Considerations for the selection of controls for use in spatial emanator studies

Factors which may affect the validity of studies using selected controls:

- controls not obtained from a controlled source
- inappropriate storage conditions after receipt
- active ingredient(s) (AIs) of control does not align with the AI(s) of the proposed spatial emanator product.

1. Purpose

The purpose of reference items (positive and negative controls) in studies is to validate the experimental procedures. The results from controls are used in statistical analyses to characterize proposed products and make determinations of entomological efficacy; therefore, it is crucial that the selected controls are appropriate and relevant for the study at hand.

In addition to the requirements described in this document, bodies other than WHO Prequalification of Vector Control Products, such as other WHO departments or national regulatory agencies, may have specific requirements for controls. Studies that are intended to be submitted to multiple bodies should be designed such that all control requirements are met.

2. Negative controls

All studies must be conducted with a negative control. For the purposes of studies conducted for the prequalification of spatial emanator products, negative controls should be untreated products of the product under investigation. In the case of active spatial emanator products, an empty device can be used as the negative control.

The criteria for the acceptance of negative control results must be clearly stated in the study report.

Negative control results must always be presented.

3. Positive controls

The role of the positive control is to give a consistent, quantifiable signal that can be used to validate experimental procedures. The positive control(s) should be selected based on the intent and design of the study, including the selection of method(s), endpoint(s), and species/strains, to support the assessment of the validity of the study. All positive controls should be prequalified products that have an entomological mode of action and combination of AI(s) (if relevant) consistent with the intended entomological mode of action of the proposed spatial emanator product. The selected positive control should be as similar as possible with respect to AI(s), intended useful life and type of product (passive/active emanation).

In some cases, if the product under investigation contains a novel combination of AIs that has not previously been prequalified, the use of two positive controls may be indicated.

It is critical that the selected positive control(s) is used consistently in all studies for data generation.

4. Documentation of source and storage conditions

The source from which reference items are obtained can influence the results obtained when the items are used in subsequent studies, particularly if the items are obtained from sources that have undocumented and/or uncontrolled storage conditions. It is recommended that reference items be obtained directly from manufacturers.

The means by which reference items were obtained, the number of items obtained, batch numbers and storage conditions after receipt should be documented and reported, and the certificate of conformity should be provided.

5. Related documents

- WHO PQT/VCP Implementation guidance – Free-flight room studies
- WHO PQT/VCP Implementation guidance – Semi-field studies for spatial emanator products
- WHO PQT/VCP Implementation guidance – Semi-field methods for spatial emanator products: Experimental hut tests