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उत्पाद मैन्युअल
एज़ोस्पिरिलम जीवाणु कल्चर — विशिष्टि
IS 14806: 2021 के अनुसार

PRODUCT MANUAL FOR
AZOSPIRILLUM INOCULANTS — SPECIFICATION
ACCORDING to IS 14806: 2021

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 14806: 2021
	शीर्षक **Title**	:	Azospirillum Inoculants — Specification
	संशोधनों की संख्या **No. of amendments**	:	01
2.	नमूना दिशानिर्देश **Sampling Guidelines**		
a)	कच्चा माल **Raw material**	:	No specific Requirements. 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**	:	NA

c)	**नमूने का परिमाण** **Sample Size**	:	500 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)	**परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर** **Parameters to be Declared in Test Request**	:	Name of the product Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	Please refer to Annex-A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex-B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	1. Fineness of Carrier 2. pH 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 14806: 2021 with the following scope:		
	Name of the product		Azospirillum Inoculants

ANNEX-A
LIST OF TEST EQUIPMENT
(INDICATIVE LIST, FOR GUIDANCE ONLY)

	Tests used in with Clause Reference	Test Equipment / Chemical
1.	Viable Cells and Contaminants, Clause 4.1 & 4.3	Analytical balance (LC-0.01g, 0.010 to 600 g), pH meter 0.01 (0 to 14), Autoclave (120 °C). BOD Incubator 0.1°C (28±2°C): Hot air oven (160°C Water bath/Incubator40-450°C, Orbital shaker (reciprocal shaker), Protective Chamber with Burner, Cyclomixer; Colony counter, Pipette - 1ml, 10ml, Conical flasks — 150 ml & 250 ml, Petri dishes, screw cap tubes - 10 ml, Bunsen burner, Cotton, NEB medium-Nitrogen free bromothymol blue medium (Malic acid- Potassium hydroxide, Dipotassium hydrogen phosphate, Ferrous sulphate, Manganese sulphate, Magnesium sulphate, Sodium chloride, Calcium chloride, Sodium molybdate, Bromothymol blue: Isopropyl alcohol, Agar agar), Sodium hydroxide, Hydrochloric acid, Distilled water, Sterile
2	Fineness of Carrier, Clause 4.2	Analytical balance: IS sieve (150 to 212µ (72 to 100 mesh): Lignite/Peat/Charcoal, Calcium carbonate, Autoclave for sterilization.
3	pH, Clause 4.4	pH meter, Analytical balance (0-200g, LC-0.01 mg), Rotary shaker (0 to 120 RPM), conical flasks —250 ml, Measuring cylinder-50ml, Funnels, Filter paper, Glass beaker, Glass rod, Standard pH buffers, Distilled water.
4	Effective nodulation, Clause 4.5	Analytical balance (0-200g, LC-0.01 g). Autoclave capable of operating at 120°C: Hot air oven — capable of operating at 60°C, pH meter, Incubator- capable of operating at 30°C, Mortar & pestle, Beaker, Pipette, Seed, Earthenware glazed pots, Soil, Coarse Sand, Scissors, screw capped bottles/ Test tubes with rubber hung, Desiccator, Pot culture house (growth rooms/cabinets), Orbital shaker (0 to 120 RPM), Plastic tube, Nitrogen Free Bromothymol Blue, Semi-Solid Malate Media, Potassium chloride, Potassium hydrogen phosphate, Calcium sulphate, Manganese sulphate, Magnesium sulphate, Copper sulphate, Zinc sulphate, Ammonium molybdate, Boric acid, Ferrous sulphate, Citric acid, Ammonium nitrate, Soft tap water/RO water, 95% alcohol, Chlorine water/0.1% mercuric chloride, Sterile water, Conc. Sulphuric acid, Calcium chloride. PLANT NUTRIENT SOLUTION: Potassium chloride, Potassium hydrogen phosphate, Calcium Sulphate, Magnesium sulphate, Trace elements solution (Copper Sulphate, Zinc Sulphate, Magnesium sulphate, Ammonium molybdate, Boric acid), Iron solution(Ferrous sulphate, Citric acid), Mortar, Distilled water.

6	Quality of broth, Clause 4.6	Laminar Alr flow, NFB medium, Inoculation Loop, Incubator (28±2°C), Microscope-100x lens, Hot air oven — capable of operating at 30 to 450°C, Autoclave —capable of operating at 27 to 150°C. Glass slides, pH meter, Refrigerator, freezer, Water bath, Ammonium oxalate, Gram staining kit- Crystal violet solution, Iodine solution, Ethyl alcohol, Safranin (erythrosine), Immersion oil, Test tubes containing media broth. MEDIUM: (Agar, Yeast extract, Mannitol, Potassium hydrogen phosphate, Magnesium sulphate, Sodium chloride, Cango red, Distilled water), MPN method Bunsen burner, Filter paper.

ANNEX-B

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: the quantity of the material blended in a blender at a time and taken from the same consignment of raw material.

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 polyethylene pack of Azospirillum Inoculants, 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 **Additional Marking requirements**: The material shall also be marked with the following additional requirement on each polyethylene pack of Azospirillum Inoculants:

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)			
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Clause	**Requirements**	**Test Method**			**No. of Samples**	**Frequency**	**Remarks**
		Clause	**Reference**				
4.1	Viable Cells	Annex A	IS 14806	R	One	Each control unit	
4.2	Fineness of Carrier	4.2	-do	R	-do-	Each consignment of the carrier material received.	
4.3	Contaminants	Annex A	-do	R	-do-	Each control unit	
4.4	pH	Annex B	-do	R	-do-	-do-	
4.5	Effective nodulation	Annex C	-do	R	-do-	Once in a season for each strain of Azospirillum.	Record of Isolation and identification of various strains of Azospirillum culture used for different crops, nodulation ability and effectiveness shall be maintained in a separate register.