PRODUCT MANUAL FOR
FOLLOW- UP FORMULA – COMPLEMENTARY FOODS
ACCORDING TO IS 15757 : 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 15757 : 2007
	Title	:	Follow-Up Formula- Complementary Foods
	No. of Amendments	:	05
2.	**Sampling Guidelines:**		
a)	Raw material	:	No specific requirement
b)	Grouping guidelines	:	NA
c)	Sample Size	:	2 x 500gm
3.	**List of Test Equipment**	:	Please see ANNEX - A
4.	**Scheme of Inspection and Testing**	:	Please see ANNEX - B
5.	**Possible tests in a day:**		
	(i) Description (ii) Flavour, Taste and Odour (iii) Scorched Particles (iii) Moisture (iv) Total ash (v) Total Fat (vi) Total Milk Protein (vii) Acid insoluble ash		
6.	**Scope of the Licence** :		
	"Licence is granted to use Standard Mark as per IS 15757:2007 with the following scope:		
	Name of the product	Follow-Up Formula-Complementary Foods	

ANNEX-A
TO PRODUCT MANUAL
FOR FOLLOW-UP FORMULA-COMPLEMENTARY FOODS
ACCORDING TO IS 15757 : 2007

LIST OF TEST EQUIPMENTS

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

Sr. No.	Test Equipment	Tests used in with Clause Reference
1.	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 Cl 5.9, Table 1
2.	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	Total milk protein Cl 5.9, Table 1
3.	Ammonia solution, Ethanol, Congo red solution, Diethyl ether, Light petroleum with any boiling range between 30 °C and 60 °C, pentane with a boiling point of 36 °C, Analytical balance- capable of weighing to the nearest 1 mg, with a readability of 0.1 mg, Centrifuge, capable of holding the fat-extraction flasks or tubes and capable of spinning at a rotational frequency of 500 min−1 to 600 min−1 to produce a radial acceleration of 80*g* to 90*g* at the outer end of the flasks or tubes, Distillation or evaporation apparatus, Drying oven, electrically heated, with ventilation port(s) fully open, capable of being maintained at a temperature of 102 °C ± 2 °C throughout its working space, Water bath, capable of being maintained at a temperature of 65 °C ± 5 °C, Mojonnier-type fat-extraction flasks, Rack, for holding the fat-extraction flasks, Wash bottle, suitable	Total fat Cl 5.9, Table 1

	for use with the mixed solvent, Fat-collecting vessels, such as boiling flasks (flat-bottomed), of capacities 125 ml to 250 ml, conical flasks, of capacity 250 ml, or metal dishes, Boiling aids, fat-free, of non-porous porcelain or silicon carbide, Measuring cylinders, of capacities 5 ml and 25 ml, Pipettes, graduated, of capacity 10 ml, Tongs, Volumetric flask, one-mark, of capacity 100 ml.	
	Glycerol/Potassium Hydroxide regaent, Ethyl alcohol, Spectrophotometer, Heat resistant glass boiling tubes, Oil bath (LC – 0.5 deg Cel), Small tubes, Solid stem thermometer (Range – upto 200 deg Cel.), graduated flask	Linoleate Cl 5.9, Table 1
4.	Flat Bottom Dish Of stainlesssteel porcelain silica or platinum, Muffle Furnace, Desiccator, Weighing Balance, Hot air Oven, Heating Mantle.	Total ash Cl 5.9, Table 1
5.	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	Acid insoluble ash Cl 5.9, Table 1
6.	Silicon antifoaming agent Thermometers for measuring 24°C and 50°C, error +0.2°C max Water bath, upto 100°C, LC 0.1°C Scoop Analytical balance LC 0.01g Electric mixer Interval timer Centrifuge with Centrifuge tubes Siphon fitting or suction tube attached to water pump Scoop Camel hair brush Stirring rod Magnifying glass. Analytical Weighing balance, boiling tube with cork, water bath, Centrifuge and centrifuge tubes, refrigerator, or ice, needle, spatula, rod or wire, Aluminum dish (No. 1) with tight fitting lid. Pipette, air oven, desiccator.	Solubility Cl 5.9, Table 1 Insolubility index Solubility percent
7.	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 Cl 5.9, Table 1

