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उत्पाद मैनुअल

शिशुओं के लिए विशेष चिकित्सीय प्रयोजन हेतु आहार- विशिष्ट

IS 17945: 2022 के अनुसार

**PRODUCT MANUAL FOR
FOOD FOR SPECIAL MEDICAL PURPOSE INTENDED FOR INFANTS-SPECIFICATION
ACCORDING TO IS 17945: 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 17945: 2022
	शीर्षक Title	:	Food for Special Medical Purpose Intended for Infants
	संशोधनों की संख्या No. of amendments	:	01
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	a) Manufacturer to submit declaration/undertaking in compliance to Cl. 5.5 of IS 17945. 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. 5.5 of IS 17945:2022) b) In case, the manufacturer opts for addition of any Optional Ingredients as per provisions of Cl. 5.6 of IS 17945:2022, test report/ test certificates as per table 1 of IS 14433:2022 to be submitted. However, for addition of DHA/ARA, declaration/undertaking in compliance to Cl. 5.7.1 of IS 14433:2022 to be submitted. c) In case, the manufacturer opts for addition of any Food Additives, it is required to submit declaration/undertaking in compliance to Cl. 5.8.2 and 5.8.3 of IS 14433:2022 Manufacturer to submit declaration / undertaking in compliance to Cl. 5.8 and 5.9/ 5.10/ 5.11 of IS 17945.

		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	: कृ पया Annex-ए देखें Please see Annex - A
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	: Type
3.	परीक्षण उपकरणों की सूची List of Test Equipment	: कृ पया Annex-B देखें Please see Annex - B
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	: कृ पया Annex-C देखें Please see Annex - C
5.	एक दिन में संभावित परीक्षण Possible tests in a day	
	a) Description b) Scorched Particles c) Energy d) Total Protein e) Total Fat f) Calcium g) Phosphate 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 17945: 2022 with the following scope:	
	Name of the product	Food for Special Medical Purpose Intended for Infants
	Types	a) Preterm infant milk substitutes, and/or b) Lactose free infant milk substitutes, and/or c) Hypoallergenic infant milk substitutes

ANNEX – A
GROUPING GUIDELINES

1. There are three types of the product (Food for Special Medical Purpose Intended for Infants) (clause 4 of IS 17945:2022):

i.	Preterm infant milk substitutes
ii.	Lactose free infant milk substitutes
iii.	Hypoallergenic infant milk substitutes

2. The manufacturer shall declare the type of Food for Special Medical Purpose Intended for Infants which they intend to cover in the scope of licence. The sample of each type to be drawn and shall be subjected to testing for considering grant of licence/inclusion of that type.
3. It shall be ensured that the firm is having all the necessary manufacturing and testing facilities for the types to be included in the licence.
4. During the operation of licence, BO shall ensure that all the types of Food for Special Medical Purpose Intended for Infants covered in the license are drawn for independent testing on rotation over a period of time.

