WHO PQT/VCP Implementation Guidance –

Data Requirements Table – Module 3

DR Code	Requirement	Description/Notes	Method[1]/ Reference	Form/ Template	Number of Batches to test
3.1	Declaration of Product Formulation	The complete product composition and purpose of all formulants in intermediates and finished fabrics.		Y	
3.2	Product Manufacturing Details	A key difference between the manufacturing details in Module 3 and the information required in Sites Master Files for Module 6 is that the description of manufacturing process defines all equipment, settings/ranges, speeds, temperatures which must be followed to produce the product as intended. The SMF and QMS are the system by which a manufacturer, ensures that the declared process is followed.			
3.2.1	Declaration of Manufacturing Sites (DMS)	Identification of the manufacturing sites where source AIs are produced and the manufacturing sites (including their function(s)) for production and storage of the end-use products prior to release.		Y	
3.2.2	Control of Starting Materials	Presentation of the acceptance criteria for use of starting materials in the formulation of the product			
3.2.3	Batch Delineation and Formula	Presentation of how batches are defined/delineated for the product/fabric and a formula with applicable volumes for a typical batch			
3.2.4	Description of Manufacturing Process (DMP)	Complete narrative of the manufacturing process including the necessary equipment/settings to produce the product as intended			
3.3	Declaration of ITN Construction and Sampling Procedure	Declare the product construction including sizes and shapes and establish defined sampling procedures which ensure appropriate representation of the fabric(s) which comprise ITN in its declared forms			

[1] Methods identified should be used for the generation of data. Additional and/or alternative methods may be proposed by applicants provided that complete description of the method and validation is included.

DR Code	Requirement	Description/Notes	Method[1]/ Reference	Form/ Template	Number of Batches to test
3.4	Chemical Characteristics - Fabric	The chemical characteristics of the treated fabric(s), and the integral components, using established sample preparation, analytical chemistry, and bioassay s methods for the purpose of assessing the following and informing product testing activities by procurers/users:			
3.4.1	Verification of the target dose, homogeneity of the treated fabric, and consistency of production	Chemical analysis of total AI, conducted in a manner to capture heterogeneity of fabric treatment. Includes identification of the enforcement analytical method.	Relevant CIPAC, AOAC or independently validated method		5
3.4.2	Determination of Regeneration time	The time required for the reestablishment of observable intended effect(s) of a washed fabric sample using an established bioassay method(s) and appropriate strain(s) of test organism(s).	IG - Regeneration Time Study for ITN Fabric		3
3.4.3	Determination and selection of appropriate wash interval for artificial aging	Applicable supporting analytical chemistry and/or bioassay data which characterizes the translocation of AI(s) over time and analysis to justify the selection of a wash interval to be used in artificial aging of fabric/product samples.	IG – Selection of Wash Interval		
3.4.4	Determination of Wash resistance - Chemical and Bioefficacy	Analytical chemistry and bioassay data generated on fabric samples over a series of washes using the selected wash interval. Pilot under consideration for characterization of the physical presentation of AI(s) on the surface via imaging methods	IG – Wash Resistance Study for ITN Fabric		3
3.4.5	Determination of Wash Resistance Index (WRI)	WRI is based on a standardized method for sample preparation and chemical analysis to determine the rate of AI loss per wash from 0 to 4 washes.	IG – Determination of Wash Resistance Index for ITN Fabric CIPAC MT 195		5
3.5	Physical Characteristics				

