PRODUCT MANUAL FOR SKIMMED MILK POWDER PART 2 EXTRA GRADE ACCORDING TO IS 13334 PT.2:2014

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 13334 (Part 2): 2014
	Title	**:**	Skimmed Milk Powder Part 2 Extra Grade
	No. of amendments	**:**	1
2.	**Sampling Guidelines**		
a)	**Raw material**	**:**	Milk intended for production of skimmed milk powder shall be tested for its freedom from Neutralizers, Preservatives and adulterants.
b)	**Grouping Guidelines**	**:**	NA
c)	**Sample Size**	**:**	2 x 500 g (separate samples for chemical and microbiological tests) packed in air-tight containers.
3.	**List of Test Equipment**	**:**	ANNEX - A
4.	**Scheme of Inspection and Testing**	**:**	ANNEX - B
5.	**Possible tests in a day**	**:**	All tests except microbiological tests.
6.	**Scope of the Licence :**		
	Licence is granted to use Standard Mark as per IS 13334 Pt.1:2014 with the following scope:		
	Name of the product	Skimmed Milk Powder- Extra Grade	
	Process	Spray drying	

ANNEX A
TO PRODUCT MANUAL FOR
SKIMMED MILK POWDER PART 2 EXTRA GRADE
ACCORDING TO IS 13334 PT.1:2014

LIST OF TEST EQUIPMENT

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

S. No.	Test Equipment	Tests used in with Clause Reference
1.	-Drying oven capable of being maintained at $87^0C \pm 1^0C$ throughout the working space, LC 1^oC. -Metal block -Copper tubes -Constant pressure regulator -Tube, made of polycarbonate -Columns made of hard polypropylene -Synthetic stoppers -Container, suitable for holding columns and synthetic stoppers -Rod made of polyvinyl chloride -Soap-film meter, suitable for measuring a flow of 33 ml/min -Dry compressed air, minimum pressure of 200 kPa, moisture content of 0.01 mgH_2O per Iitre at atmospheric pressure, free of any organic material. Use metal tubes only to connect the source of compressed air to the equipment in the drying oven. -Analytical Balance, LC 0.1 mg -Flat bottom moisture dishes with cover -Desiccator Screw capped bottles, Durham tubes, test tubes Sterile blender jar Inoculating loop, platinum-iridium or nickel-chromium or disposable loops Stop watch Volumetric Flask, 100ml, 250 ml & 1000 ml	Moisture Cl. 5.7, Table 1
2.	-Kjeldahl flasks -Heating device -Boiling chips or glass beads -Concentrated Sulphuric acid -Mercuric Oxide or Metallic Mercury -Potassium Sulphate or Anhydrous Sodium Sulphate -Zinc granules -Sulphite or Thiosulphate Solution -Sodium hydroxide -Hydrochloric acid or Sulphuric Acid, Standard Solution -Sodium hydroxide standard solution Methyl Red Indicator Paraffin or Silicon Antifoam Analytical balance distillation assembly and Erlenmeyer flasks	Milk protein in Milk SNF Cl. 5.7, Table 1

3.	Centrifuge with Centrifuge tubes Butyrometer, 6 Percent, 8 Percent and 10 Percent Scale with stopper Pipettes Analytical Balance, 0-500 g, LC 0.1 g Water bath, upto 100°C, LC 0.1°C Sulphuric acid Amyl alcohol Stemless -Funnel Wash bottle Glass rod Grater or Pestle and Mortar Scoop Camel hair brush	Fat Cl. 5.7, Table 1
4.	Silicon antifoaming agent Thermometers for measuring 24°C and 50°C, error $\pm$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	Insolubility index Cl. 5.7, Table 1
5.	-Flat-Bottom Dish, of stainless steel, porcelain, silica or platinum -Muffle Furnace upto 1200°C, LC 1°C - Desiccator -Air-Oven, capable of maintaining 100°C $\pm$ 2°C, LC 1°C -Flame for pre-heating - Analytical Balance	Total Ash Cl. 5.7, Table 1
6.	-Heater for boiling water - Analytical balance -Sodium hydroxide -Phenolphthalein solution Porcelain Dishes -stirring rods	Titrable Acidity Cl. 5.7, Table 1
	Potassium hexacyanoferrate(II) solution Zinc sulfate solution Sodium hydroxide solutions Glycerol solution Ammonium sulfate solution Buffer solution, pH 10. Nicotinamide adenine dinucleotide solution (NAD). L-Lactate dehydrogenase (L-LDH) D-Lactate dehydrogenase (D-LDH) Glutamate pyruvate transaminase (GPT) Lithium L-lactate solution Lithium D-lactate solution	Lactate content Cl. 5.7, Table 1