ANNEX-B
List of test equipment

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	Tests used in with Clause Reference	Test equipment
1	Scorched Particles, Cl. 5.4	Balance (approximately 500 g capacity and LC=0.1 g), Mixer, Scorched Particles Filtering Discs, Scorched Particles Discs Test Cards, Scorched Particles Tester, Diglycol laurate S or Antifoam B emulsion, distilled water
2	Total Protein, Cl. 5.11, Table1, Sl.No. (ii)	<u>Kjeldahl Method (as per IS 7219)</u> Kjeldahl flasks, Boiling chips or glass beads, Erlenmeyer flask, Heating device, Measuring cylinder, Distillation Assembly Rubber stopper, Pipette, Beaker, Burette, Distillation bulb, Conc. Sulphuric Acid, Mercuric Oxide or Metallic Mercury-nitrogen-free., 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
3	Total Fat, Cl. 5.11, Table1, Sl.No. (iii, a)	<u>Gravimetric Method (as per IS 11721)</u> <u>Reagents</u> Ammonia solution, Ethanol (C ₂ H ₅ OH) or ethanol denatured by methanol, Congo red solution, Diethyl ether (C ₂ H ₅ OC ₂ H 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	Linoleic acid, Cl. 5.11, Table1, Sl.No. (iii, a)	Spectrophotometer, Glass Boiling Tubes, Oil-bath (180 ± 0.5 °C), Small Tubes, about 20 × 10 mm, closed at one end (iodine value tubes), Thermometer, reading up to 200° C, Graduated Flasks, 50 ml
5	α-Linolenic acid, Cl. 5.11, Table1, Sl.No. (ii)	Spectrophotometer, Glass Boiling Tubes, Oil-bath (180 ± 0.5 °C), Small Tubes, about 20 × 10 mm, closed at one end (iodine value tubes), Thermometer, reading up to 200° C, Graduated Flasks, 50 ml
6	Docosahexaenoic acid, (DHA), Cl. 5.11, Table1, Sl.No. (iv)	n-Hexane, Methanol, Water, HPLC grade or equivalent purity quality, Sodium methoxide solution, Transesterification solution, Sodium chloride, di-Sodium hydrogen citrate sesquihydrate, Tert-butyl methyl ether, Methyl undecanoate, Tridecanoic acid, Octadecenoic acid methyl esters, Linoleic acid methyl esters, Methyl octadecadienoate conjugated acids, Analytical balance, centrifuge, Gas-liquid chromatograph, Carrier gas(hydrogen or helium), Capillary column, flame ionization detector, Split/splitless injector, On-column injector,

		Injection syringe, capacity 10 µl.
7	Eicosapentaenoic acid (EPA), Cl. 5.11, Table1, Sl.No. (v)	n-Hexane, Methanol, Water, HPLC grade or equivalent purity quality, Sodium methoxide solution, Transesterification solution, Sodium chloride, di-Sodium hydrogen citrate sesquihydrate, Tert-butyl methyl ether, Methyl undecanoate, Tritridecanoin, Octadecenoic acid methyl esters, Linoleic acid methyl esters, Methyl octadecadienoate conjugated acids, Analytical balance, centrifuge, Gas-liquid chromatograph, Carrier gas (hydrogen or helium), Capillary column, lame ionization detector, Split/splitless injector, On-column injector, Injection syringe, capacity 10 µl.
8	Arachidonic acid (ARA), Cl. 5.11, Table1, Sl.No. (vi)	n-Hexane, Methanol, Water, HPLC grade or equivalent purity quality, Sodium methoxide solution, Transesterification solution, Sodium chloride, di-Sodium hydrogen citrate sesquihydrate, Tert-butyl methyl ether, Methyl undecanoate, Tritridecanoin, Octadecenoic acid methyl esters, Linoleic acid methyl esters, Methyl octadecadienoate conjugated acids, Analytical balance, centrifuge, Gas-liquid chromatograph, Carrier gas(hydrogen or helium), Capillary column, lame ionization detector, Split/splitless injector, On-column injector, Injection syringe, capacity 10 µl.
9	Sodium, Cl. 5.11, Table1, Sl.No. (viii)	<u>Atomic Absorption Spectrometric Method as per IS 12760:2012</u> <u>Reagents:-</u> Nitric acid (HNO 3), concentrated, with a mass fraction of 65 %,Nitric acid (HNO 3) solution, with a volume fraction of 25 %,Lanthanum trichloride solution, with $c(\text{LaCl}_3 \cdot 7\text{H}_2\text{O}) = 27 \text{ g/l}$, Calcium ion stock solution, Sodium ion stock solution, Potassium ion stock solution, Magnesium ion stock solution, Standard working solution, containing 100 mg/l calcium, 20 mg/l sodium, 20 mg/l potassium and 10 mg/l magnesium ions, Light petroleum (petroleum ether), Hydrogen peroxide (H_2O_2), with a volume fraction of 30 %. <u>Equipment:-</u> Analytical balance, capable of weighing to the nearest 1 mg, with a readability of 0,1 mg, One-mark volumetric flasks, of nominal capacities 20 ml, 50 ml, 100 ml, 250 ml and 1000 ml, complying with the requirements of ISO 1042, One-mark pipettes, of nominal capacities 1 ml, 2 ml, 5 ml and 10 ml, complying with the requirements of ISO 648, Micropipette, capable of adjusting to between 1 ml and 5 ml, with plastic pipette tips, Graduated measuring cylinder, of capacity 10 ml, High-density polyethylene (PE-HD) bottles, Silica crucibles, of capacity between 25 ml and 50 ml, Programmable furnace oven, capable of attaining a minimum temperature of $550 \text{ }^\circ\text{C} \pm 25 \text{ }^\circ\text{C}$ and of programming with a heating rate of $50 \text{ }^\circ\text{C/h}$, Open focused microwave-assisted wet digestion system, delivering 200 W microwave power, equipped with appropriate vessels of capacity 50 ml, with an adapted cooling system, Pressurized microwave-assisted wet digestion system, with operator selectable output of between 0 W and 1 000 W microwave power, provided with temperature and