8.	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.	Iron Cl 5.9, Table 1
9.	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 Cl 5.9, Table 1
10.	Patton and Reeder's Indicator (P and R Indicator), Standard Zinc Solution, Buffer solution, Standard Ethylene Diamine Tetraacetic Acid (EDTA) Solution, Sodium Hydroxide Solution, Triethanolamine Solution, Potassium Cyanide Solution, Hydroxylamine Hydrochloride Solution, Magnesium EDTA Complex Solution, conical flask, pH indicator paper or pH meter, burette	Calcium Cl 5.9, Table 1
11.	Eriochrome Black T Indicator (EBT Indicator), Standard Zinc Solution, Buffer solution, Standard Ethylene Diamine Tetraacetic Acid (EDTA) Solution, Triethanolamine Solution, Potassium Cyanide Solution, Hydroxylamine Hydrochloride Solution, Magnesium EDTA Complex Solution, conical flask, pH indicator paper or pH meter, burette	Magnesium Cl 5.9, Table 1
12.	Petri Dish, Autoclave, Incubator (30 ± 1°C), Water Bath (44 to 47°C), pH Meter, Colony Counter, Laminar Air Flow, Weighing Balance, Refrigerator, Plate Count Agar	Bacterial Count Cl 5.8.1
13.	Incubator (35±1°C), Petri Dish, Autoclave, Incubator (30 ± 1°C), Water Bath (44 to 47°C), pH Meter, Colony Counter, Laminar Air Flow, Weighing Balance, Refrigerator, VRBL Agar	Coliform Count Cl 5.8.2
14.	Nutrient Agar, Nutrient Broth, MacConkey Broth, MacConkey Agar, Eosin Methylene Blue Lactose Agar Medium, Tergitol-7 Agar Medium, Incubator (35±1°C), Petri Dish, Autoclave, Incubator (30 ± 1°C), Water	E. Coli Cl 5.8.3

	Bath (44 to 47°C), pH Meter, Colony Counter, Laminar Air Flow, Weighing Balance, Refrigerator	
15.	Yeast Extract-Destmse-Chloramphenicol-Agar Medium, Incubator(25±1°C), Petri Dish, Autoclave, Incubator (30 ± 1°C), Water Bath (44 to 47°C), pH Meter, Colony Counter, Laminar Air Flow, Weighing Balance, Refrigerator	Yeast & Mould Cl 5.8.6

List above in indicative only and may not be taken as exhaustive.

ANNEX-B

SCHEME OF INSPECTION AND TESTING

FOR FOLLOW-UP FORMULA-COMPLEMENTARY FOODS ACCORDING TO IS 15757 : 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 equipments.

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 the Schedule of the licence, shall be marked on the containers of Follow-Up Formula-Complementary Foods, or printed on the label applied to it, as the case may be, provided always that the product in each container to which this mark is thus applied, conform to every requirements of the specification.

3.1 Packing and marking shall be done as per clause 6.1 and 6.2 of the Indian Standard. In addition, the following details shall be mentioned on each container legibly and indelibly:

a) In case of flexible pack, the following information shall be marked on the label: "On opening, transfer the contents of the pack to a clear air tight container. After each use, replace the lid tightly and store in a cool dry place."
b) BIS Licence No.CM/L_____.
c) 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 entire quantity of Follow-up Formula – Complementary Foods manufactured and filled continuously in a day shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control submitted by the manufacturer 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 2.0 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 the test results, decision regarding conformity or otherwise of the material to the requirements of the specification shall be made as follows:

5.2.1 A sample shall be taken at the packing stage after every half an hour which shall be examined visually for appearance, colour, absence of dirt and extraneous matter, lumpiness, and examined by organoleptic methods for flavour, taste & odour and analyzed for scorched particles and moisture content. If the sample does not conform to the specification in any one or more of these requirements, the material manufactured during the half hour prior to the drawl of sample shall either be rejected or reprocessed for its conformity to these requirements of the Indian Standards.

5.2.2 Two samples shall be drawn from every control unit, one during the first half of the packing period and the other during the second half the packing period, these samples shall be tested individually for total fat content and Insolubility index. If any one or both of these samples fail to conform to any one or more of these requirements as laid down in the Indian Standard, the entire control unit shall either be rejected or reprocessed for its conformity to these requirements.

5.2.3 One sample from every fourth control unit of the same type shall be tested for Milk Protein, total ash and acid insoluble ash. In case of failure of the sample in either 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 all these requirements before it is considered fit for marking. All subsequent control units shall be tested for these requirements till five consecutive control units tested conform to the requirements of the specification.

5.2.4 One sample from every control unit shall be tested for the requirements of E.Coli, Yeast & Mould, bacterial count and coliform count as laid down in the Indian Standard. If it fails, the entire quantity of the material in the control unit shall be considered unfit for the purpose of marking and the material shall be rejected.

5.2.5 A sample shall be tested once a month for Heavy Metals (Lead, Arsenic, tin and cadmium) and the absence of Staphylococcus aureus, Salmonella and Shigella. 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 for Salmonella and Shigella shall be tested in an independent laboratory.

