INDIAN COUNCIL OF MEDICAL RESEARCH, NEW DELHI

Application Form for Testing of Vector Control Products

Evaluation of Public Health Pesticides

Integrated vector management is a universally accepted strategy for the prevention and control of vector-borne diseases in a cost-effective and sustainable manner. Among the available vector control methods, chemical control is the main method for control personal protection and mitigation of outbreaks of vector-borne diseases. Currently, the main vector control tools are based on insecticides and include indoor residual spraying (IRS), application of larvicides, space spray products and long-lasting insecticidal nets or insecticide treated nets (ITNs). It is mandatory that new insecticides or insecticide formulations are registered with the Central Insecticide Board & Registration Committee (CIB & RC), Directorate of Plant Protection, Quarantine and Storage (DPPQS), Ministry of Agriculture and Farmers Welfare, Govt. of India for legal authorization of their use by the National Centre of Vector Borne Diseases Control (NCVBDC) and the pest control agencies.

The authorization of use of public health pesticide products requires data on human and environmental safety, efficacy and quality. For efficacy testing, laboratory and multi-centre field trials are required to be conducted by the Indian Council of Medical Research (ICMR) and/or the National Centre for Disease Control (NCDC). The new vector management products or formulations are required to be tested and evaluated to generate entomological efficacy data, and if required epidemiological data.

The applicants or manufacturers of vector control products who wish to get efficacy of their products tested by ICMR should use the Application form given below to submit their application to ICMR for product evaluation.

The application form will facilitate the ICMR Expert Group on Evaluation of Vector Control Products (EVCP) to determine the phase(s) of evaluation of the vector control products according to the ICMR "*Common Protocol for Uniform Evaluation of Public Health Pesticides for use in Vector Control,* Third Edition (2023)". The application form may not be exhaustive and additional information and documents may be required by ICMR, as deemed necessary, for assessment of the applications.

The application form is in line with the "*Checklist of documents/information/materials to be presented by the manufacturers/applicants along with the application for evaluation of PHPs*" published on ICMR's website[1] which mentions pre-requisite data/documents needed for trial of each vector control product in different phases.

[1] https://main.icmr.nic.in/sites/default/files/upload_documents/Checklist_for_evaluation_of_PHP.pdf

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Application Form for Testing of Vector Control Products[1]

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1. APPLICANT INFORMATION

1.1. Company/manufacturer details

Company (name of manufacturer/ applicant)		
Company physical address	Street address:	
	City/town:	
	State/Union territory:	
	PIN code:	Country:
Company mailing address (if different)	Street address:	
	City/town:	
	State/Union territory:	
	PIN code:	Country:

1.2. Authorized contacts for the company

Authorized contacts are those individuals who are authorized by the companies to interact with ICMR-EVCP to discuss matters relating to the proposed product identified in this form. Individuals identified may be employees of the company or third party representatives. The details of the authorized contacts to be provided as an Annexure on company letterhead and a primary point of contact should be designated (Kindly provide details in *Annexure-I*).

[1] This application form is adapted from WHO PQT/VCP

2. PRODUCT IDENTIFICATION SUMMARY (PIS)

2.1 Summary of product information

Product name	
Other product names	
Active Ingredient(s)[1]	
Concentration of Active Ingredient(s)	
Product type[2]	
Formulation type [3] and composition/contents of the product (%, or w/w or w/v, as applicable)	
Description of target vector(s)	
Disease(s) intended to be controlled with respect to target vector(s) using the candidate product	
Is there existing WHO specification of this product?	
Manufacturing site(s)	
Type of product evaluation intended (Phase I, II or III) as per the 3rd edition of Common protocol[4]	

2.2 Product Description (append additional pages for this section if required)

2.2.1 Description of product use pattern and the specific product claim

[1] Active ingredients and any synergists used in the product
[2] Examples: LLIN, IRS product, Space Spray product, Larvicide, trap
[3] Based on formulation types specified in Appendix E of the Manual on development and use of FAO and WHO specifications for pesticides. https://www.fao.org/3/i5713e/i5713e.pdf
[4] 3rd Edition of Common Protocol available from: https://main.icmr.nic.in/sites/default/files/upload_documents/CP_Draft_Inviting_Comments_27_March_2023.pdf

