WHO Prequalification of Vector Control Products

Module 3. Manufacturing release specifications template

Instructions when using this template:

* [text] means it is needed to introduce the related appropriate text and remove the [ ].
* (text) means the table/paragraph/text to which the () refers can be inserted or not as appropriate, depending on the product specifics.
* When submitting this data requirement for your product application, **please remove this first page of this IG document** and submit pages 2-6 which constitute the manufacturing release specifications document template

# Purpose

The purpose of this implementation guidance document template is to indicate the structure and nature of the manufacturing release specifications document to be presented in Module 3. Applicants can make use of this IG as a template to ensure that all required data for Module 3 manufacturing release specifications is submitted.

# Manufacturing release specifications

|  |  |
| --- | --- |
| Company | [Company name] |
| Product name | [Product name] |
| PQ ref # | [PQ Product Ref Number] (if not yet assigned, leave blank) |
| Version number | [Version number] Version numbers should be sequential. |
| Effective date | [Date of internal company approval] |

## Summary of manufacturing release specifications

|  |
| --- |
| Table 1. Summary of manufacturing release specifications for [ product name] |
| **Description**The material shall [Guidance on how to write the description of the product according to the formulation type can be found in the appropriate formulation type template: [Specification Templates for Proposers | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)](https://extranet.who.int/prequal/vector-control-products/specification-templates-proposers) ] |
| ID | Property | Method | Declared value  |
| [product name] sides (*insert/differentiate only if sides and roof are different fabrics*) |
| 1\* | Sampling Plan | See Appendix |  |
| 2\* | [AI name] content | [test method] | [value] g/kg ± [value]% |
| 3\* | (synergist, or second AI content) | [test method] | ([value] g/kg ± [value]%) |
| 4\* |  |  |  |
| 5\* |  |  |  |
| 6\* |  |  |  |
| 7\* |  |  |  |
| 8\* |  |  |  |
| 9\* |  |  |  |
| 10\* |  |  |  |
|  | [Add any relevant property, appropriate for QC testing]  |  |  |

\* Indicates that additional information is available in Appendix.

Manufacturers are expected to rely on the information above as part of a QC management plan and for validation of product quality when released. To the extent required, Certificates of Analysis to support the release of products should present results for the attributes identified in the above table.

## Storage

Accelerated storage stability data were generated as per [CIPAC MT 46.3]. Test samples were stored for [value] days at [value] °C. ([No significant differences were recorded among the properties of the product kept at ambient temperature and after accelerated storage stability test conditions.])

([Real time storage stability data were generated for [value] months using the following test conditions: (*Add real time storage stability data study conditions)*])

([Products should be stored and transported in appropriate conditions in accordance with the recommendations of the manufacturer. (*Add manufacturer recommended conditions supported by the real time storage stability study/other analyses performed, as appropriate)*])

Appendix. Manufacturing release specifications: methods and notes

[Guidance on how to write the methods and notes for the product according to the formulation type can be found in the appropriate formulation type template, in the notes section: [Specification Templates for Proposers | WHO - Prequalification of Medical Products (IVDs, Medicines, Vaccines and Immunization Devices, Vector Control)](https://extranet.who.int/prequal/vector-control-products/specification-templates-proposers). Please, customize any methods and notes text for your specific product characterization]

**Description**

* ([Add any notes regarding the description of the product ])

**Sampling Plan**

* ([Figure [value] applicable to Attributes [values] for which samples are to be taken from various parts of the constructed ITN. ])
* ([Figure [value] applicable to Attributes [values] for which samples are to be taken from various parts of the constructed ITN. ])

([Figure [value]:*(Insert Figure)* ])

([Figure [value]:*(Insert Figure)* ])

*(Add as many as needed)*

*(Modify the methods and notes in the sampling plan example text below, as per your* [*formulation type template text*](https://extranet.who.int/prequal/vector-control-products/specification-templates-proposers) *and product specifics)*

([Samples should be taken according to Figure [value]. Samples must be sufficiently large to conduct all tests required and representative of the net or netting. Except where seams are to be tested, do not test material within 10 cm of seams or selvedges. Where a final product is made from more than one type of netting, each type of netting should 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. Roll up the strips or squares and place them in labelled, new, clean aluminium foil prior to analysis. Samples should be kept cool, avoiding heat sources (including direct sunlight) or freezing, and analyzed/tested with minimum delay. Representative portions (sub-samples) for testing should be taken as described in each test method.

For the purposes of chemical analysis, the analytical method and the number and size of test portions analyzed should be designed to provide results with a relative standard deviation (RSD) ≤ 5% or as applicable in certain justifiable cases. Test portion and replication requirements for physical test methods are defined in the methods or Notes referenced. ])

**Attributes [2] and [3]: [AI name] and [synergist, or second AI] content**

*(Modify the methods and notes in the example text below, as per your*  [*formulation type template text*](https://extranet.who.int/prequal/vector-control-products/specification-templates-proposers)  *and product specifics)*

([The content of [AI name] and [synergist, or second AI] in the sample should be determined as per Adapted CIPAC MT XX. ])

**Attribute [value] : [Attribute name]**

*(Modify the methods and notes in the template examples, as per your formulation type and product specifics)*

([XXX ])

**Attribute [value] : [Attribute name]**

*(Modify the methods and notes in the template examples, as per your formulation type and product specifics)*

([XXX ])

([add as many as needed attributes’ product specific methods and notes])

Version tracking

| Version number | Effective dates | Reason for replacement |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |

*(Add rows to the table if required.)*