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उत्पाद मैनुअल

इमीडाक्लोप्रिड डब्लू एस - विशिष्ट IS 15334 : 2003

के अनुसार

**PRODUCT MANUAL
FOR IMIDACLOPRID WS -
SPECIFICATION ACCORDING TO IS
15334 : 2003**

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity of practice and transparency in operation of certification under Scheme-I of Bureau of Indian Standards(Conformity Assessment) Regulations, 2018 for various products. The document may also be used by prospective applicants desirous of obtaining BIS certification.

1.	मानक संख्या IS No.	:	IS 15334 : 2003
	शीर्षक Title	:	Imidacloprid WS - Specification
	संशोधनों की संख्या No. of amendments	:	NIL
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	Imidacloprid, Technical employed for manufacture of Imidacloprid WS, shall conform to IS 15443 as per clause 3.1.2 of IS 15334 : 2003. The compliance to the above requirement may be established through supplier test certificate/test report from BIS recognized lab/empanelled lab or any other lab having accreditation as per IS/ISO/IEC17025 or in-house testing/combination thereof.

		Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	: Please refer to Annex-A
c)	नमूने का परिमाण Sample Quantity	: 250 g Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (in case of market surveillance, effort may be made to procure the required quantity of product sample, as far as possible since raw material sample may not be available in market)
d)	Declaration	: The manufacturer shall declare the Nominal Value, Percent (%) for <i>Imidacloprid WS</i> , intended to be covered in the scope.
3.	परीक्षण उपकरणों की सूची List of Test Equipment	: Please refer to Annex-B
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	: Please refer to Annex-C
5.	एक दिन में संभावित परीक्षण Possible tests in a day	
	Description, Imidacloprid Content and Wettability. Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.	
6.	लाइसेंस का दायरा/Scope of the Licence:	
	"Licence is granted to use Standard Mark as per IS 15334: 2003 with the following scope:	
	Name of the product	<i>Imidacloprid WS</i>
	Nominal Value	Group-1/Group-2/Group-3

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9, BAHADURSHAH ZAFAR MARG,
NEW DELHI-110002

ANNEX-A

GROUPING GUIDELINES

1) Based on the nominal value of Imidacloprid content, there are 3 groups defined in the Standard:

- i. Group 1- upto 9%
- ii. Group 2- Above 9% and below 50%
- iii. Group 3- 50% and above

2) Considering the above, following grouping guidelines for GoL/CSoL have been developed:

- i. One sample of highest nominal value shall be drawn from each group to cover all nominal values falling under the group in the scope of licence.
- ii. Scope of licence shall be restricted based on the manufacturing and testing facilities available.
- iii. During operation of licence, samples of each variety covered in the scope of licence, shall be tested in rotation, to the extent possible.

ANNEX-B

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests used in with Clause Reference	Test Equipment/Chemical
1.	Imidacloprid Content, Clause 3.3 & Table 1	i. Weighing balance ii. Volumetric Flask (100 ml) iii. HPLC(High Performance Liquid Chromatograph) with UV-VIS and detector coupled to a printer-plotter-cum-integrator. iv. Micro syringe v. Pipette (10 ml, 20 ml) vi. Micro Syringe (20 ml) vii. Acetonitrile (HPLC grade or equivalent) viii. Water (HPLC grade of equivalent) ix. Acenaphthene (AR grade or equivalent) x. Imidacloprid (Reference Standard)
2.	Sieving, Clause 3.3 & Table 1	i. Beaker (6.0 to 6.5 cm and 250 ml Capacity) ii. Pressure Assembly iii. 75 μ IS Sieve iv. Rubber Hose v. Weighing Balance vi. Paper Strip/Camel hair brush/feather vii. Oven viii. 100ml Wide Mouth bottle (with cork/rubber stopper) ix. Glass Rod (4 – 6 mm) x. Gooch Crucible
3.	Wettability, Clause 3.3 & Table 1	i. Weighing Balance ii. Beaker iii. Standard Hard Water iv. Stopwatch

ANNEX C

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: Imidacloprid WS of same nominal value, manufactured under similar conditions of production in a day.

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as “R” in Column 2 of Table 1), where different tests given in the specification shall be carried out in accordance with the method given in the specification. They shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark as given in the Schedule of the licence shall be incorporated legibly and indelibly on each Laminate Polyester Pouches/Aluminium Foil Pouches/LDPE, HDPE Containers, provided always that the material so marked conforms to each requirement of the specification.

3.1 Packing and Marking shall be done as per the Indian Standard.

3.2 Repacking of material shall be as per the requirements given in IS 8190 (Part 1). The repacker shall maintain details of the repacked material, in format given in Table 2.

3.3 Additional Marking requirements: The material shall also be marked with the following additional requirement on each Laminate Polyester Pouches/Aluminium Foil Pouches/LDPE, HDPE Containers:

a) “For BIS certification details please visit www.bis.gov.in”

4. REJECTION - All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of provisions of BIS Act, 2016.

TABLE 1
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Clause	Requirements	Test Method		Test equipment requirement R: required (or) S: Sub-contracting permitted	No of Samples	Frequency	Remarks
		Clause	Ref.				
3.2	Description	3.2	IS 15334	R	One	Each Control unit	
3.3	Imidacloprid Content	Annex A	IS 15443	R	One	Each Control unit	
3.3	Sieving	11.1	IS 6940	R	One	Each Control unit	
3.3	Wettability	11.4	IS 6940	R	One	Each Control unit	

TABLE 2
RECORD FOR REPACKED IMIDACLOPRID WS ACCORDING TO IS 15334: 2003

Name of the manufacturer	Particulars of test reports received with C.U	Date of manufacture	Quantity received	Date of receipt	Date of repacking	Batch no.	Details of repacking		Total quantity	Details of dispatch
							Size	No.		
1.	2.	3.	4.	5.	6.	7.	8.	9.	10.	11.