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भारत सरकार

Government of India

कृषि एवं किसान कल्याण मंत्रालय

Ministry of Agriculture & Farmers Welfare

कृषि एवं किसान कल्याण विभाग

Department of Agriculture & Farmers Welfare

वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय

DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE

केंद्रीय कीटनाशी बोर्ड ए वम पंजीकरण समिति

Central Insecticides Board and Registration Committee

एन. एच. 4, फरीदाबाद (हरियाणा)-121001

N.H. IV, FARIDABAD (HARYANA)-121001

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Dated: February, 2022

PUBLIC NOTICE

Subject: Modalities for Pre-Registration verification of technical grade pesticides for analysis in CIL-reg.

The Registration Committee in its 442nd meeting held on 18.11.2022 has approved the modalities of Pre-Registration verification samples for TIM cases under Section 9(3) and 9(4) (agenda 3.2). The details of the agenda are attached herewith for awareness of all the stakeholders..

This has the approval of Secretary (CIB&RC).

Encl.: As above.

Signed by Govind Ram
Date: 20-02-2023 11:38:04
Reason: Approved

(Govind Ram)
Sr. Administrative Officer

Copy to:

1. All the stakeholders
2. Chairman, Registration Committee
3. PPS to JS (PP)/ PPS to PPA
4. IT Cell, HQ, Faridabad for uploading the same on the website.
5. Guard file

Agenda item No. 3.9

Modalities for Pre-Registration Verification of technical grade pesticides for analysis in CIL

Members are well aware that the drawl of sample for PRV purposes is an integral part and an important pillar of scientific verification of claims made by the applicant. As per information available it is observed that the sample drawl started way back from 162nd RC. The process has been evolving from time to time and improved a lot. The whole process of sampling was reviewed by RC in its 334th meeting held on 29.11.2012vide agenda item no. 3.4 and various steps, criteria were added to the process.

The RC in its 440th meeting has revised all the existing guidelines. so to keep pace with science and technology it is deems fit to further improve the process as envisaged below:

Modalities of Pre-Registration Verification samples for TIM Cases under Section 9 (3) and 9(4):

The generation of Analytical Test Reports process is divided in to two parts:

A. Drawl of Sample/Submission of sample
B. Analysis of above samples in Central Insecticides Laboratory, Faridabad

A. Drawl of Sample/Submission of sample:

1. Procedures to be adopted by the Sectt. of CIB&RC:

(a) As soon as a decision to draw an in-process sample is taken in case of TIM (after establishment of Chemical equivalence in case of already registered molecule or after completion of chemistry folder in case of first timer molecule), a communication should be issued to the applicant asking his/her readiness for drawl of sample and submitting the copies of detailed stepwise and excerpts of process of manufacturing, Chemical reactions, time taken in each step, total time requires etc and seek his convenience for tentative date of drawl of sample, providing the complete information and requisite material for the sample drawing officer.

(b) The applicant has to respond to this communication in affirmative with in 30 days, if failed to do so, in such instances

his/her application shall be liable to reject without further notice.

(c) The applicant has to provide a set of necessary information, such as, claimed chemical composition(Form-I), detailed stepwise manufacturing process, total time, including time required for completion of each step of synthesis, condition of reactions, details of raw material consumed in each step, details of recovery in each step, location where the process shall be demonstrated and the name and telephone/FAX/mobile numbers of the representative (also termed as the nodal person), responsible for showing the process and authorized to sign the proforma at the time of drawl of in-process sample, as envisaged in detail in the revised proforma, for records in the Sectt of CIB & RC.

(d) Once the readiness has been expressed by the applicant. The communication shall be sent from the Sectt. of CIB&RC for deputing an officer and an APPO (team) from the Chemistry discipline to the Plant Protection Adviser (PPA) at the earliest as per the procedure in vogue. The PPA shall nominate a team as above from the eligible officers/officials. The approval of PPA shall be communicated to the nominated officers/officials within 5 working days with the instructions to draw the in-process sample within a period not exceeding 45 (Forty five) days of issue of the letter. A copy of stepwise manufacturing process, total time, including time required for completion of each step of synthesis, location where the process shall be demonstrated and the name and telephone/FAX/mobile numbers of the representative (also termed as the nodal person), responsible for showing the process and authorized to sign the proforma at the time of drawl of in-process sample, OR as submitted by the applicant as per instruction in above para (C) shall be provided to him alongwith the letter of deputation. He shall be advised that on receipt of letter of deputation, he should immediately communicate (proof to be retained) with the applicant to fix the date of in-process sampling without waiting for the applicant to contact him/her. A reasonable time limit, say 7-10 days, may be given for response.