	Analytical balance, capable of weighing to the nearest 1 mg, LC 0.1 mg. Glass beaker Graduated cylinder One-mark volumetric flasks, of capacity 100 ml Pipettes, capable of delivering 0,02 ml, 0,05 ml, 0,2 ml, 1,0 ml and 2,0 ml Graduated pipettes, capable of delivering 5 ml and 10 ml, graduated in 0,1 ml divisions. Glass filter funnel, of diameter about 7 cm Filter paper, medium fast grade, of diameter about 15 cm, free from lactic acid and lactates Glass rod Plastic paddles, capable of mixing the sample-enzyme mixture in the spectrometric cell Spectrophotometer, capable of measuring at 340 nm, equipped with cells of optical path length 1 cm Parafilm	
7.	Scorched particles filtering discs Scorched particles Discs test cards Scorched particles tester Scorched particles standard photoprints for dry milk Analytical Balance, 0-500 g, L C 0.1 g Waring blender Defoaming agent	Scorched particles Cl. 5.7, Table 1
8	Plate count agar Overlay medium Oven Autoclave Incubator (30^{o} C+1^{o}C Petri dishes Water bath Colony counter pHmeter test tubes, flasks/bottles Filtration assembly and filter paper Laminar Air Flow Bench	Bacterial count Cl. 5.7, Table 1
9	Crystal violet neutral red bile lactose (VRBL) agar Brilliant green lactose bile broth Oven or Autoclave Incubator, 30Oc+ 1Oc or 37oC+1oC Petri dishes Total delivery plates Water bath, 44Oc TO 47Oc or 100oC Colony counter Test tubes Durham tubes Bottles or flasks pHmeter loop Filtration assembly and filter paper Laminar Air Flow Bench	Coliform count Cl. 5.7, Table 1
10	Nutrient broth Nutrient agar MacConkey Agar medium	E.coli Cl. 5.7, Table 1

	MacConkey broth medium Eosin methylene blue lactose agar medium Tergitol-7 agar medium Nutrient agar mediem for motility test Tsi medium for H2S test Medium for ureas test Medium for indole production Medium for methyl red and voges Proskauer tests Simmon's citrate agar Peptone water medium for carbohydrate fermentation test Filtration assembly and filter paper Laminar Air Flow Bench BOD Incubator, 5 -50^{o}C, LC 0.1^{o}C	
11	Nutrient broth Nutrient agar Blood agar Salt medium Baird parker medium Ethyl violet azide dextrose broth MacConkey agar medium Filtration assembly and filter paper Laminar Air Flow Bench	Coagulase positive staphylococcus aureus Cl. 5.7, Table 1
12	Buffered peptone water Rappaport-vassiliadis magnesium chloride/malachidte green medium (RV medium) Selenite/cystine medium Solid selective plating-out media Phenol red/brilliant green agar Nutrient agar Triple sugar/iron agar Urea agar L-Lysine decarboxylation medium Reagent for detection of β-galactosidase Reagents for Voges-Proskauer (VP reaction) -VP medium -creatine solution -1-Naphthol -Potassium hydroxide solution -Reagents for indole reaction Water bath Loops pHmeter culture bottles and flasks culture tubes measuring cylinders graduated pipettes petri dishes Filtration assembly and filter paper Laminar Air Flow Bench	Salmonella Cl. 5.7, Table 1
13	Dilution fluid Agar medium Base medium Polymyxin B solution Egg yolk emulsion Sheep blood agar	Aerobic (Bacillus cereus) Cl. 5.7, Table 1

