



उत्पाद मानुयल
शिशु आहार - दुग्ध अनाज आधारित अनुपूरक आहार - विशिष्ट
IS 1656: 2022 के अनुसार

PRODUCT MANUAL FOR
INFANT FOOD - MILK CEREAL BASED COMPLEMENTARY FOODS
ACCORDING TO IS 1656: 2022

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो) अनुरूपता मूल्यांकन (विनियम, 2018 की योजना -I के तहत प्रमाणन के संचालन में एकरूपता और पारदर्शिता के लिए इस उत्पाद मैनुअल का उपयोग सभी क्षेत्रीय / शाखा कार्यालयों और लाइसेंसधारियों द्वारा संदर्भ सामग्री के रूप में किया जाएगा। दस्तावेज़ का उपयोग बीआईएस प्रमाणन प्राप्त करने के इच्छुक संभावित आवेदकों द्वारा भी किया जा सकता है।

This Product Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure uniformity 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.

1.	मानक संख्या IS No.	:	IS 1656: 2022
	शीर्षक Title	:	Infant Food - Milk Cereal Based Complementary Foods
	संशोधनों की संख्या No. of amendments	:	02
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	a) Manufacturer to submit declaration/ undertaking in compliance to Clause 4.2 and 4.4 of IS 1656:2022. b) Manufacturer to submit declaration/undertaking in compliance to Cl. 4.3 of IS 1656:2022. In case sucrose and/or fructose is added as a carbohydrate source, records of their addition shall be maintained by the manufacturer (may also refer Note under Cl. 4.3 of IS 1656:2022) c) In case the manufacturer opts for addition of any Optional Ingredients as per provisions of Cl. 4.5 of IS 1656:2022, test report/test certificates as per table 1 of IS 1656:2022 to be submitted. However, for addition of DHA/ARA, declaration/ undertaking in compliance to Cl. 4.5.1 of IS 1656:2022 to be submitted. d) In case the manufacturer opts for addition of any Food Additives

		for Type II-Infant Formula, it is required to submit declaration/undertaking in compliance to Clause 4.6.1 and/or Clause 4.6.2 of IS 1656:2022 Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance.
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	: Not applicable
c)	नमूने का परिमाण Sample Quantity	: 2 X 500 gms Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (in case of market surveillance, effort may be made to procure the required quantity of product sample, as far as possible since raw material sample may not be available in market)
d)	परीक्षण अनुरोध में घोषित किए जाने वाले पैरामीटर Parameters to be Declared in Test Request	: Name of the product
3.	परीक्षण उपकरणों की सूची List of Test Equipment	: Please see Annex – A
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	: Please see Annex – B
5.	एक दिन में संभावित परीक्षण Possible tests in a day	
	i) Description ii) Moisture iii) Protein (Total Protein including milk protein and Milk Protein) iv) Fat (Total Fat and Milk Fat) v) Total Carbohydrates vi) Total Ash vii) Acid Insoluble Ash in dilute hydrochloric acid viii) Iron Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide ready reference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.	
6.	लाइसेंस का दायरा /Scope of the Licence:	
	“Licence is granted to use Standard Mark as per 1656: 2022 with the following scope:	
	Name of the product	Infant Food - Milk-Cereal Based Complimentary foods

ANNEX – A
List of test equipment

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	Tests used in with Clause Reference	Test equipment/Chemical
1.	Moisture Cl. 4.8, Table 2, Sl. No. (i)	Hot Air Oven, Electronic Balance, Desiccator
2.	Protein a) Total Protein including milk protein; b) Milk protein Cl. 4.8, Table 2, Sl. No. (ii)	Potassium sulfate (K_2SO_4) nitrogen free, Copper (II) sulfate pentahydrate solution, Sulfuric acid (H_2SO_4), Sodium hydroxide ($NaOH$) solution, methyl red, ethanol, bromocresol green, Boric acid solution, Hydrochloric acid, Ammonium sulfate, Tryptophan or lysine hydrochloride, Water Bath, Analytical balance, Burette or automatic pipette, Graduated measuring cylinders, Digestion flasks (Kjeldahl), of 500 ml or 800 ml capacities, Boiling aids, e.g. hard pieces of porcelain or high-purity amphoteric alundum (i.e. carbarundum) granules, Digestion apparatus, Distillation apparatus, Digestion block and Digestion tubes, Exhaust manifold, Centrifugal scrubber apparatus or filter pump or aspirator, Distillation unit, Automatic titrator provided with a pH meter, Filter paper, Illuminated magnetic stirrer plate.
3.	Fat a) Total fat; b) Milk fat Cl. 4.8, Table 2, Sl. No. (iii)	<u>Gravimetric Method (as per IS 11721)</u> <u>Reagents</u> Ammonia solution, Ethanol (C_2H_5OH) or ethanol denatured by methanol, Congo red solution, Diethyl ether ($C_2H_5OC_2H_5$), Light petroleum <u>Apparatus</u> Analytical balance, Centrifuge, Distillation or evaporation apparatus, Drying oven, Water bath, Mojonnier-type fat-extraction flasks, Rack, Wash bottle, Fat-collecting vessels, Boiling aids, Measuring cylinders, Pipettes, Tongs, Volumetric flask
4.	Total ash Cl. 4.8, Table 2, Sl. No. (v)	Flat Bottom Dish Of stainless steel porcelain silica or platinum, Muffle Furnace, Desiccator, Weighing Balance
5.	Acid insoluble ash in dilute hydrochloric acid Cl. 4.8, Table 2, Sl. No. (vi)	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
6.	Vitamin A Cl. 4.8, Table 2, Sl.	Methyl-t-butyl ether, n-Hexane, Ethanol Methanol, Iso-octane (2,2,4-trimethylpentane), Papain (from Carica papaya), Hydroquinone,