DR Code	Requirement	Description/Notes	Method[1]/ Reference	Form/ Template	Number of Batches to test
3.5.1	Integral Components (e.g., yarn)				
3.5.1.1	Verification of denier	Supporting data to verify the declared yarn denier and determine the potential inter-/intra-batch variability	TBD		3
3.5.1.2	Tensile Strength	Determination of yarn tensile strength based on the declared formulation and manufacturing process.	TBD		3
3.5.1.3	Other representative attributes relevant to the integral component(s)	To be proposed by applicant as necessary			
3.5.2	Fabric				5
3.5.2.1	Description of fabric formation (e.g., knitting pattern)	Should include a narrative description and image(s) of the formed fabric			
3.5.2.2	Fabric Weight	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	ISO 3801 / EN 12127		
3.5.2.3	Mesh size	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	IG – Determination of Mesh Size		
3.5.2.4	Flammability	Verification of product being classified as "not flammable"	EN 1102		
3.5.2.5	Bursting Strength	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	EN ISO 13938 part 2: 2019		
3.5.2.6	Snag Strength	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.2.7	Abrasion	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.2.8	Resistance to hole formation	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.3	Constructed ITN				5
3.5.3.1	Bursting Strength - Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.3.2	Snag Strength - Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			

DR Code	Requirement	Description/Notes	Method[1]/ Reference	Form/ Template	Number of Batches to test
3.5.3.3	Abrasion - Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.3.4	Resistance to hole formation - Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.5.3.5	Dimension Stability to Washing	Supporting data to verify compliance with limits of shrinkage and expansion	EN ISO 6330: 2021		
3.5.3.6	Dimensional Stability to Compression packing	Supporting data to verify compliance with limits of shrinkage and expansion	TBD		
3.6	Storage Stability	Storage stability data should be generated using samples which have been subjected to accelerated storage conditions as well as real-time storage conditions. Data from real-time storage samples may be submitted post-prequalification	IG – Accelerated preparation of samples for use in storage stability studies		3 - Accelerated 3 - Real-time
3.6.1	Verification of the target dose	Chemical analysis of total AI, conducted in a manner to capture heterogeneity of fabric treatment. Includes identification of the enforcement analytical method.	Relevant CIPAC, AOAC or independently validated method		
3.6.2	Determination of Regeneration time	The time required for the reestablishment of observable intended effect(s) of a washed fabric sample using an established bioassay method(s) and appropriate strain(s) of test organism(s).	IG - Regeneration Time Study for ITN Fabric		
3.6.3	Determination of Wash resistance - Chemical and Bioefficacy	Analytical chemistry and bioassay data generated on fabric samples over a series of washes using the selected wash interval. Pilot under consideration for characterization of the physical presentation of AI(s) on the surface via imaging methods	IG – Wash Resistance Study for ITN Fabric		
3.6.4	Determination of Wash Resistance Index (WRI)	WRI is based on a standardized method for sample preparation and chemical analysis to determine the rate of AI loss per wash from 0 to 4 washes.	IG – Determination of Wash Resistance Index for ITN Fabric CIPAC MT 195		

DR Code	Requirement	Description/Notes	Method[1]/ Reference	Form/ Template	Number of Batches to test
3.6.5	Fabric Weight	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	ISO 3801 / EN 12127		
3.6.6	Mesh size	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	IG – Determination of Mesh Size		
3.6.7	Flammability	Verification of product being classified as "not flammable"	EN 1102		
3.6.8	Bursting Strength - Fabric and Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability	EN ISO 13938 part 2: 2019		
3.6.9	Snag Strength - Fabric and Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.6.10	Abrasion - Fabric and Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.6.11	Resistance to hole formation - Fabric and Seam	Supporting data to verify the declared value and determine the potential inter-/intra-batch variability			
3.7	Specifications	A set of QC tests relying on validated methods and established limits that the product needs to meet to be considered of acceptable quality			
3.7.1	Manufacturing release specifications	Proposed specifications including identification of the attributes, methods, values, tolerances and/or limits for use in validating product identity and quality at the time of manufacturer release.		Y	
3.7.2	Post-storage specifications	Proposed specifications including identification of the attributes, methods, values, tolerances and/or limits for use in validating product identity and quality for products which have been in storage.			
3.7.3	In-use specifications	Proposed specifications including identification of the attributes, methods, values, tolerances and/or limits for use in validating product identity and potential for continued use.			
3.8	Other Related Information	To be proposed by applicant as necessary			