	Oven or autoclave for sterilization Drying cabinet or incubator capable of operating between 37 °C ± 1 °C and 55 °C ± 1 °C. Incubator, capable of operating at 30 °C ± 1 °C. 6.4 Water baths, capable of being maintained at 44 °C to 47 °C. pH-meter, accurate to within ± 0,1 pH units at 25 °C. Petri dishes Graduated pipettes Spreaders Colony counter Filtration assembly and filter paper Laminar Air Flow Bench	
14	Plate count medium Saline peptone diluent Incubator - capable of being maintained at 37±1°C. Volumetric pipettes Test tubes Water bath (thermostatically controlled)	Anaerobic (sulfite reducing clostridia) Cl. 5.7, Table 1
15	Lithium chloride acriflavine and nalidixic acid (half fraser broth) Fraser broth Oxford agar PALCAM agar Selective solid plating-out media Tryptone soya yeast extract agar (TSYEA) Tryptone soya yeast extract broth (TSYEB) Sheep blood agar Carbohydrate utilization broth (rhamnose and xylose) Motility agar Laminar Air Flow Bench CAMP (Christie, Atkins, MunchPetersen) medium and test strains Hydrogen peroxide solution Phosphate-buffered saline (PBS) Oven or autoclave for sterilization BOD Incubator, 5 -50°C, LC 0.1°C Water bath, capable of being maintained at 47 ‘c t 2 ‘c. Loops pH meter test tubes or flasks measuring cylinder Filtration assembly and filter paper	Listeria monocytogenes Cl. 5.7 Table 1

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

ANNEX B
TO PRODUCT MANUAL FOR
Skimmed Milk Powder Part 2 Extra Grade
According to IS 13334 (Part 2) : 2014

SCHEME OF INSPECTION AND TESTING

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 in various formats, Form 1 for the tests carried out to establish conformity.

3. LABELLING, PACKINGAND MARKING— Labelling and marking shall be as given below:

3.1 STANDARD MARK: The Standard Mark, as specified by BIS, shall be stencilled with indelible ink or printed on labels applied to the container of skimmed milk powder provided always that the material in each container to which this mark is applied conforms to every requirement of the specification.

3.2 MARKING - As per the requirements of IS 13334 Pt.2: 2014.

3.2.1 In addition to above, following marking shall also be marked:

a) Any other marking required under provisions of Legal Metrology Act, 2009 and Legal Metrology (Packaged Commodities) Rules, 2011 framed thereunder.
b) In case of flexible pack, the following information shall be marked on the label:'Once opened, the entire product content should immediately be placed in a clean air-tight container'.
c) BIS Licence No. CM/L…….
d) BIS website details i.e –"For details of BIS certification please visit www.bis.gov.in"

3.3 PACKING: The material shall be packed as per cl. 6.1 of IS 13334 (Part 2):2014

4. CONTROL UNIT–

4.1 For the purpose of this Scheme, the entire quantity of milk powder manufactured continuously at a time in a period of 24 hours or a part thereof shall constitute a control unit.

4.1.1 Raw Milk: The raw milk received in factory shall be tested for fat, SNF, COB, Neutralizers, Additives, etc, and appropriate records maintained. Milk intended for production for skimmed milk powder shall be tested for freedom from Neutralizers, Preservatives, Adulterants and necessary records maintained.

5. 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.

5.1 On the basis of test and analysis results decision regarding the conformity or otherwise of a control unit of skimmed milk powder to the requirements of the specification shall be made as follows:

5.1.1 A sample shall be taken at the packing stage after every half an hour which shall be examined visually for appearance, colour, absence of lump and extraneous matter; examined by organoleptic methods for flavour and taste, absence of added colour & added flavour and analysed for 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 an hour prior to the drawl of sample shall either be rejected or reprocessed and the defect(s) rectified. Such reprocessed material when tested again shall conform to all the requirements of the specification.

5.1.2 Two samples shall be drawn from every control unit – one during the first half of the packing period and other during the second half of the packing period. These samples shall be individually tested for Milk Protein in Milk Solids not fat, Insolubility index, Milk fat, Titrable acidity, Scorched particles, Bacterial count, Coliform count & Escherichia coli. If any one or both the samples fail to conform to anyone or more of these requirement(s) as given in the specification, the entire material in the control unit shall not be marked. In case of manufacturers, 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.

5.1.3 Two samples from every seventh control unit (starting from a control unit chosen at random) shall be tested for total ash. If any one or both the samples fail to satisfy the requirement, the corresponding control unit shall not be marked. The material in the control unit may, however, be reprocessed and the defect 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 characteristic where failure has occurred till seven consecutive control units are found meeting the specification requirement, whereupon the original frequency of testing may be resumed.

