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 the documentation for this data requirement, **remove page 1 of this document** and submit pages 2–4, which constitute the manufacturing release specifications template.

# Purpose

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

# Manufacturing release specifications

|  |  |
| --- | --- |
| Company | [Company name] |
| Product name | [Product name] |
| PQ ref # | [PQ product ref #] (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 vapor-releasing product shall be formed from [material], (dosed) with a formula containing [technical AI] complying with the requirements of WHO specification [value]/TC (current version) ([and with technical AI/synergist complying with the requirements of WHO specification [value]/TC (current version)]) together with any necessary other formulants. [The product shall appear clean and shall be free from visible extraneous matter, visible damage (such as tearing) and visible manufacturing defects (such as an incomplete seal)]. The product shall be suitable for use as a spatial emanator. |
| ID | Property | Method | Declared value  |
| 1\* | Sampling plan | See Appendix |  |
| 2\* | [AI name] content | [test method] | [value] g ± [value]% |
| 3\* | [synergist or second AI] content | [test method] | [value] g/ ± [value]% |
|  | Add any other relevant property as per spatial emanators IG. |  |  |

\* Indicates that additional information is available in the appendix.

Manufacturers are expected to rely on the information above as part of a quality control 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 46.4]. 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)*]). ([No significant differences were recorded among the properties of the product kept at time point [baseline time point] and after [timepoint(s) 2, 3, etc.] storage at [temperature value(s)].)

([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

**Description**

* ([Dosed formulation may appear as a liquid, a crystallized solid or a combination of both on the mesh substrate.])

**Sampling Plan**

* Figure [value] applicable to Attributes [values].
* ([Testing should be completed using the full product. Sub-samples should not be taken as representative of the whole product.])

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

*(Add as many as needed.)*

*(Modify the methods and notes in the sampling plan example text below, as per your product specifics.)* ([Samples should be taken according to Figure [value]])

**Attributes [value]: [AI name] content**

*(Input the methods and notes details, as per your product specifics.)*

([The content of [AI name] should be declared as g/unit. The content of [AI name] should be determined as per [method]).

**Attributes [value]: synergist, or second AI content**

*(Input the methods and notes details, as per your product specifics.)*

([The content of [synergist or second AI] should be declared as g/unit. The content of [synergist or second AI] should be determined as per [method].)

**Attribute [value]:** (**[any other relevant property]**)

([Add product-specific methods and notes.])

Version tracking

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

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