(e) Simultaneously with the letter to the sample drawing officer (reference (d) above), a communication shall also be sent to the applicant intimating the deputation of team of officers/officials and with the direction to facilitate the drawl of sample within a period of 45 days of the date of receipt of communication, failing which his matter shall be reported to the Registration Committee for taking a suitable decision on his application

(f) In case, the applicant agrees, in-process sample should be immediately drawn after filling up the relevant portion of the proforma and collecting requisite information and material. The proforma may be completed at the time of drawl of in-process sample. (Proforma attached as **Annexure-I**). The team have to collect the sufficient quantity of technical preferably more than 100 gm for PRV. The CRM should be ISO 17034:2016 compliant only. In case, the team draws in-process sample without collecting all requisite information and material as per the proforma, the team shall be liable to explanation and disciplinary action for dereliction of duty. It shall be ensured that all the standard of impurities are supported with their chromatograms.

(g) In case, the applicant does not either respond within the time-limit or does not agree to facilitate in-process sampling within a period of 45 days of the date of issue of communication, the matter may be brought to the notice of PPA for taking suitable action, including informing the Registration Committee about unwillingness of the applicant and accordingly taking a decision on his application.

B. **Procedures to be adopted by the deputed sample drawing Officer/Officers:**

a. The officers nominated by the PPA for completion of this task shall use his mobile device installing geo tagging app like **GPS Map Camera Lite (On android and iOS)** and registered themselves to use it. The officer/officers shall use this device/software twice in a day (Morning and Evening daily) for the duration of sample drawl to capture the GPRS coordinates

at the designated location. The same shall be saved and print should be attached with the proforma of sample drawl. (Failing which it shall be treated as leniency in performing the duties). No explanation, justification; what so ever shall be entertained in this matter. (A specimen photo is attached for ready reference)

b. The officers shall ensure that the face of the officers are clearly visible in snapshot while using the above said GPS.

c. Any omission to the above said activity shall be treated as dereliction of duty leading to rejection of PRV sample by CIL.

d. The officers are required to remain present at the site at the time of change of step during the day mandatorily.

e. The officers should take the sample immediately on completion of process of manufacturing and packed the same in HDPE/Aluminum container or other packing material as the case may be so as to save the sample from spilling, breaking or getting moisturized etc during the transport.

f. The Officer/Officers shall submit the sample as per proforma, along with all the information/material collected, to the APPA & Director (CIL) under intimation to the PPA immediately [who will mark this copy to the APPA & Secretary (CIB & RC) for records] against an acknowledgement. APPA & Director (CIL) shall ensure its analysis.

C. Procedures to be adopted by the applicant in case of FIM/TI/FIM-WRT/FI-WRT u/s 9(3):

a. The applicant should submit 100 gram of minimum sample in case of technical and 500 gm minimum in case of formulation to the CIL with three times quantity of CRM specified in MOA (ISO 17034:2016 compliant only) and standard of impurities as applicable along with required documents/information such as, claimed chemical composition(Form-I), BIS/Product Specification, Method of Analysis (MOA), Chromatograms, Spectra etc. (including their purity and source and storage

condition, if any), so that deficiencies do not arise and samples could be taken up straight for analysis.

b. A sufficient quantity of standard of impurities at least 100mg minimum each impurities shall be submitted to CIL.

2. **Procedures to be adopted by the Central Insecticides Laboratory:**

a. The Central Insecticide Laboratory shall ensure the analysis of the samples as per BIS/Product Specification for generation of Analytical Test Report and identification & quantification of identifiable impurities as per MOA given by the applicant.

b. CRMs provided by the applicant shall be ISO 17034: 2016 compliant. If the molecule is recently invented and CRM is not available then Standard of the molecules shall be acceptable.

c. The same MOA shall be used by the CIL as provided by the applicant. If any change is required or noticed the same may be brought to the notice of Sectt. of CIB&RC. If changes is minor which doesn't have any bearing on the AI content or the principal of MOA, revised ATR and other data shall be asked from the applicant by Sectt. of CIB&RC.

d. If any improvisation/alteration/change in parameters is adopted in MOA, the same shall be communicated to the knowledge of the Sectt. of CIB&RC with the submission of report.

e. All the standard of impurities shall be tested for the presence/verification of designated molecules using GC-MSMS or LC-MSMS as the case may be. Spectra, Chromatograms of impurities shall be attached with report.

