WHO Prequalification of Vector Control Products

WHO Specifications vs Product Manufacturing Release Specifications

BACKGROUND

When considering specifications for pesticides within the roles of WHO PQT/VCP there are two distinct published outputs which need to be recognized. This document was prepared to respond to frequently asked questions about the differences between:

- **WHO specifications** developed through the processes of the Join Meeting on Pesticide Specifications (JMPS) in association with the UN Food and Agriculture Organization (FAO), and
- **manufacturing release specifications** proposed by applicants, reviewed through the prequalification assessment process and published in the prequalification WHO Public Assessment Reports (WHOPARS)

WHO Specifications

The WHO specifications, as well as FAO specifications, are a point of reference as an international standard for the quality of pesticides used in public health and agriculture. The specifications are developed and published for chemicals classified as active ingredients (AI) and/or synergists. The specifications are then presented for the manufacturing use materials (e.g. technical materials and technical concentrates) as well as for those formulation types in which end use products containing the compound may be manufactured. Specifications are developed based on applications from the legal manufacturers of the products. The specifications are published along with the supporting JMPS evaluation reports.

For end use formulations, the WHO specifications are intended to be generic, i.e. applicable to the AI and the end use formulation type(s) of relevance. The WHO specification may be viewed as a point of reference for quality of the AI/formulation type combination; however, the specification may be applicable to a diverse set of products/formulations with differing non-active formulants and concentrations of AI intended for a wide variety of potential uses.

Product manufacturing specifications

Manufacturing release specifications are product specific and reflect the declared and assessed physical/ chemical characteristics of the product. In comparison to a related WHO specification, the manufacturing release specification may have different attributes, values or tolerances based on the complete prequalification product assessment (quality, safety, efficacy).

Applicants are required to submit proposed manufacturing release specifications for review as part of the WHO Prequalification assessment of vector control products. The WHO PQT/VCP Template Manufacturing Release Specifications facilitates providing this information.

The information provided on this template and assessment of all supporting data will be used to publish the product manufacturing release specifications upon prequalification (WHO Public Assessment Report – WHOPAR Part 3-Quality). Not all physical/chemical characteristics of the product are necessary nor appropriate for inclusion in the manufacturing release specification and thereby quality control related product testing activities.

The complete summary of supporting physical and chemical characteristics based on testing from the required 3 to 5 batches is published in Section 1 of the WHOPAR Part 3-Quality.

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The purpose of the manufacturing release specifications is to present the values and tolerances for physical and chemical properties of the product which are relied upon as indicators for confirming the quality of commercially released batches. It is critical that the values and tolerances are established to reflect the data submitted supporting the prequalification assessment of the product. It may therefore occur that the product specific information presented in the manufacturing release specification differs from that in a related published WHO specifications for the same AI/formulation type combination. For the purposes of quality control testing in relation to the procurement of prequalified products, the manufacturing release specification should be utilized as the point of reference for confirmation of quality.

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

Submitting new VCPs for prequalification for which a WHO specification has not been established

In situations where a manufacturer is submitting a new VCP to WHO for prequalification assessment and a corresponding WHO specification has not been established, the manufacturer is requested to include in the application a proposed specification for consideration in the JMPS assessment process using the available templates.

Note: Since 2021, JMPS no longer assess ITNs. Applications for assessment of ITNs should follow all available information for the prequalification of ITNs.

Availability of Manufacturer release specifications vs WHO specifications

With the advancement of PQT/VCP and the recent inclusion of manufacturing release specifications in the WHOPAR, it is important to denote the appropriate point of reference for confirmation of quality.

For the purposes of quality control testing in relation to the procurement of prequalified VCPs, the manufacturing release specification should be utilized as the point of reference for confirmation of batch quality.

If a manufacturing release specification is not yet available, the related WHO specification being the point of reference as an international standard for the quality, can be relied upon for confirmation of batch quality.