5.1.4 Two sample(s) for Lactate content and one sample each for testing of and Coagulase Positive Staphylococcus aureus, Salmonella, Spore Count a) Aerobic (Bacillus cereus), b) Anaerobic (sulphite reducing clostridia), and Listeria monocytogenes shall be drawn from the product every month for testing as given under Table-2 of this scheme. 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 meeting the specification requirement(s) whereupon the original frequency of testing may be resumed.

Note: The requirement for pathogens (like Salmonella, etc) shall be tested in a laboratory situated away from the production area or in an outside recognised lab.

5.1.5 Skimmed Milk Powder shall be the material prepared by spray drying of fresh skimmed milk of cow or buffalo or a combination thereof.

5.1.6 The product may contain added calcium chloride, citric acid and sodium citrate, sodium salts of orthphosphoric acid and polyphosphoric (as linear phosphate), not exceeding 0.3 percent by mass of the finished product.

5.1.7 All processing and drying should be carried out in a manner that minimizes loss of nutritive value, particularly protein quality.

5.1.8 Undertaking w.r.t clause 5.8 of ISS to be submitted by the manufacturer stating that it shall be the responsibility of the manufacturer/repacking unit to comply with the relevant requirements as per Food Safety and Standards (Contaminants, toxins and residue) Regulations, 2011 and maintain records of the conformance.

6. HYGIENIC CONDITIONS – The material shall be manufactured packed, stored and distributed under hygienic conditions (see 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.

TABLE 1
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement** R: required (or)S: Sub-contracting permitted	**Recommended Levels of Control**		
Cl.	Requirement	Test Methods Clause	Reference		No. of Sample	Frequency	Remarks
4	Description	4	IS 13334 (Pt 2)	R	One	Every half an hour	See clause 5.1.1 of SIT
5.2	Freedom from extraneous matter, added colour & added flavour	5.2	-do-	R	One	-do-	-do-
5.4	Flavour and Taste	5.4	-do-	R	One	-do-	-do-
5.7 & Table 1	Moisture	-	IS 11623 or IS 16072	R	One	-do-	-do-
-do-	Milk Protein in milk solids not fat	-	IS 7219	R	Two	Each Control Unit	See Cl. 5.1.2 of SIT
-do-	Milk Fat	- Annex B	IS 11721 or IS 13334 (Pt 1)	R	Two	-do-	-do-
-do-	Insolubility Index	-	IS 12759	R	Two	-do-	-do-
-do-	Total Ash (On dry basis)	Annex B	IS 14433	R	Two	Every 7th Control Unit	See Cl. 5.1.3 of SIT
-do-		-	IS 11766	R	Two	Each Control Unit	See Cl. 5.1.2 of SIT
-do-	Titrable Acidity	-	IS 11202	S	Two	Once in a month	See Cl. 5.1.4 of SIT
-do-	Lactate Content	-	IS 13500	R	Two	Each Control Unit	-do-
	Scorched Particles						

TABLE 1 (Contd.)

(1)				(2)	(3)		
Test Details				**Test equipment requirement** R: required (or)S: Sub-contracting permitted	**Recommended Levels of Control**		
Cl.	Requirement	Test Methods Clause Reference			No. of Sample	Frequency	Remarks
5.7& Table 1	Bacterial Count	-	IS 5402	R	Two	Each Control Unit	See Cl. 5.1.2 of SIT
-do-	Coliform Count	-	IS 5401 (Part 1)	R	Two	-do-	-do-
-do-	*Escherichia coli*	-	IS 5887 (Part 1)	R	Two	-do-	-do-
-do-	Coagulase positive *Staphylococcus aureaus*	-	IS 5887 (Part 2)	S	One	Once in a Month	See Cl. 5.1.4 of SIT
-do-	Salmonella	-	IS 5887 (Part 3)	S	One	-do-	-do-
-do-	Spore Count a) Aerobic (*Bacillus cereus*)	-	IS 5887 (Part 6)	S	One	-do-	-do-
	b) Anaerobic (Sulfite reducing clostridia)	-	ISO 15213	S	One	-do-	-do-
-do-	*Listeria mono cytogenes*	-	IS 14988 (Part 2)	S	One	-do-	-do-

Notes: 1. The requirement for pathogens (like *Salmonella*, etc) shall be tested in a laboratory situated away from the production area or in an outside recognised lab.

2. 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.

3. Levels of control given in column 3 are obligatory to which the licensee shall comply with.