5.2.6 Once a fortnight a sample from a control unit shall be tested for vitamin A, Iron content, vitamin C, Calcium and Magnesium to ensure that the correct quantity of these constituents is being added to the follow up formula complementary foods. 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 all these requirements before it is considered fit for marking. All subsequent control units shall be tested for these requirements till five consecutive control units tested conform to the requirements of the specification.

5.2.7 One sample each from three consecutive Control Units shall be tested simultaneously for the requirements of Vitamin E, Phosphorous, Iodine, Copper, Zinc, Manganese, Sodium, Potassium, Chloride, Selenium and Linoleate once in twelve months.

5.2.7.1 In the event of failure of any one sample in any one or more of these requirements, the matter shall be investigated immediately and appropriate corrective actions taken under intimation to BIS.

In the event of two or more of these samples failing in one or more of these requirements, the matter shall be immediately reported to BIS for further actions in the matter.

5.2.8 For the quality of ingredients added, the provisions of clause 5.5 of IS 15757:2007 shall be complied with and appropriate records maintained.

5.2.9 Till such time suitable test methods are available, appropriate records shall be separately maintained giving details of Vitamins and Choline as given in Table 1 of IS 15757:2007, which are added in the formulation of the product. The total quantity of these materials in stock, the quantities used during the day and the balance in stock shall also be recorded. A similar record shall be maintained for the other nutrients and food additives as mentioned in Cl. 5.2 to 5.4 of IS 15757:2007.

6. HYGIENIC CONDITIONS – The material shall be manufactured packed, stored and distributed under hygienic conditions (see IS 2491). All the processing equipments shall be properly cleaned and care shall be taken to prevent infestation of any type.

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.

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 Methods Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
3.1	Protein derived from whole or skimmed milk in g / 100 available kcal	3.1	IS 15757	R	-	Each control unit	Calculation / Record / Declaration @
3.1	Energy provided by 100ml of the ready – for – consumption product in kcal or kJ	-do-	-do-	R	-	-do-	-do-
4	Description	4	-do-	R	One	Every half hour at the packing stage	See 5.2.1 of SIT
5.1	Starch, added colour & flavour, dirt & extraneous matter	5.1	-do-	R	One	-do-	-do-
5.1	Scorched particles	-	IS 13500	R	One	-do-	-do-
5.1	Free from any material harmful to human health	5.1	IS 15757	R	-	Each control unit	Declaration @
5.2 a)	Protein in g/available kcal	5.2 (a)	-do-	R	-	-do-	Calculation / Records @ See 5.2.9 of SIT
5.2 a)	Quality of protein, Amino Acid -do-addition if any	-do-	-do-	R	-	-do-	Calculation / Record / Declaration @ See 5.2.9 of SIT
5.2 b)	Fat in g/available kcal	5.2 (b)	-do-	R	-	-do-	Calculation / Records @ See 5.2.9 of SIT

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
5.2 (c)	Nutritionally available carbohydrates	5.2 (c)	IS 15757	R	-	Each control unit	Declaration / Records @ See 5.2.9 of SIT
5.3	Other Nutrients (if any)	5.3	-do-	R	-	-do-	Declaration / Records @ See 5.2.9 of SIT
5.4	Food Additives	5.4	-do-	R	-	-do-	Declaration / Records @ See 5.2.9 of SIT
5.5.1	All ingredients used	5.5.1	-do-	R	-	-do-	Declaration @ See 5.2.8 of SIT
5.5.2	Vitamins & Minerals (food grade, source & high bio availability of Iron)	5.5.2	-do-	R	-	-do-	Declaration @ See 5.2.8 of SIT
5.7	Flavour, taste & odour	5.7	-do-	R	One	Every half hour at the packing stage	See 5.2.1 of SIT
5.8	Bacteriological Specifications						
5.8.1	Bacterial Count	-	IS 5402	R	One	Each control unit	See 5.2.4 of SIT
5.8.2	Coliform Count	-	IS 5401 (Pt 1)	R	-do-	-do-	-do-
5.8.3	Escherichia Coli	-	IS 5887 (Pt 1)	R	-do-	Each control unit	See 5.2.4 of SIT
5.8.4	Staphylococcus Aureus	-	IS 5887 (Pt 2)	S	-do-	Once in a month	See 5.2.5 of SIT
5.8.5	Salmonella and Shigella	-	IS 5887(Pt 3) & IS 5887 (Pt 7)	S	-do-	-do-	-do-
5.8.6	Yeast and Mould Count	-	IS 5403	R	-do-	Each control unit	See 5.2.4 of SIT

