PRODUCT MANUAL
FOR PROCESSED -CEREAL BASED COMPLEMENTARY FOODS
ACCORDING TO IS 11536 : 2007

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 11536 : 2007
	Title	:	PROCESSED -CEREAL BASED COMPLEMENTARY FOODS
	No. of Amendments	:	2
2.	**Sampling Guidelines:**		
a)	Raw material	:	No specific requirement
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 :**		

	Tests	**Clause no.**
	(i) Description	4
	(ii) Flavour and odour	5.7
	(iii) Moisture	5.9
	(iv) Total ash	5.9
	(v) Protein	5.9
	(vi) Vitamin –C	5.9
	(vii) Aflatoxin	5.10
	(viii) Ash insoluble in dilute HCl	5.9

6.	**Scope of the Licence** :	
	"Licence is granted to use Standard Mark as per IS 11536 : 2007 with the following scope:	
	Name of the product	Processed-Cereal Based Complementary Foods

ANNEX-A

TO PRODUCT MANUAL

FOR PROCESSED -CEREAL BASED COMPLEMENTARY FOODS

ACCORDING TO IS 11536 : 2007

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sr. No.	Test Equipment and chemicals	Tests used in with Clause Reference
1	**Flavour & odour**	Flavour and odour Clause 5.7
2	Hot air oven (Dry sterilisation) Wet sterilization(Autoclave) Incubator(30º C±1 ºC) Petri dish(size-90 mm to 100 mm in dia) Pipette(Capacity 1ml) Water bath(44 º C to 47 º 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	Bacterial count, Clause 5.8.1
3	Hot air oven(Dry sterilisation) Wet sterilization(Autoclave) Incubator Petri dishes (dia- 90 mm to 100 mm) Pipette(Capacity 1ml) Water bath (45 º C ± 0.5 º C) Colony counting equipment pH meter Sterile blender jar Microscope Laminar air flow VRBL Agar	Coliform Count Clause 5.8.2
4	Dry Sterilization (Oven) Wet sterilization (Autoclave) Incubator Water-Bath Temperature Compensated pH Meter Culture Bottles or Flasks Graduated Pipettes Petri Dishes (of diameter 90 to 100mm) Sterile blender jar Microscope Laminar air flow Micropipette (1,0.1,10 ml)	Yeast and Mould Clause 5.8.3

	BOD Incubator Thermometer Yeast Extract-Diastase-Chloramphenicol-Agar	
5	Inoculation loop Test tubes Electronic weighing balance Dry Sterilization (Oven) Wet sterilization (Autoclave) Incubator Water-Bath Durhams tube Sterile blender jar Grease free Slide Microscope Laminar air flow Pipette Cyclomixture Petri Plate Distilled water MacConkey broth medium Nutrient Agar Tergitol-7 Agar Gram Stain Kit	Escherichia Coli Clause 5.8.5
6	Analytical balance, Drying oven, Metal black, Copper tubes, Constant pressure regulator, Tube(made up of polycarbonate), Desiccator, Columns(polypropylene), Synthetic stoppers(made of soft polyethylene), container (to hold the column and Synthetic stopper), rod (polyethylene filter-lenth-120mm,dia-18mm), Tweezer, Soap film meter, Dry compressed air, Glass container with lid	Moisture Clause 5.9 & Table 1
7	Kjeldahl flasks, 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.	Total Protein Clause 5.9 & Table 1

	Potassium Sulphate or Anhydrous Sodium Sulphate - nitrogen-free Zinc (Granules Sulphite or Thiosulphate Solution Sodium Hydroxide –pellets Hydrochloric or Sulphuric Acid, Standard Solution Sodium Hydroxide Standard Solution Methyl Red Indicator	
8	Soxhlet extraction Apparatus Thimble Ammonia solution, containing a mass fraction of NH_3 of approximately 25% Ethanol (C_2H_50H), or ethanol denatured by methanol. Congo red solution Diethyl ether, free from peroxides (see A.3), containing no more than 2 mg/kg of antioxidants, and complying with the requirements for the blank test Light petroleum, with any boiling range between 30^0C and 60^0C or, as equivalent, pentane Mixed solvent- Shortly before use, mix equal volumes of diethyl ether (5.4) and light petroleum (5.5).	Total Carbohydrates Clause 5.9 & Table 1
9	Flat Bottom Dish Of stainless steel porcelain silica or platinum, Muffle Furnace, Desiccator, Weighing Balance, Hot air Oven, Heating Mantle.	Total Ash Clause 5.9 & Table 1
10	Flat-Bottom Dish of stain less steel porcelain Silica or platinum, Muffle Furnace, Desiccator, Measuring Cylinder, Heating Mantle, Watch-glass, Water bath, Hot Air oven, Weighing Balance. Dil. HCl	Ash Insoluble in dilute Hydrochloric Acid Clause 5.9 & Table 1
11	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,	Iron Clause 5.9 & Table 1

