केन्द्रीय मुहर विभाग-2

हमारा संदर्भ : के.मु.वि.-2/16: 7021 16 10 2018

विषय: IS 7021:2017 (Incorporating Amendment no. 1) (First Revision) के अनुसार Scheme of Inspection and Testing (SIT)

1. IS 7021:2017 (Incorporating Amendment no. 1) के अनुसार Scheme of Inspection and Testing (SIT) अवलोकन हेतु संलग्न है।

(आदित्य दास)
वैज्ञानिक सी (सी एम डी-2)

प्रमुख (के.मु.वि.-2)
सभी क्षेत्रीय/शाखा कार्यालयो को इंट्रानेट के माध्यम से परिचालित

प्रतिलिपि:
आई टी एस विभाग - बीआईएस इंट्रानेट पर अपलोड करने के लिए

CENTRAL MARKS DEPARTMENT-2

Our Ref: **CMD-2/16: 7021** **16 10 2018**

Subject: Scheme of Inspection and Testing (SIT) for IS 7021:2017 (Incorporating Amendment no. 1) (First Revision)

1. Please find enclosed Scheme of Inspection and Testing (SIT) for IS 7021:2017 (Incorporating Amendment no. 1)

(Aditya Das)
Sc. 'C' (CMD-2)

Head (CMD-2)

Circulated to all ROs/BOs through intranet

Copy to: ITS for hosting on BIS Intranet

SCHEME OF INSPECTION AND TESTNG FOR CERTIFICATION OF PROTEIN RICH FOOD SUPPLEMENT FOR INFANTS AND PRESCHOOL CHILDREN ACCORDING TO IS 7021:2017 (Incorporating Amendment no. 1) (First Revision)

1. **LABORATORY**- A laboratory shall be maintained, which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipment.

2. **TEST RECORDS -** The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. **PACKING AND MARKING**–The Standard Mark as given in Schedule of the license and Licence Number (i.e. CM/L……..) shall be incorporated, and the packing and marking shall be done as per the provisions of the Indian Standard, provided always that the product thus marked conforms to all the requirements of the specification. In addition, details of BIS website shall be marked as follows: "For details of BIS certification please visit www.bis.gov.in"

4. **CONTROL UNIT -** For the purpose of this scheme, the quantity of protein rich food supplement manufactured continuously in a shift shall constitutes a control unit.

4.1 On the basis of test results, the decision regarding conformity or otherwise of a control unit to a given requirement shall be made.

4.2 A sample shall be taken at the packing stage every hour which shall be examined visually for Description, absence of harmful & extraneous matter, free from lumps, brown & black peeks and examined by organoleptic methods for flavor, taste &odour. If the samples do not conforms to the specification in any of these requirements, the material manufactured during the hour prior to the drawal of sample shall either be rejected or reprocessed and checked for these requirements & conformity of the product shall be ensured.

4.3 Two samples shall be taken from every control unit (One sample is to be drawn in the beginning & other before end of the shift i.e. at equal intervals of time say 4 hours I continuous operation) for testing moisture. In case of failure of any of these samples the material in the control unit be either rejected or reprocessed for rectification of the defect. The material so reprocessed shall be tested for moisture after every two hours for next four control units. The original frequency of testing shall be restored when all the four control units are found confirming in moisture content.

4.4One sample shall be tested for Total Protein, Bacterial Count and Coliform Count in each Control unit. If the sample fail to conform to the requirements of bacterial Count or Coliform Count as given in the specification, the entire material in the control unit shall not be marked.

The material, may, however, be reprocessed and the defect rectified for failure in the requirement of total protein. Such reprocessed material when tested again shall conform to all the requirements

of the specification. However, for failures in the requirement of Bacterial Count and Coliform Count, the entire material in the control unit shall be rejected, segregated and suitably destroyed.

4.5 One sample from every fourth control unit shall be tested for Calcium, Vitamin A, AscorbicAcid, Iron, Total ash, Acid Insoluble Ash and Crude fiber and Fat. In case of failure of the sample in any of these requirements, the control unit shall be considered unfit for the purposes of marking. The control unit may, however, be reprocessed and the defects rectified. Such reprocessed material when tested again shall conform to all the requirements of the specification before it is considered fit for marking. All subsequent control units shall be tested for the requirements where failure has occurred till four consecutive control units tested conform to these requirements of the specification, whereupon the original frequency of testing may be resumed.

In case the production is started after shut down of the plant for more than a week's time for any reason, it shall be ensured before packing and dispatching the material with Standard Mark, that the material is tested and found confirming to all the requirements of the specification.

4.6In respect of all other clauses of the specification, the factory shall maintain appropriate controls and checks to ensure that the product conforms to the various requirements of the specification.

5. For Vitamin D1 Thiamine, Riboflavin, Nicotinic acid, Vitamin B 12 and Folic acid content of the product, the manufacturer would be required to maintain a record showing the quantity of these vitamins added to each batch of the product. A register shall also be maintained separately giving details of added vitamins. The total quantity of these materials in stock, the quantity used in each batch and the balance in stock shall be recorded. However, one sample of the product shall be sent to a BIS approved outside laboratory once in six months for ensuring conformity of the product in these requirements.

5.1 One sample shall be sent to an outside recognized laboratory once in two years for Protein Efficiency Ratio if the source and proportion of raw materials do not change and also whenever there is a change in the basic formula of the product.

5.2 One sample shall be taken once in three months and also whenever there is a change in the basic formula and tested for Aflatoxin, Gossypol and Urease Activity (whichever is applicable) based on the edible oil seed flour used for the Protein Rich Food Supplement, i.e. Aflatoxin if Groundnut Flour is used, Urease Activity if Soya Flour is used and Gossypol if Cotton seed Four is used. This may be done in a BIS approved outside laboratory in case facility does not exist with the firm.