	No. (vii)	Glacial acetic acid, Anhydrous sodium acetate, Dilute hydrochloric acid solution, HPLC mobile phase A, HPLC mobile phase B, Retinyl palmitate reference standard, Retinyl acetate reference standard, α -tocopheryl acetate reference standard, α -tocopherol reference standard, Retinyl palmitate stock standard solution, Retinyl acetate stock standard solution, α -tocopheryl acetate stock standard solution, α -tocopherol stock standard solution, HPLC system, HPLC column, Water bath, Centrifuge, UV-VIS spectrometer, Analytical balance, Amber HPLC vials, Disposable centrifuge tubes, Laboratory mechanical test tube shaker, Sonicator bath, One-mark volumetric flasks, Vacuum filtration apparatus, Laboratory glass bottles
7.	Vitamin C, Cl. 4.8, Table 2, Sl. No. (viii)	<u>2.6 -Dichlorophenol Indophenol Method as per IS 5838</u> Trichloroacetic Acid, Metaphosphoric Acid, Standard Ascorbic Acid Solution, Standard Indophenol Solution, Analytical Balance, Glass Stoppered Graduated Flask, Dessicator, Sodium Bicarbonate, Fluted Filter Paper, Amber Glass Stoppered Bottle, Refrigerator, Erlenmeyer Flasks, Titration Assembly, Mortar, Acid Washed Sand <u>2,4-Dinitrophenylhydrazine Method as per IS 5838</u> Photoelectric Colorimeter, Standard Ascorbic Acid Solution, Sulphuric Acid Solution, 2,4 Dinitrophenylhydrazine, Thiourea, Trichloroacetic Acid, Acid Washed Animal Charcoal, Sulphuric Acid, Mortar, Acid Washed Sand, Homogenizing Tube and Rod, Whatman No.42 Filter Paper, General Glasswares, Incubator, Titration Assembly <u>Determination of Vitamin C by (Ultra) High Performance Liquid Chromatography with Ultraviolet Detection ((U) HPLC-UV) as per IS 17176</u> Acetonitrile, Ascorbic acid, Decylamine, Phosphoric acid, Ultra-pure water, Sodium acetate trihydrate, Trichloroacetic acid (TCA), Tris [2-carboxyethyl]phosphine (TCEP), Isoascorbic acid, Orotic acid, Balances, Volumetric flasks, Beaker, pH meter, Paper filter, Membrane filters, UHPLC column, HPLC column, LC system, HPLC or UHPLC system
8.	Iron, Cl. 4.8, Table 2, Sl. No. (ix)	<u>Inductively coupled plasma atomic emission spectrometry (ICP-AES) method as per ISO 15151:2018</u> Water, Nitric acid (HNO₃), Nitric acid solution (HNO₃), Element stock solutions of Ca, P, K, Standard working solution of Fe, Internal standard solution H₂O₂, Analytical balance, One-mark volumetric flasks, One-mark pipettes, Micropipettes, Dispenser, High-density polyethylene bottles, Pressurized microwave assisted wet digestion system, ICP-AES instrument, Water bath, Appropriate grinding device, Sampler tubes, Cyclonic spray chamber, Concentric nebulizer

