” samples per fabric x 1 ITN per sampling time point x 3 batches “n” refers to the appropriate number of samples to perform the parameter test to be able to assess the results for the parameter separately for each batch. For example, for the mean AI content parameter: <ul style="list-style-type: none"> • For accelerated storage stability: 	See IG – Storage stability

Attribute	Sample size (area)	Method	Guidance on sampling plan	Number of samples	Notes
				1 sample per fabric x 1 ITN x 3 batches <ul style="list-style-type: none"> For real time storage stability: 1 sample per fabric x (1 ITN per sampling time point) x 3 batches For example, for the Wash resistance index parameter (to be able to obtain t_0 from the 'initial washed' samples and t_4 from the '4 x washed' samples), a minimum of 2 samples per fabric is required: <ul style="list-style-type: none"> For accelerated storage stability: 2 samples per fabric x 1 ITN x 3 batches For real time storage stability: 2 samples per fabric x (1 ITN per sampling time point) x 3 batches 	

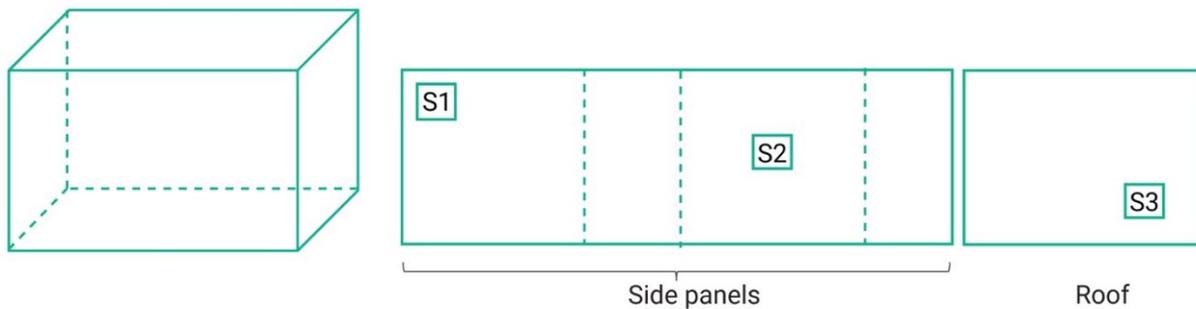
Fig. 1 shows an example of ITN sampling schemes for physical/chemical characterization studies for ITNs (homogeneous ITN and a mosaic ITN constructed from two fabric types). The position of samples should be measured from the left hand and top seams of each panel.

Fig. 1. Recommended positions from which 3 pieces of netting (for the case of a homogeneous ITN) and 6 pieces of netting (for the case of a mosaic ITN constructed from two fabric types) should be taken from a finished ITN to perform the physical/chemical characterization studies (shown in Table 1). In the case of any other net construction, an appropriate sampling plan must be developed to adequately represent the fabrics. For the studies which require 3 samples, S1, S2, S3 should be used. For studies that require 2 samples, S1, S3 should be used. For studies that require 1 sample, S2 should be used.

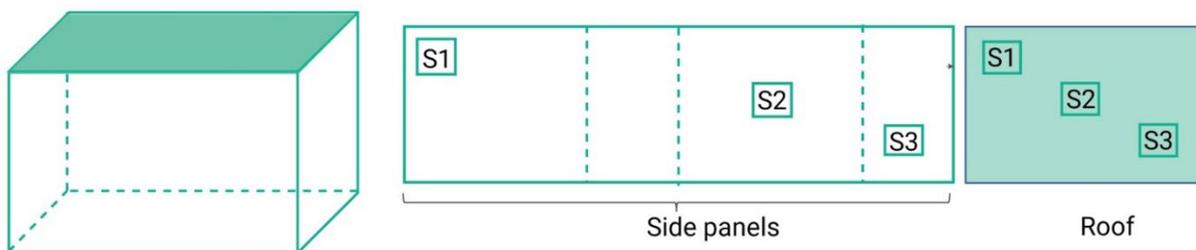
Example ITN sampling schemes for physical/chemical characterization studies for ITNs

Fabric samples are cut from ITNs in defined positions to capture fabric variability. Each fabric type in the constructed ITN must be sampled and tested separately.

A Rectangular ITN constructed from one fabric type



B Mosaic ITN constructed from two fabric types



4. Guidance for submission of the sampling plan used for generation of pre-market data

Manufacturers should submit a figure or set of figures, which conveys the sampling plan used for the physical/chemical tests required in Module 3.

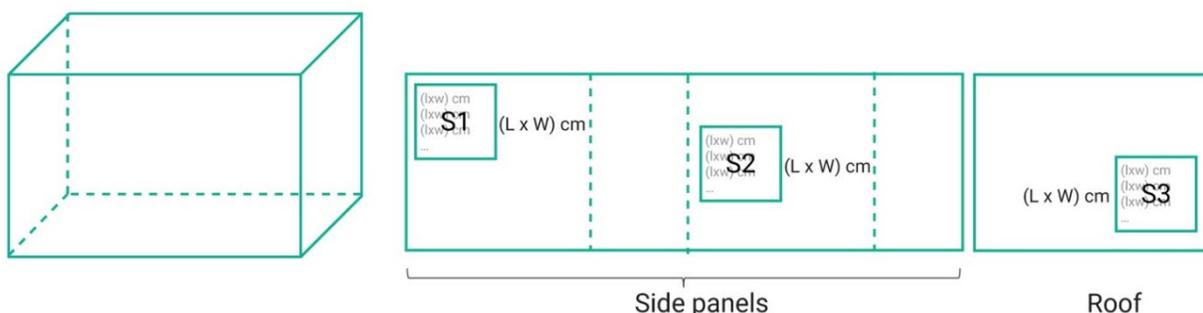
The figure should consist of a schematic of the location of sampling for each of the tests represented through a single ITN (e.g. see Fig. 2). A [template](#) in .pptx format has been developed to support preparation and submission of this information.