		pressure controllers and an air cooling device, equipped with appropriate vessels of capacity 50 ml, commercially available or equivalent, Decomposition vessels, made of stainless steel, with adapted PTFE inner vessels of capacity 23 L with screw caps (pressurized wet decomposition PTFE vessel), commercially available or equivalent, Oven, capable of attaining a temperature of 150 °C (for digestion bombs), Flame atomic absorption spectrometer, with an air-acetylene burner, suitable for measuring at different wavelengths: at 422,7 nm for calcium, at 589,6 nm for sodium, at 766,5 nm for potassium and 285.2 nm for magnesium ion content-determination procedures; equipped with hollow cathode lamps of single element type or combined type, Water baths, capable of maintaining temperatures of 20 °C ± 2 °C, at 40 °C ± 1 °C, at 45 °C ± 1 °C and at 65 °C ± 1°C, Centrifuge, capable of producing a radial acceleration of 2500g, with tubes of capacity at least 150 ml, Appropriate grinding device, Sieve, free of contaminated material, with nominal size of aperture 0.5 mm. <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
10	Potassium, Cl. 5.11, Table1, Sl.No. (ix)	<u>Atomic Absorption Spectrometric Method as per IS 12760:2012</u> <u>Reagents:-</u> Nitric acid (HNO₃), concentrated, Lanthanum trichloride solution, Calcium ion stock solution, Sodium ion stock solution, Potassium ion

stock solution, Magnesium ion stock solution, Standard working solution, containing 100 mg/l calcium, 20 mg/l sodium, 20 mg/l potassium and 10 mg/l magnesium ions, Light petroleum (petroleum ether), Hydrogen peroxide (H₂O₂), with a volume fraction of 30 %.

Equipment:-

Analytical balance, capable of weighing to the nearest 1 mg, with a readability of 0,1 mg, One-mark volumetric flasks, of nominal capacities 20 ml, 50 ml, 100 ml, 250 ml and 1000 ml, complying with the requirements of ISO 1042, One-mark pipettes, of nominal capacities 1 ml, 2 ml, 5 ml and 10 ml, complying with the requirements of ISO 648, Micropipette, capable of adjusting to between 1 ml and 5 ml, with plastic pipette tips, Graduated measuring cylinder, of capacity 10 ml, High-density polyethylene (PE-HD) bottles, Silica crucibles, of capacity between 25 ml and 50 ml, Programmable furnace oven, capable of attaining a minimum temperature of 550 °C ± 25 °C and of programming with a heating rate of 50 °C/h, Open focused microwave-assisted wet digestion system, delivering 200 W microwave power, equipped with appropriate vessels of capacity 50 ml, with an adapted cooling system, Pressurized microwave-assisted wet digestion system, with operator selectable output of between 0 W and 1 000 W microwave power, provided with temperature and pressure controllers and an air cooling device, equipped with appropriate vessels of capacity 50 ml, commercially available or equivalent, Decomposition vessels, made of stainless steel, with adapted PTFE inner vessels of capacity 23 L with screw caps (pressurized wet decomposition PTFE vessel), commercially available or equivalent, Oven, capable of attaining a temperature of 150 °C (for digestion bombs), Flame atomic absorption spectrometer, with an air-acetylene burner, suitable for measuring at different wavelengths: at 422,7 nm for calcium, at 589,6 nm for sodium, at 766,5 nm for potassium and 285.2 nm for magnesium ion content-determination procedures; equipped with hollow cathode lamps of single element type or combined type, Water baths, capable of maintaining temperatures of 20 °C ± 2 °C, at 40 °C ± 1 °C, at 45 °C ± 1 °C and at 65 °C ± 1 °C, Centrifuge, capable of producing a radial acceleration of 2500g, with tubes of capacity at least 150 ml, Appropriate grinding device, Sieve, free of contaminated material, with nominal size of aperture 0.5 mm.