		<u>Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 21424</u> Methanol, Nitric acid (HNO₃) concentrated ultrapure reagent grade, Nitric acid (HNO₃), trace metal grade H₂O₂, Laboratory water, Surfactant, Argon gas, Helium gas, Hydrogen gas, Iron Standard Stock Solution, Standard Reference Material (SRM) of cereal with certified values of Fe, inductively coupled plasma mass spectrometer, Microwave oven, Hydrogen generator, Magnetic stir plate and PTFE-coated magnetic stir bars, Analytical balance, Fume hood, Common laboratory glassware/plasticware, Repipetter, Bottle top dispenser, Volumetric pipettes, Digital pipettes <u>Method as per AOAC 985.35</u> Glassware, Evaporating dish, Atomic absorption spectrophotometer, Furnace, Water, Standard stock solution of Fe, Nitric acid, Lanthanum oxide, Lanthanum chloride solution, Cesium chloride solution, Filter pulp, Microwave Oven, Analytical Balance, Hot Plate, Steam Bath
9.	Crude Fibre (on dry basis), Cl. 4.8, Table 2, Sl. No. (x)	Sulphuric acid, Sodium hydroxide, Acetone, Hydrochloric acid, Filter aid, Anti-foam agent, Anti-bumping agent, Grinding device, Sieve, of metal wire cloth, Drying oven, Heating device, Incineration dish, Muffle furnace, Desiccator, Analytical balance, Separating device (like Filter crucible / Centrifuge / Buchner funnel pre- weighed to the nearest 1 mg, in about 100 ml of water provided with a stainless steel screen/ Filter flask and Glass funnel / Fine filter cloth and Gooch crucible), Bromothymol blue
10.	Vitamin D Cl. 4.8, Table 2, Sl. No. (xi)	Vitamin D ₂ (ergocalciferol), Vitamin D ₃ (cholecalciferol), <i>d</i> 6-Vitamin D ₂ , <i>d</i> 6-Vitamin D ₃ , PTAD (4-phenyl-1,2,4-triazoline-3,5-dione), Formic acid, Potassium hydroxide, Pyrogallol, Ethanol, Methanol, Isooctane, Acetone, Acetonitrile, Ultra high performance liquid chromatography (UHPLC) system, consisting of dual pump system, a sample injector unit, a degasser unit, and a column oven, Triple quadrupole mass spectrometer, Solid core silica column, Spectrophotometer, Centrifuge tubes(polypropylene), Boiling tubes(glass), Water bath (range= 20 °C to 70 °C), Disposable syringes, Syringe filters, Centrifuges, Pasteur pipette(glass), Horizontal shaker, Micro centrifuge tubes, Filter membranes(0.45 µm), Cryogenic vials
11.	Thiamine, Cl. 4.8, Table 2, Sl. No. (xii)	Niacinamide (nicotinamide), Niacin (nicotinic acid), Pyridoxine hydrochloride, Riboflavin, Thiamine hydrochloride, Pyridoxamine dihydrochloride, Pyridoxal hydrochloride, 2 H ₄ -Niacinamide, 2 H ₄ -Nicotinic acid, 13 C ₄ -Pyridoxine: pyridoxine:HCl (4,5-bis(hydroxymethyl)- 13 C ₄), 2 H ₃ -Pyridoxal, 2 H ₃ -Pyridoxamine,

		13 C 4 -Thiamine chloride, 13 C 4 ,15 N 2-Riboflavin, Acid phosphatase, Papain from Carica papaya, α -amylase from aspergillus oryzae, Hydrochloric acid concentrated, Ammonium formate, Glacial acetic acid, Formic acid, Laboratory water, Methanol, Ethylenediaminetetracetic acid, disodium salt dihydrate (EDTA), Potassium phosphate dibasic, meta-Phosphoric acid, Buffer solutions for pH meter calibration, Phosphoric acid, Potassium hydroxide, Waters Acquity BEH C18 column2) or equivalent, UHPLC system, Waters Acquity Classic2), or equivalent, Tandem quadrupole mass spectrometer with ESI probe, Waters Xevo TQ- S2), or equivalent, Analytical balances, Water purifier, Water bath shaker, Bottle-top dispenser, pH meter, Vortex mixer, Multi-position magnetic stir plate, Room light shields, Graduated cylinders, Beakers, Volumetric flasks, Mobile phase bottles, Disposable plastic Pasteur pipettes, Amber bottles, Weighing vessels, Positive displacement pipettes, Positive displacement pipette tips, Plastic syringe, Syringe filters, Plastic centrifuge tubes, Autosampler vials, PTFE coated magnetic stir bars.
12.	Riboflavin, Cl. 4.8, Table 2, Sl. No. (xiii)	Niacinamide (nicotinamide), Niacin (nicotinic acid), Pyridoxine hydrochloride, Riboflavin, Thiamine hydrochloride, Pyridoxamine dihydrochloride, Pyridoxal hydrochloride, 2 H4 -Niacinamide, 2 H4 -Nicotinic acid, 13 C 4 -Pyridoxine: pyridoxine: HCl (4,5-bis(hydroxymethyl)- 13 C 4), 2 H3 -Pyridoxal, 2 H3 -Pyridoxamine, 13 C 4 -Thiamine chloride, 13 C 4 ,15 N 2-Riboflavin, Acid phosphatase, Papain from Carica papaya, α -amylase from aspergillus oryzae, Hydrochloric acid concentrated, Ammonium formate, Glacial acetic acid, Formic acid, Laboratory water, Methanol, Ethylenediaminetetracetic acid, disodium salt dihydrate (EDTA), Potassium phosphate dibasic, meta-Phosphoric acid, Buffer solutions for pH meter calibration, Phosphoric acid, Potassium hydroxide, Waters Acquity BEH C18 column2) or equivalent, UHPLC system, Waters Acquity Classic2), or equivalent, Tandem quadrupole mass spectrometer with ESI probe, Waters Xevo TQ- S2), or equivalent, Analytical balances, Water purifier, Water bath shaker, Bottle-top dispenser, pH meter, Vortex mixer, Multi-position magnetic stir plate, Room light shields, Graduated cylinders, Beakers, Volumetric flasks, Mobile phase bottles, Disposable plastic Pasteur pipettes, Amber bottles, Weighing vessels, Positive displacement pipettes, Positive displacement pipette tips, Plastic syringe, Syringe filters, Plastic centrifuge tubes, Autosampler vials, PTFE coated magnetic stir bars.
13.	Niacin equivalent, Cl. 4.8, Table 2, Sl. No. (xiv)	Niacinamide (nicotinamide), Niacin (nicotinic acid), Pyridoxine hydrochloride, Riboflavin, Thiamine hydrochloride, Pyridoxamine dihydrochloride, Pyridoxal hydrochloride, 2 H4 -Niacinamide, 2 H4 -Nicotinic acid, 13 C 4 -Pyridoxine: pyridoxine: HCl (4,5-bis(hydroxymethyl)- 13 C 4), 2 H3 -Pyridoxal, 2 H3 -Pyridoxamine, 13 C 4 -Thiamine chloride, 13 C 4 ,15 N 2-Riboflavin, Acid phosphatase, Papain from Carica papaya, α -amylase from aspergillus oryzae, Hydrochloric acid concentrated, Ammonium