6. HYGIENIC CONDITIONS- The Protein rich food supplements for infants & preschool children shall be manufactured, packed, stored & distributed in premises maintained under hygienic conditions (See IS 2491).

7. LEVELS OF CONTROL -The tests, as indicated in Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the entire production of the factory which is covered by this scheme and appropriate records maintained in accordance with paragraph 2 above.

7.1All production which conforms to the Indian Standard and covered in the licence should be marked with Standard mark.

8. RAW MATERIALS - For quality of ingredients added the provisions of clause 4.1 of IS 7021:2017 shall be complied with.

9. REJECTION -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. A separate record providing the detailed information regarding the rejected control unit and mode of their disposal shall be maintained. Such material shall in no case be stored together with that conforming to the specification. The Standard Mark (if already applied) on rejected material should be defaced

IS 7021:2017 (Incorporating Amendment no. 1)
PROTEIN RICH FOOD SUPPLEMENT FORINFANTS AND PRESCHOOL CHILDREN
TABLE 1 LEVELS OF CONTROL
(Para 7 of the Scheme of Inspection and Testing)

Test Details				Test equipment requirement R:required (or) S:Sub-contracting permitted	Levels of Control		Remarks
Clause	Requirements	Test Method			No.of samples	Frequency	
		Clause	Reference				
4.3.1	Description	4.3.1	IS 7021 : 1973	R	One	Every hour	See 4.3 of SIT
4.3.2	Flavor	4.3.2	IS 7021 : 1973	R	One	Every hour	See 4.3 of SIT
4.3.3, Table 2, Sl No. (i)	(i) Protein, % by mass	Annex C	IS 4684	R	One	Each Control Unit	
4.3.3, Table 2, Sl No. (ii)	(ii) Moisture, % by mass	Annex B	IS 4684	R	Two	Each Control Unit	Sec 4.4 of SIT
4.3.3, Table 2, Sl No. (ii)	(iii) Fat, % by mass	Annex F	IS 4684	R	One	Every 4th Control Unit	Sec 4.6 of SIT
4.3.3, Table 2, Sl No. (iv)	(iv) Total Ash, % by mass	Annex D	IS 4684	R	One	Every 4th Control Unit	Sec 4.6 of SIT
4.3.3, Table 2, Sl No.	(v)Acid Insoluble Ash, %	Annex E	IS 4684	R	One	Every 4th Control Unit	Sec 4.6 of SIT

(v)	by mass						
4.3.3, Table 2, Sl No. (vi)	(vi) Crude Fibre, , % by mass	Annex H	IS 4684	R	One	Every 4th Control Unit	Sec 4.6 of SIT
4.3.3, Table 2, Sl No. (vii)	(vii)Bacterial Count, per g	-	IS 5402	R	One	Each Control Unit	Sec 4.5 of SIT
4.3.3, Table 2, Sl No. (viii)	(viii)Coliform Count, CFU per g	-	IS 5401 (Part 1)	R	One	Each Control Unit	Sec 4.5 of SIT
	Type Test	-					
4.2.5, Table 1, Sl. No. (i)	(i) Vitamin C, mg	-	IS 5838	S	One	Each 4th Control Unit	Sec 4.6 of ST
4.2.5, Table 1, Sl. No. (ii)	(ii) Vitamin A, µg	-	IS 5886	S	One	Each 4th Control Unit	Sec 4.6 of ST
4.2.5, Table 1, Sl. No. (iii)	(iii)Vitamin D, µg	-	IS 5835	S	One	Once in 6 months	Sec 5.0 of SIT
4.2.5, Table 1, Sl. No. (iv)	(iv)Thiamine, mg	-	IS 5398	S	One	Once in 6 months	Sec 5.0 of SIT
4.2.5, Table 1, Sl. No. (v)	(v)Riboflavin, mg	-	IS 5399	S	One	Once in 6 months	Sec 5.0 of SIT
4.2.5, Table 1, Sl. No. (vi)	(vi)Niacin, mg	-	IS 5400	S	One	Once in 6 months	Sec 5.0 of SIT

4.2.5, Table 1, Sl. No. (vii)	(vii) Folate, µg	-	IS 7234	S	One	Every 4th Control Unit	Sec 4.6 of SIT
4.2.5, Table 1, Sl. No. (viii)	(viii) Vitamin B_{12}, µg	-	IS 7529	S	One	Every 4th Control Unit	Sec 5.0 of SIT
4.2.5, Table 1, Sl. No. (ix)	(ix) Calcium, mg	-	IS 5949	S	One	Once in 6 months	Sec 4.6 of SIT
4.2.5, Table 1, Sl. No. (x)	(x) Iron, mg	-	Annex D of IS 14433	S	One	Once in 6 months	Sec 4.6 of SIT
4.2.1	Protein Efficiency Ratio	-	IS 7481	S	One	Once in a 2 years	Sec 5.1 of SIT
4.2.2	Aflatoxin[@]	-	IS 16287	S	One	Once in 3 months	Sec 5.2 of SIT
4.2.3	Gossypol [@]	Annex B& Annex C	IS 4876	S	One	Once in 3 months	Sec 5.2 of SIT
4.2.4	Urease Activity [@]	Annex B	IS 7835	S	One	Once in 3 months	Sec 5.2 of SIT

(*) It would be required to get one sample tested every 6 months from outside laboratory and also maintain a record showing the quantity of these Vitamins added to each Control Unit.

(@)Aflatoxin content, Gossypol content and Urease Activity shall be determined only if flours of Groundnut, Cotton seed and Soya respectively have been added to the protein rich food supplements for infants and pre-school children.