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Directorate of Plant Protection, Quarantine & Storage
N.H.-IV, Faridabad-121 001
Proforma for drawl of In-process sample of pesticides

S. No.	Item	Information/Material
1.	Common/Chemical Name of the Insecticide along with the category of registration applied for [9(3) or 9(4)]:	
2.	Particulars of the premises of in-process sampling: **(i)** Name of the institution: **(ii)** Postal address with PIN Code: **(iii)** Tel/FAX/Mobile No.: **(iv)** E-mail ID:	
3.	Details of manufacturing activities at different scale of production/manufacturer:	
4.	Is sample drawn from the same premises, where pesticide is purported to be manufactured	
5.	If sample drawn from the different premises than designated to manufacture, please specify and give address:	
6.	GPRS Geo tagging of both the Govt. officers at the site of sample drawl (Please attach screen shot of all days and value should be filled here)	
7.	Details in respect of this insecticide	

			Officer-I	Officer-II
Day-I	M	Lat		
		Long		
	E	Lat		
		Long		
Day- II	M	Lat		
		Long		
	E	Lat		
		Long		
Day-III	M	Lat		
		Long		
	E	Lat		
		Long		
Day-IV	M	Lat		
		Long		
	E	Lat		
		Long		
Day-V	M	Lat		
		Long		
	E	Lat		
		Long		

	(i) Name of raw materials used in this POM: (ii) Type packaging materials:	
8.	Infrastructure regarding effluent treatment and disposal/decontamination system:	
9.	Storage of raw materials including gases and other explosive/hazardous materials:	
10.	Quality control system for (i) Raw materials: (ii) Finished product: (iii) Packaging material:	
11.	Provide the quality control method to test the quality of following material used in POM: (i) Raw materials: (ii) Finished product:	
12.	Complete Chemical Composition(CC) of the Insecticide as claimed in the application: (i) **Active Ingredient:(Name), min. (Isomer(s) min./max, if any)** (ii) **Impurities:** 1) (Name of impurity & %purity) 2) (Name of impurity & %purity) 3) (Name of impurity & %purity) 4) (Name of impurity & %purity) 5) (Name of impurity & %purity) Total number of impurities provided:	
13.	Certified Reference Material of the molecule provided (i) Quantity: (ii) Source: (iii) % purity: (iv) Storage condition (SC): Note: CRM should be in sealed condition from the source accredited to ISO 17034:2016)	
14.	Certified Reference Material/Standard of the impurities provided I. Quantity: II. Source: III. % purity: IV. Storage condition (SC):	

	Note: CRM/Standard submitted should be in sealed condition and supported with chromatograms	
15.	Certified Reference Material/Standard of the impurities provided 1) Quantity: 2) Source: 3) % purity: 4) Storage condition (SC): The above details shall be provided for all the impurities: **1)** (Name of impurity & %purity) **2)** (Name of impurity & %purity) **3)** (Name of impurity & %purity) **4)** (Name of impurity & %purity) **5)** (Name of impurity & %purity) **6)** (Name of impurity & %purity) **7)** (Name of impurity & %purity) **8)** (Name of impurity & %purity) **9)** (Name of impurity & %purity) Total number of impurities provided: (Note: (a) If any impurity is not provided, state "Not Provided" against its name; and (b) quantity should not be less than thrice the quantity given in method of analysis)	
16.	Enclose complete product specification in BIS format as claimed in the application, including methods of analysis for **(i)** Active ingredient: **(ii)** Each of impurity: **(iii)** Other parameters: (Note: If the specification or a method of analysis is not provided,, state "Not Provided" giving its particulars	
17.	Enclose chromatogram/spectra as per method of analysis for the following: **(i)** Active ingredient (standard): **(ii)** Impurities (standards): **(iii)** Sample showing a.i. and impurities: **(iv)** Spectra: **(a)** UV: **(b)** IR : **(c)** Mass: **(d)** NMR:	