		formate, Glacial acetic acid, Formic acid, Laboratory water, Methanol, Ethylenediaminetetracetic acid, disodium salt dihydrate (EDTA), Potassium phosphate dibasic, meta-Phosphoric acid, Buffer solutions for pH meter calibration, Phosphoric acid, Potassium hydroxide, Waters Acquity BEH C18 column2) or equivalent, UHPLC system, Waters Acquity Classic2), or equivalent, Tandem quadrupole mass spectrometer with ESI probe, Waters Xevo TQ- S2), or equivalent, Analytical balances, Water purifier, Water bath shaker, Bottle-top dispenser, pH meter, Vortex mixer, Multi-positionmagnetic stir plate, Room light shields, Graduated cylinders, Beakers, Volumetric flasks, Mobile phase bottles, Disposable plasticPasteur pipettes, Amber bottles, Weighing vessels, Positive displacement pipettes, Positive displacement pipette tips, Plastic syringe, Syringe filters, Plastic centrifuge tubes, Autosampler vials, PTFE coated magnetic stir bars.
14.	Dietary Folate equivalent, Cl. 4.8, Table 2, Sl. No. (xv)	<u>UHPLC-MS/MS method as per AOAC 2013.13</u> UHPLC Column, liquid chromatograph, Detector, Amber glassware, Analytical balance, Homogeniser, pH meter, Water Bath, Whatman filer paper, Solid-phase extraction cartridges, Amber vials, L-ascorbic acid, Ammonium acetate, Disodium hydrogen phosphate powder, a-Amylase from porcine pancreas, α-Amylase from Bacillus subtilis, Protease from Streptomyces griseus, Ethanol, Methanol, Isopropanol, Acetonitrile, Formic acid, Acetic acid glacial, Sodium hydroxide solution, Hydrochloric acid, Ortho-phosphoric acid
15.	Zinc, Cl. 4.8, Table 2, Sl. No. (xvi)	<u>Method as per IS 1699</u> Kjeldahl 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 zinc solution, Weighing Balance, General Glasswares, Burner/ Heating Element/ Hot Plate <u>Inductively coupled plasma atomic emission spectrometry (ICP-AES) method as per ISO 15151:2018</u> Water, Nitric acid (HNO₃), Nitric acid solution (HNO₃), Element stock solutions of Ca, P, K, Standard working solution of Zn, Cu, Internal standard solution H₂O₂, Analytical balance, One-mark volumetric flasks, One-mark pipettes, Micropipettes, Dispenser, High-density polyethylene bottles, Pressurized microwave assisted wet digestion system, ICP-AES instrument, Water baths, Appropriate grinding device, Sampler tubes, Cyclonic spray chamber, Concentric nebulizer <u>Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 21424</u> Methanol, Nitric acid (HNO₃) concentrated ultrapure reagent grade, Nitric acid (HNO₃), trace metal grade H₂O₂, Laboratory water,