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
5.9 & Table 1							
i)	Moisture	-	IS 16072 (routine purpose) and IS 11623 (reference purpose)	R	One	Every half hour at packing stage.	See 5.2.1 of SIT
ii)	Total Milk Protein		IS 7219*or ISO 8968-1[2)]	R	-do-	Every 4 th control unit	See 5.2.3 of SIT
iii)	Total Fat		IS 11721	R	Two	Each control unit	See 5.2.2 of SIT
iii)	Linoleate in g / 100 g	Annex G	IS 14433	S	One from each of three control units	Three consecutive control units, Once in a year.	See 5.2.7 of SIT
iv)	Total Ash	Annex B	IS 14433	R	One	Every 4 th control unit	See 5.2.3 of SIT
v)	Acid Insoluble Ash	Annex C	IS 14433	R	-do-	Every 4 th control unit	See 5.2.3 of SIT
vi)	Solubility						
	a) Insolubility Index		IS 12759	R	Two	Each control unit	See 5.2.2 of SIT
	b) Solubility		-do-	R	-do-	-do-	-do-
vii)	Vitamin A		IS 5886	S	One	Once a fortnight	See 5.2.6 of SIT

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
viii)	Iron	Annex D	IS 14433 or AOAC 984.27 or AOAC 985.35	S	One	-do-	See 5.2.6 of SIT
ix)	Added vitamin D	-	IS 5835	-	-	-	See note 1
x)	Thiamine	-	IS 5398	-	-	-	-do-
xi)	Riboflavin	-	IS 5399	-	-	-	-do-
xii)	Niacin	-	IS 5400	-	-	-	-do-
xiii)	Vitamin B6	-	IS 7530	-	-	-	-do-
xiv)	Folic Acid	-	IS 7234	-	-	-	-do-
xv)	Pantothenic Acid	-	IS 9840	-	-	-	-do-
xvi)	Vitamin B 12	-	IS 7529	-	-	-	-do-
xvii)	Biotin	-	IS 9820	-	-	-	-do-
xviii)	Vitamin C	-	IS 5838	S	One	Once a fortnight	See 5.2.6 of SIT
xix)	Vitamin E	-	IS 7235	S	One from each of the three control units	Three consecutive control units, once in year	See 5.2.7 of SIT
xx)	Vitamin K	-	-	-	-	-	See note 2

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Methods Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
xxi)	Choline	-	-		-	-	See note 2
xxii)	Sodium	-	IS 12760	S	One from each of the three control units	Three consecutive control units. Once in a year.	See 5.2.7 of SIT
xxiii)	Potassium	-	IS 12760	S	-do-	-do-	-do-
xxiv)	Chloride	-	IS 11763	S	One from each of the three control units	Three consecutive control units, Once in a year	See 5.2.7 of SIT
xxv)	Calcium	-	IS 5949*or AOAC 984.27 or AOAC 985.35	S	One	Once a fortnight	See 5.2.6 of SIT
xxvi)	Phosphorous	-	IS 12756	S	One from each of the three control units	Three consecutive control units, Once in a year.	See 5.2.7 of SIT
xxvii)	Magnesium	-	IS 5949*or AOAC 984.27 or AOAC 985.35	S	One	Once a fortnight	See 5.2.6 of SIT
xxviii)	Iodine	Annex H	IS 7224	S	One from each of the three control units	Three consecutive control units, Once in a year.	See 5.2.7 of SIT
xxix)	Copper	15	IS 1699	S	-do-	Three consecutive control units, Once in a year.	See 5.2.7 of SIT
xxx)	Zinc	15	IS 1699	S	-do-	-do-	-do-

xxxi)	Manganese	-	IS 3025(Pt 59)	S	-do-	-do-	-do-
xxxii)	Selenium	-	IS 3025(Pt 56) or IS 15303	S	-do-	-do-	-do-
xxxiii)	Heavy Metals						
	a) Lead	-	IS 12074	S	One	Once a month	See 5.2.5 of SIT
	b) Arsenic	-	IS 11124	S	-do-	-do-	-do-
	c) Tin	17	IS 2860	S	-do-	-do-	-do-
	d) Cadmium	15	IS 1699	S	-do-	-do-	-do-

Note: 1. The Indian Standards on methods for test indicated under clause 5.2.9 & Table 1 sl. No. (ix) to (xvii), (xx) and (xxxi) as given in column 1 are given for guidance only as they are under revision at present. As there is no other suitable and easily workable method at present, the manufacturers would be required to maintain record showing the quantity of these 'added vitamins', added to each batch.

Note: 2. Test method to be specified till such time test methods are prescribed, factory records shall be maintained of the addition per batch.

Note: 3. Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Subcontracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note: 4. The control unit and levels of control as decided by the Bureau are obligatory to which the licensee shall comply with.

Note: 5. @ Declaration or calculation or records (as the case may be) indicating conformity to the requirement.