<table>
<tr><td></td><td>(Note: If any of these is not provided, state "Not Provided" giving its particulars)</td><td></td></tr>
<tr><td>18.</td><td>Any other relevant information/material to be provided by the applicant:</td><td></td></tr>
<tr><td>19.</td><td>Stepwise time noted for completion of each step of synthesis and total time taken for synthesis:

(i) Step I:
(ii) Step II:
(iii) Step III:
(iv) Step IV:
Total Steps:</td><td>Start (Date & Time) Completion (Date & Time) Duration (hours)

Total Time taken:</td></tr>
<tr><td>20.</td><td>Stepwise consumption of raw materials and yield obtained:</td><td><table><tr><td></td><td>Raw Material</td><td>Quantity (gm)</td><td>Yield (gm)</td></tr><tr><td>(i) Step I:</td><td>A & B</td><td>GH</td><td>XYZ</td></tr><tr><td>(ii) Step II:</td><td>XYZ + D</td><td>JK</td><td>LMO</td></tr><tr><td>(iii) Step III:</td><td>Continued</td><td></td><td></td></tr><tr><td>(iv) Step IV:</td><td></td><td colspan="2"></td></tr><tr><td></td><td colspan="3">Final Yield obtained (gm/ml):</td></tr></table></td></tr>
<tr><td>21.</td><td>Steps followed in synthesis (with reference to the manufacturing process submitted with application):
(i) Total steps in manufacturing process:
(ii) Step from which synthesis started:
(iii) Total steps actually adopted in synthesis:
(iv) Reason(s) for skipping the step(s):</td><td></td></tr>
<tr><td>22.</td><td>Particulars of the synthesized product:

(i) Batch number assigned:
(ii) Date of manufacture:
(iii) Date of expiry:</td><td></td></tr>
<tr><td>23.</td><td>Sampling
(i) Quantity sampled:
(ii) Packaging details:
(Pack sample by using inner liner, Teflon tape, etc in case of liquid samples and polythene bag of adequate thickness in case of solid samples to avoid leakage)</td><td></td></tr>
</table>

24.	Sample drawn at (i) Place: (ii) Date & Time:	
25.	Sample Drawn by:	
26.	Any other related information/remark by the sample drawing officer(s):	
27.	Name of the authorized representative of the applicant, responsible for in-process sampling:	
28.	Specimen seal of the officers who took the sample:	
29.	Specimen seal of the applicant/authorized representative:	
30.	Signature& official stamp of the applicant/authorized representative:	
31.	Signature(s) & official stamp of the officer(s) who took the sample:	

Note: Sample drawing officer(s) should number each page of this form as the page number/total number of pages and sign each page of this form with date.

Directorate of Plant Protection, Quarantine & Storage
N.H.-IV, Faridabad-121 001

Proforma for submission of Formulation samples by the applicants u/s 9(3) to CIL for test/analysis for pre-registration verification

S. No.	Item	Information/Material
1.	Name & address (alongwith PIN Code) of the applicant:	
2.	Common/Chemical Name of the Insecticide:	
3.	(i) Type of formulation: (ii) % purity/strength of formulation: (iii) Exact coding (MUP/DP/EC/SC etc)	
4.	Complete Chemical Composition(CC) of the Insecticide as claimed in the application: (i) Active Ingredient:(Name), min. (Isomer(s) min./max, if any) (ii) Raw material: (1) (Name of raw material & %purity) (2) (Name of raw material & %purity) (3) (Name of raw material & %purity) (4) (Name of raw material & %purity)	
5.	Certified Reference Material provided (i) Quantity: (ii) Source: (iii) % purity: (iv) Storage condition (SC):	
6.	Enclose complete product specification in BIS format as claimed in the application, including methods of analysis for **(iv)** Active ingredient: **(v)** Each of impurity: **(vi)** Other parameters: (Note: If the specification or a method of analysis is not provided,, state "Not Provided" giving its particulars)	
7.	Enclose chromatogram/spectra as per method of analysis for the following: (i) Active ingredient (standard): (ii) Sample showing a.i. and Internal Standard: (Note: If any of these is not provided, state "Not Provided" giving its particulars)	

8.	Enclose following spectra in case of technical grade insecticides, if applicable: (a)UV: (b)IR : (c)Mass: (d)NMR: (Note: If any of these is not provided/applicable, state "Not Provided/applicable" giving its particulars)	
9.	Any other relevant information/material to be provided by the applicant:	