Inductively coupled plasma atomic emission spectrometry (ICP-AES) method as per ISO 15151:2018

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
11	Calcium, Cl. 5.11, Table1, Sl.No. (x)	<u>Atomic Absorption Spectrometric Method as per IS 12760:2012</u> <u>Reagents:-</u> Nitric acid (HNO₃), concentrated, Lanthanum trichloride solution, Calcium ion stock solution, Sodium ion stock solution, Potassium ion stock solution, Magnesium ion stock solution, Standard working solution, containing 100 mg/l calcium, 20 mg/l sodium, 20 mg/l potassium and 10 mg/l magnesium ions, Light petroleum (petroleum ether), Hydrogen peroxide (H₂O₂), with a volume fraction of 30 %. <u>Equipment:-</u> Analytical balance, capable of weighing to the nearest 1 mg, with a readability of 0,1 mg, One-mark volumetric flasks, of nominal capacities 20 ml, 50 ml, 100 ml, 250 ml and 1000 ml, complying with the requirements of ISO 1042, One-mark pipettes, of nominal capacities 1 ml, 2 ml, 5 ml and 10 ml, complying with the requirements of ISO 648, Micropipette, capable of adjusting to between 1 ml and 5 ml, with plastic pipette tips, Graduated measuring cylinder, of capacity 10 ml, High-density polyethylene (PE-HD) bottles, Silica crucibles, of capacity between 25 ml and 50 ml, Programmable furnace oven, capable of attaining a minimum temperature of 550 °C ± 25 °C and of programming with a heating rate of 50 °C/h, Open focused microwave-assisted wet digestion system, delivering 200 W microwave power, equipped with appropriate vessels of capacity 50 ml, with an adapted cooling system, Pressurized microwave-assisted wet digestion system, with operator selectable output of between 0 W and 1 000 W microwave power, provided with temperature and pressure controllers and an air cooling device, equipped with appropriate vessels of capacity 50 ml, commercially available or

		equivalent, Decomposition vessels, made of stainless steel, with adapted PTFE inner vessels of capacity 23 L with screw caps (pressurized wet decomposition PTFE vessel), commercially available or equivalent, Oven, capable of attaining a temperature of 150 °C (for digestion bombs), Flame atomic absorption spectrometer, with an air-acetylene burner, suitable for measuring at different wavelengths: at 422,7 nm for calcium, at 589,6 nm for sodium, at 766,5 nm for potassium and 285.2 nm for magnesium ion content-determination procedures; equipped with hollow cathode lamps of single element type or combined type, Water baths, capable of maintaining temperatures of 20 °C ± 2 °C, at 40 °C ± 1 °C, at 45 °C ± 1 °C and at 65 °C ± 1 °C, Centrifuge, capable of producing a radial acceleration of 2500g, with tubes of capacity at least 150 ml, Appropriate grinding device, Sieve, free of contaminated material, with nominal size of aperture 0.5 mm. <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
12	Phosphate, Cl. 5.11, Table1, Sl.No. (xi)	<u>Molecular Absorption Spectrometric Method as per IS 12756:2019</u> <u>Reagents:-</u> Sulfuric acid (concentrated), Hydrogen peroxide, Molybdate-ascorbic acid solution, Sodium molybdate solution, Ascorbic acid solution, Phosphorus, standard solution <u>Equipment:-</u>