		Surfactant, Argon gas, Helium gas, Hydrogen gas, Iron Standard Stock Solution, Standard Reference Material (SRM) of cereal with certified values of Fe, inductively coupled plasma mass spectrometer, Microwave oven, Hydrogen generator, Magnetic stir plate and PTFE-coated magnetic stir bars, Analytical balance, Fume hood, Common laboratory glassware/plasticware, Repipetter, Bottle top dispenser, Volumetric pipettes, Digital pipettes
16.	Aerobic Plate count, Cl. 4.8, Table 3, Sl. No. (i)	Diluents, Agar Medium, Oven, Incubator, Water bath, pH-meter, Petri dishes, Total delivery graduated pipettes, Colony-counting equipment, Tubes, flasks or bottles
17.	Coliform count, Cl. 4.8, Table 3, Sl. No. (ii)	Crystal violet neutral red bile lactose (VRBL) agar, Brilliant green lactose bile broth, Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Incubator, Water bath, Colony-counting equipment, Tubes, flasks or bottles, Durham tubes, pH-meter, Loop of platinum-iridium or nickel-chromium
18.	<i>Staphylococcus aureus</i> (Coagulase positive), Cl. 4.8, Table 3, Sl. No. (iii)	Diluent, Baird-parker Agar Medium, Potassium Tellurite solution, Egg Yolk Emulsion, Sulfamethazine, Brain-heart infusion broth, Rabbit Plasma, Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Incubator, Drying cabinet or incubator, Water bath, Test tubes, flasks or bottles with screw caps, Petri dishes, Straight wire, Pasteur pipette, Total-delivery graduated pipettes, Spreaders, pH meter
19.	Yeast and mould count, Cl. 4.8, Table 3, Sl. No. (iv)	Diluent (0.1 % (mass concentration) peptone water broth), Culture medium (Dichloran 18 % (mass concentration) glycerol agar (DG18)), Incubator (capable of operating at 25°C±1°C), Total delivery pipettes, Water bath (capable of operating at 44 °C to 47 °C), pH meter, Bottles, flasks and tubes, Petri dishes (sterile, in glass or plastic, with a diameter 90 mm to 100 mm), Microscope (magnification 250 to 1 000 times)), Spreaders (made of glass or plastic of diameter less than 2 mm and length 80 mm), Binocular magnifier
20.	<i>Salmonella sp.</i> , Cl. 4.8, Table 3, Sl. No. (v)	Buffered peptone water, Rappaport-Vassiliadis medium with soya (RVS broth) or Modified Semi-solid Rappaport-Vassiliadis (MSRV) agar and Muller-Kauffmann tetrathionate-novobiocin broth (MKTT) broth, Xylose Lysine Deoxycholate agar (XLD agar), Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Drying cabinet or oven, Incubator, Water bath, Refrigerator, Freezer Sterile loops, pH-meter, Sterile tubes, bottles, or flasks, Sterile Petri dishes
21.	<i>Listeria monocytogenes</i> , Cl. 4.8, Table 3, Sl. No. (vi)	Acriflavine and nalidixic acid, Fraser broth, Listeria Agar, Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Drying cabinet, Incubators, Water bath, Sterile loops, pH meter, Graduated pipettes or automatic pipettes, Petri dishes, Microscope, Refrigerator

22.	<i>Bacillus cereus</i> , Cl. 4.8, Table 3, Sl. No. (vii)	Dilution fluid, Agar medium, Polymyxin B solution, Egg yolk emulsion, Complete medium (MYP agar), Sheep blood agar, Defibrinated sheep blood, Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Drying cabinet, Incubator, Water baths, pH-meter, Petri dishes, Graduated pipettes, Spreaders
23.	<i>Sulphite reducing clostridia</i> , Cl. 4.8, Table 3, Sl. No. (viii)	<u>Horizontal method for enumeration of sulfite-reducing bacteria growing under anaerobic conditions as per ISO 15213</u> Iron sulfite agar, Saline peptone diluents, Homogenization equipment, Water bath, Anaerobic jars, Incubator, Test tubes
24.	<i>E. Coli</i> , Cl. 4.8, Table 3, Sl. No. (ix)	Diluent, Lauryl sulfate broth, EC broth, Peptone water (indole free), Indole reagent (Kovacs' reagent), Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Incubator (capable of operating at 37 °C ± 1 °C and 44 °C ± 1 °C), Water bath (capable of being maintained at 44 °C ± 1 °C), Test tubes, of dimensions approximately 16 mm × 160 mm and 18 mm × 180 mm or 20 mm × 200 mm, Sampling loops, made of platinum/iridium or nickel/chromium, approximately 3 mm in diameter, or approximately 10 µl sterile disposable sampling loops, Durham tubes, Total-delivery pipettes, having nominal capacities of 1 ml and 10 ml, pH-meter, Microscope, Refrigerator
25.	Lead, Cl. 4.11, Table 4, Sl. No. (i)	<u>Method as per IS 12074</u> Atomic Absorption Spectrophotometer, Pure Lead Metal, Concentrated Nitric Acid, Concentrated Hydrochloric Acid, Standard Lead Solution, Drying Oven, Filter Papers, General Glasswares <u>Inductively Coupled Plasma-Mass Spectrometry Method as per AOAC 2015.01</u> ICP-MS instrument, High-purity grade liquid argon 99.996%, Analytical Balance, Clean Room Gloves, Microwave Digestion System, Autosampler Vials and Cups, Spatulas, Nitric acid (HNO ₃), Hydrogen peroxide (H ₂ O ₂), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Internal Standard Solution, Certified Reference Materials, Analytical Balance
26.	Copper, Cl. 4.11, Table 4, Sl. No. (ii)	<u>Method as per IS 1699</u> Kjeldahl 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 zinc solution, Weighing Balance, General Glasswares, Burner/ Heating Element/ Hot Plate <u>Inductively coupled plasma atomic emission spectrometry (ICP-AES) method as per ISO 15151:2018</u> Water, Nitric acid (HNO ₃), Nitric acid solution (HNO ₃), Element stock solutions of Ca, P, K, Standard working solution of Zn, Cu, Internal standard solution H ₂ O ₂ , Analytical balance, One-mark volumetric flasks, One-mark pipettes, Micropipettes, Dispenser, High-density polyethylene bottles, Pressurized microwave assisted