Manufacturers may want to optimize the sampling procedure by combining sampling plans for different studies (e.g. in order to reduce the number of finished nets produced for data generation). However, in doing so, the manufacturer should show that their optimized sampling procedure does not impact the intention of the study and required representation of sampling across ITN units and batches.

Fig. 2. Example guiding how a figure representing the sampling plan used for the attributes/tests required in Module 3 might be submitted.

Example ITN sampling schemes for physical/chemical characterization studies for ITNs for Product “X”
Fabric samples are cut from ITNs in positions “X”, “Y”, “Z” to capture fabric variability.

A Rectangular ITN constructed from one fabric type



Attributes/tests performed in S1:	Attributes/tests performed in S2:	Attributes/tests performed in S3:
AI content (lxw) cm	AI content (lxw) cm	AI content (lxw) cm
WRI (lxw) cm	WRI (lxw) cm	WRI (lxw) cm
Fabric weight (lxw) cm	Fabric weight (lxw) cm	Fabric weight (lxw) cm
Mesh size (lxw) cm	Flammability (lxw) cm	Mesh size (lxw) cm
Dimensional stability (lxw) cm	Abrasion (lxw) cm	Dimensional stability (lxw) cm
Bursting strength (lxw) cm	Snag strength (lxw) cm	Bursting strength (lxw) cm
Abrasion (lxw) cm	Resistance to hole formation (lxw) cm	Abrasion (lxw) cm
Snag strength (lxw) cm		Snag strength (lxw) cm
Resistance to hole formation (lxw) cm		Resistance to hole formation (lxw) cm

5. 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).

The figure should consist of a schematic of the location of sampling for each of the tests represented through a single ITN (e.g. see Fig. 2). A [template](#) in .pptx format has been developed to support preparation and submission of this information.

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.

6. Related documents

- WHO PQT/VCP Implementation Guidance - Declaration of ITN construction and sampling - Template
- WHO PQT/VCP Implementation Guidance - Data Requirements Table – Module 3
- WHO PQT/VCP Implementation guidance – Declaration of product formulation (DPF) for ITN Fabric
- 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 - IG – Wash Resistance Index Test for ITN Fabrics
- WHO PQT/VCP Implementation Guidance - IG – Determination of Mesh Size
- WHO PQT/VCP Implementation Guidance - IG – Flammability
- WHO PQT/VCP Implementation Guidance - IG – Abrasion
- WHO PQT/VCP Implementation Guidance - IG – Resistance to hole formation
- WHO PQT/VCP Implementation Guidance - IG – Snag strength
- WHO PQT/VCP Implementation Guidance - IG – Storage stability
- WHO PQT/VCP Implementation Guidance - IG – Manufacturing release specifications
- WHO PQT/VCP Implementation Guidance - IG – Product Manufacturing Details ITNs
- Physical testing requirements for ITNs: Accreditation and compliance with international standards for the generation of data intended to be submitted to WHO prequalification

7. References

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

1. Manual on the development and use of FAO and WHO specifications for chemical pesticides – Second edition. Rome: Food and Agriculture Organization of the United Nations and Geneva: World Health Organization; 2022 (<https://iris.who.int/bitstream/handle/10665/373945/9789240049093-eng.pdf>, accessed 13 December 2023).
2. Pigeon O, Müller M, Kozuki Y, Rodler M. CIPAC method MT 195, wash resistance index of LNs. In: CIPAC Handbook O. Budapest: Collaborative International Pesticides Analytical Council Ltd; 2017:205.
3. International Organization for Standardization. ISO 3801:1977. *Textiles - Woven fabrics - Determination of mass per unit length and mass per unit area*. Geneva: ISO; 1977.
4. German Institute for Standardization. DIN EN 12127:1997. *Textiles - Fabrics - Determination of mass per unit area using small samples*. Berlin: DIN; 1997.
5. International Organization for Standardization. ISO 6330:2021. *Textiles - Domestic washing and drying procedures for textile testing*. Geneva: ISO; 2021.
6. International Organization for Standardization. ISO 3759:2011. *Textiles - Preparation, marking and measuring of fabric specimens and garments in tests for determination of dimensional change*. Geneva: ISO; 2011.
7. International Organization for Standardization. ISO 5077:2007. *Textiles - Determination of dimensional change in washing and drying*. Geneva: ISO; 2007.
8. International Organization for Standardization. ISO 13938-2:2019. *Textiles - Bursting properties of fabrics - Part 2: Pneumatic method for determination of bursting strength and bursting distension*. Geneva: ISO; 2019.
9. British Standards Institution. BS EN 1102:2016. *Textiles and textile products. Burning behaviour. Curtains and drapes. Detailed procedure to determine the flame spread of vertically oriented specimens*. London: BSI group; 2016.
10. Pigeon O, Müller M, Kozuki Y. CIPAC method MT 46.4, accelerated storage procedure for LN formulations. In: CIPAC Handbook P. Budapest: Collaborative International Pesticides Analytical Council Ltd; 2017.

8. Bibliography

- International Organization for Standardization. ISO 139:2005. *Textiles – Standard atmospheres for conditioning and testing*. Geneva: ISO; 2005.