PM/ 7021/ 1
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PRODUCT MANUAL
FOR PROTEIN- RICH FOOD SUPPLEMENTS FOR INFANTS AND PRE-SCHOOL CHILDREN ACCORDING TO IS 7021 : 2017

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.	**Product**	:	IS 7021 : 2017
	Title	:	Protein- Rich Food Supplements for Infants and Pre-School Children
	No. of Amendments	:	01
2.	**Sampling Guidelines:**		
a)	Raw material	:	For quality of ingredients added, the provisions of clause 4.1 of IS 7021 shall be complied with. Edible oilseed flour (s) if used– shall conform to IS 4875 (for Groundnut flour), IS 4876 (for cottonseed flour), IS 7835, IS 7836 or IS 7837 (for edible soya flour).
b)	Grouping guidelines	:	NA
c)	Sample Size	:	2 x 500gm
3.	**List of Test Equipment**	:	ANNEX - A
4.	**Scheme of Inspection and Testing**	:	ANNEX - B
5.	**Possible tests in a day :**		
	(i) Description (Cl.4.3.1) (ii) Flavour (Cl.4.3.2) (iii) Moisture (Cl. 4.3.3, Table-2) (iv) Protein **(**Cl. 4.3.3, Table-2)		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard mark as per IS 7021 : 2017 with the following scope:		
	Name of the product		Protein- Rich Food Supplements For Infants And Pre-School Children

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ANNEX-A
TO PRODUCT MANUAL
FOR PROTEIN- RICH FOOD SUPPLEMENTS FOR INFANTS AND PRE-SCHOOL CHILDREN ACCORDING TO IS 7021 : 2017

List of Test Equipment

Major test equipment required to test as per requirements of Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Protein Clause 4.3.3 & Table 2 (Annex C of IS 4684)	Kjeldahl flasks of 500ml capacity, Analytical Balance, Boiling chips or glass beads, Erlenmeyer flask(500ml), Heating device, Measuring cylinder, Distillation Assembly Rubber stopper Pipette, Beaker Burette, Distillation bulb, Conc. Sulphuric Acid, Mercuric Oxide or Metallic Mercury - nitrogen-free, Copper Sulphate, Anhydrous Sodium Sulphate Sodium Hydroxide –pellets, Hydrochloric or Sulphuric Acid, Standard Solution Sodium Hydroxide Standard Solution, Methyl Red Indicator, Round Bottom Flask , Pumice stone
3	Moisture Clause 4.3.3 & Table 2 (Annex B of IS 4684)	Analytical balance, Hot air oven 105 ± 2°C, Desiccator, Silica gel, Calcium Chloride.
4	Fat Clause 4.3.3 & Table 2 (Annex F of IS 4684)	Soxhlet Apparatus, Ethyl ether or petroleum ether, Soxhlet flask, Desiccator, Hot air oven, Analytical balance, Muffle Furnace 550 °C to 600°C.
5	Total Ash Clause 4.3.3 & Table 2 (Annex D of IS 4684)	Flat Bottom Dish Of stainless steel porcelain silica or platinum, Muffle Furnace 550 ° to 600°C, Desiccator, Analytical Balance, Hot air Oven, Heating Mantle.
6	Acid Insoluble Ash Clause 4.3.3 & Table 2 (Annex E of IS 4684)	Flat-Bottom Dish of stain less steel porcelain Silica or platinum, Muffle Furnace 550 ° C to 600°C, Desiccator, Measuring Cylinder, Heating Mantle, Watch-glass, Water bath, Hot Air oven, 135± 2°C, Weighing Balance. Dil. HCl, 5N.
7	Crude fibre Clause 4.3.3 & Table 2 (Annex H of IS 4684)	Dilute Sulphuric Acid, Sodium Hydroxide Solution, Analytical Balance, Ethyl Alcohol, Petroleum Ether, Measuring cylinder, Thimble, Beaker, Reflux condenser, Soxhlet apparatus, Linen Drying oven (105 ± 1°C), Gooch crucible, Muffle furnace at 600 ± 2°C, Desiccator.
8	Bacterial count, Clause 4.3.3 & Table 2 (IS 5402)	Hot air oven (Dry sterilization) Wet sterilization(Autoclave) Incubator(30° C±1 °C), Petri dish(size-90 mm to 100 mm in dia) Pipette(Capacity 1ml), Water bath (44 ° C to 47 ° C) Colony– Counting equipment (magnifying lens about 1,5x) pH meter Test tubes, Flasks/bottles, Bag mixture with sterile