		wet digestion system, ICP-AES instrument, Water baths, Appropriate grinding device, Sampler tubes, Cyclonic spray chamber, Concentric nebulizer <u>Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 21424</u> Methanol, Nitric acid (HNO₃) concentrated ultrapure reagent grade, Nitric acid (HNO₃), trace metal grade H₂O₂, Laboratory water, Surfactant, Argon gas, Helium gas, Hydrogen gas, Iron Standard Stock Solution, Standard Reference Material (SRM) of cereal with certified values of Fe, inductively coupled plasma mass spectrometer, Microwave oven, Hydrogen generator, Magnetic stir plate and PTFE-coated magnetic stir bars, Analytical balance, Fume hood, Common laboratory glassware/plasticware, Repipetter, Bottle top dispenser, Volumetric pipettes, Digital pipettes
27.	Arsenic, Cl. 4.11, Table 4, Sl. No. (iii)	<u>Method as per IS 11124</u> Atomic Absorption Spectrophotometer, Vapour Generation Kit, Concentrated Hydrochloric Acid, Concentrated Nitric Acid, Concentrated Sulphuric Acid, Potassium Iodide, Sodium Borohydride, Standard Arsenic Solution, Quartz Tube, Burner, Inert Gas Supply, Reaction Vessel, Stopper Assembly, Stirrer, Laboratory Glasswares <u>Inductively Coupled Plasma-Mass Spectrometry Method as per AOAC 2015.01</u> ICP-MS instrument, High-purity grade liquid argon 99.996%, Analytical Balance, Clean Room Gloves, Microwave Digestion System, Autosampler Vials and Cups, Spatulas, Nitric acid (HNO₃), Hydrogen peroxide (H₂O₂), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Certified Reference Materials, Analytical Balance
28.	Tin, Cl. 4.11, Table 4, Sl. No. (iv)	Water, Hydrochloric acid, Tin stock solution, Tin standard working solution, Tin standard working solution in diluted (evaporated) milk, Matrix modifier solutions, Balance, Water bath, One-mark volumetric flasks, Dosing pipettes, Atomic absorption spectrometer
29.	Cadmium, Cl. 4.11, Table 4, Sl. No. (v)	<u>Method as per IS 1699</u> Kjeldahl 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 zinc solution, Weighing Balance, General Glasswares, Burner/ Heating Element/ Hot Plate <u>Inductively Coupled Plasma-Mass Spectrometry Method as per AOAC 2015.01</u> ICP-MS instrument, High-purity grade liquid argon 99.996%, Analytical Balance, Clean Room Gloves, Microwave Digestion System, Autosampler Vials and Cups, Spatulas, Nitric acid (HNO₃),

		Hydrogen peroxide (H ₂ O ₂), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Certified Reference Materials, Analytical Balance
30.	Melamine, Cl. 4.11, Table 4, Sl. No. (vi)	<u>Simultaneous quantitative determination of melamine by liquid chromatography electrospray ionization tandem mass spectrometry</u> Water, Acetonitrile, Ammonium acetate, Melamine and its standard solutions, Conical tubes, Centrifuge, Volumetric pipettes, Automatic micropipette, Nylon syringe filter, Degassing system, Analytical balance, Sonification device, Vials, LC-MS/MS equipment, HPLC Column, One-mark volumetric flasks <u>Quantitative analysis melamine in milk-based infant formula and cow milk by liquid chromatography using linear ion-trap mass spectrometry</u> Water, Acetonitrile, Ammonium acetate, Formic acid, Melamine and its standard solutions, Centrifuge tubes, Centrifuge, HPLC Column, Plastic syringes, Syringe filters, HPLC Surveyor MS pump, Analytical balance, One-mark volumetric flasks
31.	Bisphenol A(BPA), Cl. 6.1.1	<u>Gas chromatographic-mass spectrometric determination of Bisphenol A by ISO 18857-2</u> Hydrochloric acid or sulfuric acid, Acetone, Internal standardsolutions, 2,2,2-Trifluoro-N-methyl-N-(trimethylsilyl)acetamide, Solid-phase material, on styrene-divinylbenzene polymer basis, Sand, Nitrogen, Sodium thiosulfate pentahydrate, Narrow-neck flat bottomed glass bottles, Solid-phase extraction cartridges, Vacuum or pressure assembly, Quartz wool, Pear-shaped flask, Evaporation assembly, e.g. rotary evaporator with vacuum stabiliser and water bath, Vials, brown glass with PTFE-lined septa, Stainless steel cocks, with stainless steel cone. Gas chromatograph OR <u>Method as per EN 13130-1:2004</u> Cruciform specimen supports, Tubes, Glass rods and beads, foodcells, thermostatically controlled ovens or incubators

ANNEX B
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 and implement 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 license shall be printed on each container of the product; provided always that the material to which this mark is thus applied conforms to every requirement of the specification.