	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. 18. Dilute Hydrochloric Acid 19. Potassium Persulphate Solution, 2 percent (m/m) in distilled water (see IS 1070) 20. Potassium Thiocyanate Solution, 20 percent (m/m) in distilled water (see IS 1070) 1. Isobutyl Alcohol Anhydrous Sodium Sulphate	
12	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 : 255-1967 Glass Wool or Fat-Free Cotton Beaker, Glass rod, Measuring Cylinder, Weighing Balance, Separating funnel.	Vitamin A 5.9 & Table 1
13	Weighing balance, Fluted filter paper, Erlenmeyer flasks, Burette, Pestle and moter, Graduated flask, Chemicals used may be verified from IS 5838 for different test methods mentioned	Vitamin C Clause 5.9 & Table 1
14	Weighing Balance Wide mouthed vessel Measuring cylinder Grinding device Seive (size-1mm) Drying oven (130±2º C) Heating device (Electrically heater) Incineration dish (25-50ml capacity)/Filter crucible Muffle furnace-(550±25º C temperature control) Desicattor Separating device (Asbestos, Sea sand, filter cloth, filter paper)	Crude fibre Clause 5.9 & Table 1
15	Kjaldahl flask Atomic absorption spectrophotometer	Zinc Clause 5.9 & Table 1

	hydride generation vessel accessory potentiometric recorder Nitric acid Perchloric acid Sulphuric acid Hydrochloric acid Metal free water Sodium sulphate Sodium borohydride pellets Potassium chloride Standard zinc solution	
16	Atomic absorption spectrophotometer provided with background corrector and consisting of lamp current, support, fuel Pure Lead Metal Concentrated Nitric Acid Concentrated Hydrochloric Acid Standard Lead Solution	Lead Clause 5.9 & Table 1
17	Kjaldahl flask Atomic absorption spectrophotometer hydride generation vessel accessory potentiometric recorder Nitric acid Perchloric acid Sulphuric acid Hydrochloric acid Metal free water Sodium sulphate Sodium borohydride pellets Potassium chloride Standard Copper solution	Copper Clause 5.9 & Table 1
18	Atomic Absorption Spectropbotometer – with lamp current, Support, Fuel. Vapour Generation Kit Concentrated Hydrochloric Acid Concentrated Nitric Acid Concentrated Sulphuric Acid Potassium Iodide - Solid. Sodium Borohydride - Pellets. Standard Arsenic Solution	Arsenic Clause 5.9 & Table 1
19	Ammonium hydroxide solution Concentrated hydrochloric acid Dilute sulphuric acid Hydrogen sulphide gas Wash solution Ammonium Polysulphide solution dilute Acetic acid Beakers, Watch glass Heating arrangement Filter paper Porcelain crucible Bunsen or Meker burner	Tin Clause 5.9 & Table 1

	Desiccator Analytical weighing balance	
20	Kjaldahl flask Atomic absorption spectrophotometer hydride generation vessel accessory potentiometric recorder Nitric acid Perchloric acid Sulphuric acid Hydrochloric acid Metal free water Sodium sulphate Sodium borohydride pellets Potassium chloride Standard Cadmium solution	Cadmium Clause 5.9 & Table 1
21	Disc Mill Wrist-Action Shaker Chromatographic Column Funnel fluted filter paper Buchner funnel Rotary Evaporator with Continuous Feed Thin-Layer Chromatographic Apparatus Glass Plates Applicator Mounting Board Spotting Template Micro syringe Desiccating Storage Cabinet Storage Rack Ultraviolet Lamp Weighing balance Erlenmeyer flask. Pastel and mortar Spatula polyethylene stopper Silica Gel - for chromatography 0·15 to 0'2 mm Chloroform Hexane Diethyl Ether Methyl Alcohol Acetone Sodium Sulphate (Anhydrous) Boiling Chips Aflatoxin Standard Solution	Aflatoxin Clause 5.10

-List above is only indicative and may not be taken as exhaustive

-The list does not cover the following requirements, as these parameters are to be got tested from outside approved lab:

a) Salmonella and shigella
b) Staphylococcus Aureus

ANNEX – B

SCHEME OF INSPECTION AND TESTING

FOR PROCESSED -CEREAL BASED COMPLEMENTARY FOODS

ACCORDING TO IS 11536 : 2007

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.