		bag Microscope, Laminar air flow, Plate Count Agar.
9	Coliform count, Clause 4.3.3 & Table 2 (IS 5401 Part 1)	Hot air oven(Dry sterilization) Wet sterilization(Autoclave), Incubator, Petri dishes (dia- 90 mm to 100 mm), Pipette (Capacity 1ml), Water bath , Colony counting equipment, pH meter, Sterile blender jar, Microscope, Laminar air flow, VRBL Agar.
10	Vitamin C Clause 4.2.5 & Table 1 (IS 5838)	Analytical balance, Fluted filter paper, Erlenmeyer flasks, Burette, Pestle and mortar, Graduated flask, Chemicals used may be verified from IS 5838 for different test methods mentioned.
11	Vitamin A Clause 4.2.5 & Table 1 (IS 5886)	Spectrophotometer, Chromatographic apparatus, Extraction Apparatus, N-Hexane or Petroleum Ether Petroleum Ether Acetone Mixture Diethyl Ether – purified, Absorbent -Mix equal proportion by weight of activated magnesia and hyflo-super cell or equivalent Granular anhydrous Sodium Sulphate - conforming to IS 255, Glass Wool or Fat-Free Cotton, Beaker, Glass rod, Measuring Cylinder, Analytical Balance, Separating funnel.
18	Calcium Clause 4.2.5 & Table 1 (IS 5949)	Analytical Balance, Patton readers indicator, Erichrome black T Indicator, Volumetric flask, Standard zinc solution, Pipette Buffer solution, Burette, Sodium Hydroxide, Triethanolamine, Potassium Cyanide, Hydroxylamine, Hydrochloride, Standard Ethylene Diamine Tetra acetic Acid (EDTA).
19	Iron Clause 4.2.5 & Table 1 (Annex D of IS 14433)	Volumetric Flasks, One-Mark Graduated Flask, Separating Funnel, Graduated Glass Measuring Cylinder (Stoppered), Spectrophotometer, Pipette, Measuring cylinder, Weighing Balance, porcelain or platinum dish, muffle furnace, Heating Mantle, Graduated flask, Hydrochloric Acid, 20 percent Re-distilled Nitric Acid Concentrated Hydrochloric Acid, Distilled Water (see 1S 1070), Bromine Water- a saturated solution of bromine in water, Dilute Hydrochloric Acid Potassium Persulphate Solution, 2 percent (m/m) in distilled water, Potassium Thiocyanate Solution, 20 percent (m/m) in distilled water, Isobutyl Alcohol, Anhydrous Sodium Sulphate.
20	Aflatoxin Clause 4..2.2 (IS 16287)	HPLC system, Post column derivatization system, Fuming hood, UV spectrophotometer, Micropipette, Immuno affinity column, Blender, Flutted filter paper, Glass microfiber filter, Volumetric flask, Quartz cuvette, Membrane filter, Centrifuge, Volumetric flask, Measuring cylinder, Phosphate buffer saline, Sodium chloride, Iodine, Pyridinium, Hydrobromide per bromide, Aflatoxin Standards (B1, B2, G1, G2), Acetonitrile, Toluene, Methanol, Post column derivatization reagents, Sulphuric acid, Nitrogen.
21	Gossypol Clause 4.2.3 (Annex B & C of IS	Mechanical Wrist Action Shaker, Photo-Electric Colorimeter 440 mu to 460 mu, Grinding Mil, Solid Glass Beads, Conical Flask – 250ml glass stoppered, Pipettes, Volumetric -1ml,2ml,

	4876)	3ml, 4ml, 10 ml, 15ml, 20ml.,30ml, 35ml,and 50-ml Flasks, Volumetric 25-ml and 50-rnl capacity, Water-Bath Acetone, Potassium hydroxide, Ethyl alcohol, Aluminum granules, Glacial Acetic Acid, p-Anisidine, Sodium sulphite Decolorizing carbon, Buchner funnel under gentle suction, Refrigerator, vacuum desiccator, sulphuric acid, Brown bottle, Standard Gossypol Solutions, Sieve -1.0 mm, Whatman No. 1 filter paper, watch-glass, Hexane, 3-amino-1-propanol N-N Dimethyl formaldehyde, Aniline, pure gossypol.
22	Urease Activity Clause 4.2.4 (Annex B of IS 7835)	Water bath, PH meter, Test tubes 20 mm * 150 mm Rubber stopper, Volumetric flask, Potassium di-hydrogen phosphate, Di-potassium hydrogen phosphate, urea, Toluene

The list above is indicative only and may not be treated as exhaustive.

ANNEX B

SCHEME OF INSPECTION AND INSPECTION FOR PROTEIN- RICH FOOD SUPPLEMENTS FOR INFANTS AND PRE-SCHOOL CHILDREN ACCORDING TO IS 7021 : 2017

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 licence shall be stenciled/printed on each container of **Protein- Rich Food Supplements For Infants And Pre-School Children** or printed on the labels applied to the container, as the case may be, provided always that the material in each container to which this mark is thus applied conforms to every requirement of the specification.