2.2.2. Brief summary of the mode of action of the active ingredient(s) and/or synergist(s) or device
2.2.3 Registration Status: List the countries where the product is currently registered for sale and use, under review and/or intended to be submitted for review (if not registered, state so)

2.3. Equivalence – If the candidate product is being submitted as equivalent to CIB-registered and/or a WHO prequalified product, provide the following information:

2.3.1 Reference product's name	
2.3.2 Details about manufacturer of reference product	

2.4. Type of packaging of the candidate product submitted for testing

How is the product packaged (e.g., glass/plastic/metal bottles; aluminium/paper packaging; water soluble bags in a box etc.)?	
What is the weight of a packaging unit (g/kg):	

2.5. Declaration of product labelling:

How is the product label submitted along with the application (e.g. affixed to product containers or packaging; provided as a separate paper etc)?[1]

[1] The FAO/WHO guidance on labelling is available from: https://www.fao.org/3/i4854e/i4854e.pdf

2.6 Commercial agreements and re-branding:

Note: Rebranding refers to the process of relabeling a finished product or the distribution of a product by a company which is identified on the label that is not the legal manufacturer. Applications for ICMR evaluation of Vector Control Products (VCPs) are accepted only from the legal manufacturer of the product.

Do you sell or supply this product for re-branding? If yes, please provide an attachment to this form indicating the company or companies and name(s) of the product under which it is distributed.

3. SAFETY DECLARATION/INFORMATION

Provide the following information:

3.1 Is the hazard assessment on the active ingredients used in the candidate product available with the applicant or is the hazard assessment summary publicly available?

3.2 Material Safety Data Sheet (MSDS) of the candidate (test) product as ***Annexure-II.***

3.3 Technical specifications/ certificate of analysis (CoA) of the formulated product as ***Annexure-III.***

3.4 If the product is submitted as an active ingredient for determination of discriminating concentration for insecticide resistance testing, provide a certificate of analysis of such active ingredient product as ***Annexure-IV***.

3. Data on the efficacy of the product, if available

Efficacy testing may include Phase 1 (laboratory testing); Phase II (small-scale field testing or testing in experimental huts of ITN and IRS products, as required); and Phase III (large-scale/village-scale) field evaluation) of the candidate product at ICMR/NCDC /WHO CCs/GLP-certified laboratories. If the efficacy of the candidate product has been tested by an institution in India and/or abroad, attach a summary of the results ***(Annexure –V)***. If the results have been published, include web/DOI links.

4. DECLARATION BY MANUFACTURER/APPLICANT

The undersigned authorized representative of the manufacturer makes the following declarations on behalf of the manufacturer and, in signing this application form, declares that he/she has the authority to bind the manufacturer.

I declare that:

- I am authorized to represent the manufacturer specified in this ICMR application form (the "manufacturer") for the purposes of bio-efficacy evaluation of the product specified in this application form (the "product").
- All the information provided in this application is current and correct.
- Any changes to the information provided in the application will be readily communicated to ICMR in a written form.
- The manufacturer holds data in support of all claims made on product labelling as presented to ICMR.
- The manufacturer understands and agrees that, in the event that ICMR agrees to undertake efficacy testing of the product:
    i. ICMR will have absolute unfettered control over the manner in which the testing is carried out, including the maintenance and interpretation of data and publication of the results of the efficacy assessment, regardless of the outcome; and
    ii. that the manufacturer will pay the cost of product testing.

The manufacturer understands that the outcome or results of the ICMR testing of the candidate product will not be used by the manufacturer or any other party for promotional purposes. The data can be used for product registration purpose.

Name of authorized contact person for the manufacturer:

Signature of authorized contact person for the manufacturer:

[Company seal]

Place:
Date:

Annexures

1. **Annexure-I: Authorized contacts for the company**
   (to be provided as an on company letterhead)

Name	
Contact's job title/position/designation	
Company (if third party representative)	
Mailing address	
Telephone number(s) Mobile number	
E-mail	

2. **Annexure-II: Material safety data sheet (MSDS) of the candidate (test) product**

3. **Annexure-III: Technical specifications/certificate of analysis (CoA) of formulated product**

4. **Annexure-IV: Certificate of analysis of active ingredient product, if applicable**

5. **Annexure-V: Efficacy evaluation report (Phase 1: Laboratory evaluation; Phase II: Small-scale field evaluation (e.g., in experimental huts); Phase III: Large-scale (village-scale) field evaluation).**