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उत्पाद मैन्युअल
प्रबलित चावल दानों के उत्पादन हेतु
विटामिन एवं मिनरल का पूर्वमिश्रण– विशिष्टि
IS 17781:2021 के अनुसार

PRODUCT MANUAL FOR VITAMIN AND MINERAL PREMIX FOR MANUFACTURING FORTIFIED RICE KERNELS -SPECIFICATION ACCORDING TO IS 17781:2021

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 coherence 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 licence / certificate.

1.	**मानक संख्या** **IS No.**	:	IS 17781:2021
	शीर्षक **Title**	:	प्रबलित चावल दानों के उत्पादन हेतु विटामिन एवं मिनरल का पूर्वमिश्रण – विशिष्टि Vitamin and Mineral Premix for Manufacturing Fortified Rice Kernels — Specification
	संशोधनों की संख्या **No. of Amendments**	:	NIL
2.	**नमूना दिशानिर्देश** **Sampling Guidelines:**		
a)	**कच्चामाल** **Raw material**	:	a) Manufacturer is required to submit undertaking/declaration as per Clause 4.8(a), 4.8(b) of IS 17781:2021 b) Manufacturer is required to maintain test records/ test certificate in accordance Clause 4.4 of IS 17781:2021 c) In case the manufacturer opts for addition of any ingredients as per provisions of Cl. 4.5 of IS 17781:2021, he is required to maintain records in accordance Clause 4.5 of IS 17781:2021 d) Manufacturer to provide Certificate of Analysis (CoA) for Micronized ferric pyrophosphate, Sodium iron (III)

			ethylenediamine tetraacetate trihydrate (sodium feredetate-NaFeEDTA), Folic acid, Cyanocobalamine or hydroxycobalamine, Zinc oxide (ZnO), Retinyl palmitate, Thiamine hydrochloride or Thiamine mononitrate, Riboflavin or riboflavin 5'-phosphate sodium, Nicotinamide or nicotinic acid, Pyridoxine hydrochloride as per provisions of Table 1 of IS 17781:2021
b)	**समूहीकरण दिशानिर्देश** **Grouping guidelines**	:	Not Applicable
c)	**नमूने का परिमाण** **Sample Quantity**	:	1 kg of sample for complete testing 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)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	कृपया Annex-A देखें Please see Annex – A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	कृपया Annex-B देखें Please see Annex – B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day:**		
	i) Moisture content 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:**		
	IS 17781:2021 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है। "Licence is granted to use Standard Mark as per 17781:2021 with the following scope:		
	उत्पाद का नाम Name of the product	Vitamin and Mineral Premix for Manufacturing Fortified Rice Kernels	

ANNEX – A
TO THE PRODUCT MANUAL FOR
VITAMIN AND MINERAL PREMIX FOR MANUFACTURING FORTIFIED RICE KERNELS ACCORDING TO IS 17781:2021
LIST OF TEST EQUIPMENT

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr No.	Tests used in with Clause Reference	Test Equipment/Chemicals/Glassware
1	Moisture content (Clause 4.9, 6.2 and 8)	Flat Bottom Moisture Dishes with cover of glass, Nickel, Stainless steel, aluminum or porcelain having approximately 50 mm diameter & 25 mm depth Drying Oven (Thermostatically controlled at 102 +/- 2ºC) Desiccator with effective desiccant Bottles with tight fitting stoppers for mixing the product Weighing balance
2	Particle size of micronized ferric pyrophosphate (D90 particles) (Clause 4.9, 6.2 and 8)	Fixed Position Pipette Incremental Method – Pipette At The Top : Sedimentation Vessel (5 cm internal diameter) Pipette (10 ml capacity) Ancillary Apparatus Balance (Not less than 0.1 mg) Drying Oven Wide mouthed Weighing Bottle – (Not less than 20 ml capacity) Liquid and Dispersing Agent - Rape oil + acetone

ANNEX B
TO THE PRODUCT MANUAL FOR VITAMIN AND MINERAL PREMIX FOR MANUFACTURING FORTIFIED RICE KERNELS — SPECIFICATION ACCORDING TO IS 17781: 2021
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 material manufactured with same composition 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/empaneled 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/empaneled 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 bag 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 bag:

a) "For BIS certification details please visit www.bis.gov.in"
b) BIS Licence No. CM/L…… .

4. HYGENIC and STORAGE CONDITIONS The product shall be manufactured, packed, stored in premises maintained under hygienic conditions as per IS 2491and stored in a clean, dry and cool place as per provisions of Clause 5.3 of IS 17781:2021.

5. 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 (Levels of Control)
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Test Details				**Test equipment requirement R:required (or) S: Sub-contracting permitted**	**Levels of Control**		
Clause	**Requirements**	**Test Method**			**No. of Samples**	**Frequency**	**Remarks**
		Cl. Ref.	**IS Ref.**				
4.1	Description		IS 17781:2021	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
4.2	Colour, Odour and Foreign Matter		IS 17781:2021	R	Firm to have adequate in-process controls to check compliance of this parameter as per the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity		
Table 2, Cl 4.9, 6.2 and 8	Moisture Content, percent by mass		IS 16072	R	One	Each Control Unit	
Table 2, Cl 4.9, 6.2 and 8	Particle size of micronized ferric pyrophosphate (D90 particles), µm	Sl. No. 44 of Appendix B of IS 5282	IS 5282	S	One	Once in three months	