2. **PACKING AND MARKING** – The Standard Mark as given in Schedule of the licence, shall be marked on the container of Processed-Cereal based complementary foods or printed on the label applied to it, provided always that the products marked conforms to every requirements of the specification.

2.1 Packing and marking on the containers shall be done as per the provision of IS 11536 : 2007. In addition, the following details shall be marked on each container:

a) BIS Licence No. CM/L _____.

b) BIS website details i.e –"For details of BIS certification please visit www.bis.gov.in"

c) For processed cereal based complementary foods for use in specific conditions, where protein needs to be restricted and where other cereals like wheat, soya, legumes and milk cannot be used and prepared with single cereal like rice or ragi, which shall have the protein content of 6-9 percent, such products shall be conspicuously labelled 'Processed Mono Cereal Based Complementary Food' for use in specific conditions under medical guidance only.'

3. CONTROL UNIT – For the purpose of this scheme, the quantity of Processed –Cereal Based Complementary Foods manufactured continuously from the same consignment of raw material in a day shall constitute a control unit.

4. LEVELS OF CONTROL - The tests as indicated in column 1 of 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 plan and appropriate records maintained in accordance with paragraph 2 above.

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

4.2 On the basis of test results, the decision regarding conformity or otherwise of a control unit to a given requirement of the specification shall be made as follows:

4.2.1 A sample shall be taken at the packing stage every hour which shall be examined visually for description, colour, absence of dust and extraneous matter; examined by organoleptic methods for flavour and odour. If the sample does not conform to the specification in any one or more of these requirements, the material manufactured during the hour prior to the drawl of sample either be rejected or reprocessed for its conformity to the requirements of the standard.

4.2.2 Four samples from every control unit before packing and at equal intervals of time shall be taken 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 and shall conform to the requirements of the specification. Thereafter, samples shall be drawn after every two hours for consequent four such control units and when all these samples conform to the requirements of the specification, the original frequency given in Table 1 for the parameter shall be restored.

4.2.3 Two samples shall be taken from every control unit before packing and at equal interval of time (one sample to be drawn after every 12 hours in case of 3 shifts operation and one sample after 8 hours in case of 2 continuous shift operation) and individually tested for total carbohydrates, bacterial count, coliform count, *Yeast and Mould Count* and *Escherichia coli*. If any one or both the samples fail to conform to any one or more of these requirements 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(s) rectified. Such reprocessed material when tested again shall conform to all the requirements of the specification.

4.2.4 Two samples from every seventh control unit shall be tested for Vitamin A, Vitamin C and Iron. Two samples from every 15th control unit shall be tested for Crude Fibre. If anyone sample fails to satisfy the requirements of any one or more of these characteristics, the corresponding control unit shall not be marked. The material in the failing control unit may, however, be reprocessed and the defect(s) rectified. Such reprocessed material when tested again shall conform to all the requirements of the specification. Two samples from every subsequent control unit shall be tested for the characteristics where failure has occurred till seven consecutive control units are found meeting the specification requirements, whereupon the original frequency of testing may be resumed. In case the production is started after the shutdown 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 conforming to all the requirements of the specification.

4.2.5 One sample shall be tested once in a month for Zinc, Heavy metals, Salmonella, Shigella and Staphylococcus Aureus. In case of failure of the sample in any one or more of these characteristics, the corresponding control unit shall not be marked and two samples from every subsequent control unit shall be tested for the characteristic(s) where failure has occurred till five consecutive control units are found to meet the specified requirements, whereupon the original frequency of testing may be resumed. The requirements of Salmonella and Shigella shall be tested in a laboratory situated away from the production area.

4.2.6 One sample from every fourth control unit shall be tested for total proteins, total ash and acid insoluble in dilute Hydrochloric Acid. In case of failure of the sample in any of these requirements, the control unit shall be considered unfit for the purpose of marking. The control unit may, however, be reprocessed and the defect(s) rectified. Such reprocessed material when tested again shall conform to 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 five consecutive control units tested conforms to these requirements of the specification.

4.2.7 One sample shall be tested once in a month for Aflatoxins. In case of failure of sample, the corresponding control unit shall not be marked and two samples from every subsequent control unit shall be tested for the characteristic(s) where failure has occurred till five consecutive control units are found to meet the specified requirements, whereupon the original frequency of testing may be resumed.

4.2.8 All ingredients used in manufacturing the product including the optional ones shall be clean, of good quality, safe and suitable for ingestion by infants. They shall conform to their normal quality requirements such as colour, flavour and odour. The vitamins and minerals used shall be of Food grade. The source of Vitamin Compounds and Mineral Salts may be used as given under clause 5.5.3 of IS 11536:2006. Appropriate records in relation to the statement made in the para shall be maintained.