3.1 Packing – The material shall be packed in suitable form of packing as per provisions of Clause 5.1.1 of IS 1656:2022. However, the packaging material shall be free from Bisphenol A(BPA), when tested as per ISO 18857-2 :2009 or EN 13130-13

3.2 The product shall be packed in quantities as stipulated under Legal Metrology (Packaged Commodities) Rules, 2011 and in accordance with requirements under the Food Safety and Standards (Packaging) Regulations, 2018 as per provisions of Clause 5.1.2 of IS 1656: 2022.

3.3 Marking – The containers of the product shall bear legibly and indelibly the information as mentioned under clause 5.2.1 of IS 1656:2022. In addition, the following details shall be mentioned 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”.

3.3.1 In case of flexible packs, the following information as per provisions of Clause 5.2.1.1 of IS 1656:2022 shall be printed on the container:

“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.”

3.4 In case of manufacturers who have opted for ECO-Mark, the product package/leaflet accompanying it, may also display the information as per provisions of Clause 4.13.1.3, 4.13.1.6 and 4.13.2.3 (if fruit juice/pulp is added) of IS 1656:2022

4. CONTROL UNIT – For the purpose of this Scheme, the quantity of Infant Food - Milk Cereal Based 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 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 All the production which conforms to the Indian standards and covered by the licence should be marked with Standard Mark.

6. HYGIENIC CONDITIONS – The product shall be manufactured and packed under strict hygienic conditions as per provisions of IS 2491, cross-referred in clause 4.12 of IS 1656: 2022.

7. REJECTION- Disposal of non-conforming product shall be done in such a way so as to ensure that there is no violation of the provisions of BIS Act, 2016.

TABLE 1 (Levels of Control)
(Para 5 of Scheme of Inspection and Testing)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub- contracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
4	Description	----					
4.1	a) Shall be in the form of powder, small granules or flakes, free from lumps and shall be uniform in appearance. It shall be free from dirt, extraneous matter,free from preservatives, added colour and flavour and from any material which are harmful to infant’s health.	----	IS 1656	---	One	Every half an hour	See Note 3 below
	b) Free from rancid taste and musty odour	----	IS 10641	R	One	Every half an hour	See Note 3 below
4.2	Free from scorched particles	----	IS 1656	---	---	Every half an hour	See Note 3 below (Manufacturer to submit declaration / undertaking)
4.9	Protein Efficiency Ratio (PER)	---	IS 7481	---	----	-----	To be kept under abeyance
4.8, Table 2, Sl. No.(i)	Moisture	---	IS 16072 (Routine purpose) & IS 11623	R	Two	Each control unit	See Note 4 below

			(Reference purpose)				
4.8, Table 2, Sl. No.(ii)	Protein a) Total Protein including milk protein a) Milk protein	--	IS 11917	R	Two	Every control unit	See Note 4 below
4.8, Table 2, Sl. No. (iii)	Fat a) Total fat b) Milk fat	Annex-B	IS 1656	R	Two	Each control unit	See Note 4 below
4.8, Table 2, Sl. No. (iv)	Total Carbohydrates	Annex-C	IS 1656	R	Two	Each control unit	See Note 4 below (By calculations)
4.8, Table 2, Sl. No. (v)	Total ash	Annex-C	IS 14433	R	Two	Each control unit	See Note 4 below
4.8, Table 2, Sl. No. (vi)	Acid insoluble ash in dilute hydrochloric acid	Annex-D	IS 14433	R	Two	Each control unit	See Note 4 below
4.8, Table 2, Sl. No. (vii)	Vitamin A	--	IS 16639	S	One	Once in a month	See Note 6 below
4.8, Table 2, Sl. No. (viii)	Vitamin C	--	IS 5838 or IS 17176	S	One	Once in a month	See Note 6 below
4.8, Table 2, Sl. No. (ix)	Iron	-----	AOAC 985.35 or ISO 15151 or ISO 21424	S	One	Once in a month	See Note 6 below
4.8, Table 2, Sl. No. (x)	Crude Fibre (on dry basis)	---	IS 10226 (Part-1)	S	One	Once in 3 months or whenever there is change in formulation of the product or	See Note 7 below

						change in raw material supplier	
4.8, Table 2, Sl. No. (xi)	Vitamin D	--	IS 17177	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below
4.8, Table 2, Sl. No. (xii)	Thiamine	----	IS 17669	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below
4.8, Table 2, Sl. No. (xiii)	Riboflavin	----	IS 17669	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below
4.8, Table 2, Sl. No. (xiv)	Niacin equivalent	----	IS 17669	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below
4.8, Table 2, Sl. No. (xv)	Dietary Folate Equivalent (DFE)	--	AOAC 2013.13	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below
4.8, Table 2, Sl. No. (xvi)	Zinc	15 of IS 1699	IS 1699 or ISO 15151 or ISO 21424	S	One	Once in 3 months or whenever there is change in formulation of the product or change in raw material supplier	See Note 7 below