3.1 Packing and Marking of protein-rich food supplements shall be done as per clause 5.1 and 5.2 of IS 7021. In addition, the following details shall be mentioned on each container legibly and indelibly:

a) BIS Licence No. CM/L_____.

b) BIS website details i.e – "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 constitute a control unit.

5. 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 whole production of the factory which is covered by this scheme and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

5.2 On the basis of tests and analysis results, the decision regarding conformity or otherwise of a control unit shall be taken as follows:

5.2.1 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 specks and examined by organoleptic methods for flavor, taste & odour. If the samples do not conform 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.

5.2.2 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 in 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.

5.2.3 One 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.

5.2.4 One sample from every fourth control unit shall be tested for Calcium, Vitamin A, Ascorbic Acid, 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.

5.2.5 For Vitamin D, Thiamine, Riboflavin, Niacin, 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.

5.2.6 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.

5.2.7 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 as per IS 2491.

7. RAW MATERIAL – For quality of ingredients added, the provisions of clause 4.1 of IS 7021 shall be complied with.

8. 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.

TABLE 1
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement R:required (or) S:Sub- contracting permitted**	**Levels of Control**		
Clause	**Requirements**	**Test Method Cl. Ref.**	**Test Method IS**		**No. of Samples**	**Frequency**	Remarks
4.3.1	Description	4.3.1	IS 7021	R	One	Every hour	See 5.2.1 of SIT
4.3.2	Flavor	4.3.2	IS 7021	R	One	Every hour	See 5.2.1 of SIT
4.3.3 & Table 2 (i)	Protein, % by mass	Annex C	IS 4684	R	One	Each Control Unit	See 5.2.3 of SIT
(ii)	Moisture, % by mass	Annex B	IS 4684	R	Two	Each Control Unit	Sec 5.2.2 of SIT
(iii)	Fat, % by mass	Annex F	IS 4684	R	One	Every 4th Control Unit	Sec 5.2.4 of SIT
(iv)	Total Ash, % by mass	Annex D	IS 4684	R	One	Every 4th Control Unit	Sec 5.2.4 of SIT
(v)	Acid Insoluble Ash,% by mass	Annex E	IS 4684	R	One	Every 4th Control Unit	Sec 5.2.4 of SIT
(vi)	Crude Fibre, % by mass	Annex H	IS 4684	R	One	Every 4th Control Unit	Sec 5.2.4 of SIT
(vii)	Bacterial Count, per g	-	IS 5402	R	One	Each Control Unit	Sec 5.2.3 of SIT
(viii)	Coliform Count, CFU per g	-	IS 5401 (Part1)	R	One	Each Control Unit	Sec 5.2.3 of SIT

4.2.5, Table 1 (i)	Vitamin C, mg	-	IS 5838	S	One	Every 4th Control Unit	Sec 5.2.4 of ST
(ii)	Vitamin A, µg	-	IS 5886	S	One	Every 4th Control Unit	Sec 5.2.4 of ST
(iii)	Vitamin D, µg*	-	IS 5835	S	One	Once in 6 months	Sec 5.2.5 of SIT
(iv)	Thiamine, mg*	-	IS 5398	S	One	Once in 6 months	Sec 5.2.5 of SIT
(v)	Riboflavin, mg*	-	IS 5399	S	One	Once in 6 months	Sec 5.2.5 of SIT
(vi)	Niacin, mg*	-	IS 5400	S	One	Once in 6 months	Sec 5.2.5 of SIT
(vii)	Folic acid, µg	-	IS 7234	S	One	Every 4th Control Unit	Sec 5.2.5 of SIT
(viii)	Vitamin B_{12}, µg	-	IS 7529	S	One	Every 4th Control Unit	Sec 5.2.5 of SIT
(ix)	Calcium, mg	-	IS 5949	S	One	Every 4th Control Unit	Sec 5.2.5 of SIT
(x)	Iron, mg	Annex D	IS 14433	S	One	Every 4th Control Unit	Sec 5.2.5 of SIT
4.2.1	Protein Efficiency Ratio	-	IS 7481	S	One	Once in 2 years	Sec 5.2.6 of SIT
4.2.2	Aflatoxin$^{@}$	-	IS 16287	S	One	Once in 3 months	Sec 5.2.7 of SIT
4.2.3	Gossypol $^{@}$	Annex B & Annex C	IS 4876	S	One	Once in 3 months	Sec 5.2.7 of SIT
4.2.4	Urease Activity$^{@}$	Annex B	IS 7835	S	One	Once in 3 months	Sec 5.2.7 of SIT

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empanelled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control and submit his own levels of control in column 3 with proper justification for approval by BO Head.

Note-3: **(*)**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.