4.2.9 Processed-cereal based Complementary foods shall be free from dirt and extraneous matter, preservative, added colour, and Complementary flavour. It shall also be free from any materials which are harmful to human health.

4.2.10 In 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. Added Vitamins - The licensee shall maintain a record showing the quantity of Vitamin D, Thiamine, Riboflavin, Niacin and folic acid added to each batch. 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 also be recorded.

6. HYGIENIC CONDITIONS – The factory should be maintained in a clean and hygienic condition as given in IS 2491. All the processing equipment should be properly cleaned and care should be taken to prevent infestation.

7. REJECTIONS – 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 shall be maintained giving information relating to the rejection of the control units of the condensed milk, partly skimmed and skimmed condensed milk not conforming to the specification and the method of their disposal. Such material, if packed, shall in no case be stored together with that conforming to the specification.

TABLE 1
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S:Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method Clause**	**Reference**		**No. of Sample**	**Frequency**	**Remarks**
4 and 5.1 to 5.5	Description	4 and 5.1 to 5.5	IS 11536	R	One	Every Hour	See 4.2.1 of SIT
5.7	Flavour and odour	5.7	IS 11536	R	One	Every Hour	See 4.2.1 of SIT
5.9 & table 1							
-do-	Moisture	-	IS 16072 (Routine Purpose) & IS 11623 (Reference Purpose)	R	Four	Each Control unit	See 4.2.2 of SIT
-do-	Total Protein	-	IS 7219	R	One	4th Control unit	See 4.2.6 of SIT
-do-	Total Carbohydrates	Annex C	IS 1656	R	Two	Each Control unit	See 4.2.3 of SIT
-do-	Total Ash	Annex B	IS 14433	R	One	4th Control unit	See 4.2.6 of SIT
-do-	Ash insoluble in dilute HCl	Annex C	IS 14433	R	One	4th Control unit	See 4.2.6 of SIT
-do-	Iron	Annex D	IS 14433	R	Two	Every 7 th Control Unit	See 4.2.4 of SIT

-do-	Vitamin A	-	IS 5886	R	Two	Every 7th Control Unit	See 4.2.4 of SIT
-do-	Vitamin C	-	IS 5838	R	Two	Every 7th Control Unit	See 4.2.4 of SIT
-do-	Added Vitamin D	-	IS 5835	-	-	-	See 5 of SIT
-do-	Thiamine	-	IS 5398	-	-	-	See 5 of SIT
-do-	Riboflavin	-	IS 5399	-	-	-	See 5 of SIT
-do-	Niacin	-	IS 5400	-		-	See 5 of SIT
-do-	Folic Acid	-	IS 7234	-	-	-	See 5 of SIT
-do-	Crude Fibre	-	IS 10226(Part 1)	R	Two	Every 15th Control Unit	See 4.2.4 of SIT
-do-	Zinc	Clause 15	IS 1699	S	One	Once in a Month	See 4.2.5 of SIT
-do-	**Heavy Metals** Lead	-	IS 12074	S	One	Once in a Month	See 4.2.5 of SIT
-do-	Copper	Clause 15	IS 1699	S	One	Once in a Month	See 4.2.5 of SIT
-do-	Arsenic	-	IS 11124	S	One	Once in a Month	See 4.2.5 of SIT
-do-	Tin	Clause 17	IS 2860	S	One	Once in a Month	See 4.2.5 of SIT
-do-	Cadmium	Clause 15	IS 1699	S	One	Once in a Month	See 4.2.5 of SIT
5.10	Aflatoxins	Appendix J	IS 4684	S	One	Once in a Month	See 4.2.7 of SIT
5.8.1	Bacterial Count	-	IS 5402	R	Two	Each Control unit	See 4.2.3 of SIT
5.8.2	Coliform Count	-	IS 5401	R	Two	Each Control unit	See 4.2.3 of SIT

5.8.3	Yeast and Mould	-	IS 5403	R	Two	Each Control unit	See 4.2.3 of SIT
5.8.4	Salmonella & Shigella	-	IS 5887(Part 3) IS 5887(Part 7)	S	One	Once in a Month	See 4.2.5 of SIT
5.8.5	E.coli	-	IS 5887(Part 1)	R	Two	Each Control unit	See 4.2.3 of SIT
5.8.6	Staphylococcus aureas	-	IS 5887(Part 2)	S	One	Once in a Month	See 4.2.5 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 empaneled by the Bureau.

Note-2: The control unit and levels of control as decided by the Bureau are obligatory to which the licensee shall comply with.