4.8, Table 3, Sl. No. (i)	Aerobic Plate count	--	IS 5402 (Part-1)	R	One	Each Control Unit	See note 5 below
4.8, Table 3, Sl. No. (ii)	Coliform count	--	IS 5401 (Part-1)	R	One	Each Control Unit	See note 5 below
4.8, Table 3, Sl. No. (iii)	<i>Staphylococcus aureus</i> (Coagulase positive)	--	IS 5887(Part 8/ Sec 1 or 2)	S	One	Once in a month	See note 6 below
4.8, Table 3, Sl. No. (iv)	Yeast and mould count	--	IS 16609 (Part 2)	R	One	Each control unit	See note 5 below
4.8, Table 3, Sl. No. (v)	<i>Salmonella sp.</i>	--	IS 5887 (Part 3/ Sec 1)	S	One	Once in a month	See note 6 below
4.8, Table 3, Sl. No. (vi)	<i>Listeria monocytogenes</i>	--	IS 14988 (Part 1)	S	One	Once in a month	See note 6 below
4.8, Table 3, Sl. No. (vii)	<i>Bacillus cereus</i>		IS 5887(Part-6)	S	One	Once in a month	See note 6 below
4.8, Table 3, Sl. No. (viii)	Sulphite reducing <i>clostridia</i>	---	IS 18349 (Part 1)	S	One	Once in a month	See note 6 below
4.8, Table 3, Sl. No. (ix)	<i>E. Coli</i>	--	IS 16424	S	One	Once in a month	See note 6 below

4.11, Table 4, Sl. No. (i)	Lead	--	IS 12074 or AOAC 2015.01	S	One	Once in a month	See note 6 below
4.11, Table 4, Sl. No. (ii)	Copper	15 of IS 1699	IS 1699 or ISO 15151 or ISO 21424	S	One	Once in a month	See note 6 below
4.11, Table 4, Sl. No. (iii)	Arsenic	---	IS 11124 or AOAC 2015.01	S	One	Once in a month	See note 6 below
4.11, Table 4, Sl. No. (iv)	Tin	---	IS 18843	S	One	Once in a month	See note 6 below
4.11, Table 4, Sl. No. (v)	Cadmium	15 of IS 1699	IS 1699 or AOAC 2015.01	S	One	Once in a month	See note 6 below
4.11, Table 4, Sl. No. (vi)	Melamine	---	IS 16195	S	One	Once in a month	See note 6 below
6.1	Bisphenol A(BPA)	--	ISO 18857-2: 2009 or EN 13130-13	S	One	Each consignment of raw material received	Manufacturer to obtain test report/ test certificate from raw material supplier

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

Note-3: A sample shall be taken at the packing/repacking stage after every half an hour which shall be examined visually to be in the form of powder, small granules or flakes, Free from lumps, uniform in appearance, free from dirt and extraneous matter; examined by organoleptic methods for freedom

from rancid taste and musty odour; Freedom from preservatives, added colour and flavour and from any material which are harmful to infant's health and free from scorched particles. 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 drawal of sample shall be rejected for its conformity to these requirements of the specification.

Note 4: Two sample 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 Moisture, Total Protein, Milk Protein, Total Fat, Milk Fat, Total carbohydrates, Total ash, Acid Insoluble Ash in dilute hydrochloric acid. If any one of the sample(s) fail to conform to the requirements(s) as given in the specification, the entire control unit shall either be rejected or reprocessed for its conformity to these requirements.

Note-5: One sample from every control unit shall be tested for the requirements of Aerobic plate count, Coliform count, Yeast and Mould count as laid down in the Indian Standard. If the sample fails 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.

Note-6: A sample shall be tested every month for Vitamin A, Vitamin C, *Staphylococcus aureus*, *Salmonella*, *Listeria monocytogenes*, *Bacillus cereus*, Sulphite reducing *Clostridia*, *E. Coli*, Lead, Copper, Arsenic, Tin, Cadmium, Melamine and Iron. In case of failure of the sample in any one or more of these parameter(s), the root cause of failure shall be investigated, Corrective actions/Preventive be taken and dispatch to be kept on hold. Thereafter, the samples from two consecutive control units shall be tested for the parameter(s) where failure has occurred and once the same has been found to be conforming, original frequency of testing be restored and dispatch resumed.

Note-7: One sample shall be tested in every 3 months or whenever there is change in formulation of the product or change in raw material supplier for the requirements of Crude Fibre (on dry basis), Vitamin D, Thiamine, Riboflavin, Niacin Equivalent, Dietary Folate Equivalent (DFE) and Zinc as laid down in the Indian Standard. If the sample fails in any of these requirements, the entire control unit shall either be rejected or reprocessed for its conformity to these requirements.