		Analytical balance, Device for grinding or grating, Water bath, Digestion flasks (Kjeldahl flasks or digestion tubes), capacity 25 ml, Heating apparatus, Micro gas burners or electric heaters, Heating block, Glass beads, One-mark volumetric flasks, graduated measuring cylinder, pipette, Spectrometer <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
13	Chloride, Cl. 5.11, Table1, Sl. No. (xii)	<u>Potentiometric Titration Method as per IS 11763:2011</u> Device for grinding, Analytical balance (LC= 0.1 mg), Blender, Stirrer, Potentiometer, Vessel, Graduated cylinders, Burette
14	Magnesium, Cl. 5.11, Table1, Sl. No. (xiii)	<u>Atomic Absorption Spectrometric Method as per IS 12760:2012</u> <u>Reagents:-</u> Nitric acid (HNO₃), concentrated, Lanthanum trichloride solution, with c(LaCl₃.7H₂O) = 27 g/l, Calcium ion stock solution, Sodium ion stock solution, Potassium ion stock solution, Magnesium ion stock solution, Standard working solution, containing 100 mg/l calcium, 20 mg/l sodium, 20 mg/l potassium and 10 mg/l magnesium ions, Light petroleum (petroleum ether), Hydrogen peroxide (H₂O₂), with a volume fraction of 30 %. <u>Equipment:-</u> Analytical balance, capable of weighing to the nearest 1 mg, with a readability of 0.1 mg, One-mark volumetric flasks, of nominal capacities 20 ml, 50 ml, 100 ml, 250 ml and 1000 ml, complying with the requirements of ISO 1042, One-mark pipettes, of nominal capacities 1 ml, 2 ml, 5 ml and 10 ml, complying with the requirements of ISO 648, Micropipette, capable of adjusting to

between 1 ml and 5 ml, with plastic pipette tips, Graduated measuring cylinder, of capacity 10 ml, High-density polyethylene (PE-HD) bottles, Silica crucibles, of capacity between 25 ml and 50 ml, Programmable furnace oven, capable of attaining a minimum temperature of $550\text{ }^{\circ}\text{C} \pm 25\text{ }^{\circ}\text{C}$ and of programming with a heating rate of $50\text{ }^{\circ}\text{C/h}$, Open focused microwave-assisted wet digestion system, delivering 200 W microwave power, equipped with appropriate vessels of capacity 50 ml, with an adapted cooling system, Pressurized microwave-assisted wet digestion system, with operator selectable output of between 0 W and 1 000 W microwave power, provided with temperature and pressure controllers and an air cooling device, equipped with appropriate vessels of capacity 50 ml, commercially available or equivalent, Decomposition vessels, made of stainless steel, with adapted PTFE inner vessels of capacity 23 L with screw caps (pressurized wet decomposition PTFE vessel), commercially available or equivalent, Oven, capable of attaining a temperature of $150\text{ }^{\circ}\text{C}$ (for digestion bombs), Flame atomic absorption spectrometer, with an air-acetylene burner, suitable for measuring at different wavelengths: at 422,7 nm for calcium, at 589,6 nm for sodium, at 766,5 nm for potassium and 285.2 nm for magnesium ion content-determination procedures; equipped with hollow cathode lamps of single element type or combined type, Water baths, capable of maintaining temperatures of $20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$, at $40\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, at $45\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$ and at $65\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$, Centrifuge, capable of producing a radial acceleration of 2500g, with tubes of capacity at least 150 ml, Appropriate grinding device, Sieve, free of contaminated material, with nominal size of aperture 0.5 mm.

Inductively coupled plasma atomic emission spectrometry (ICP-AES) method as per ISO 15151:2018

Water, Nitric acid (HNO_3), Nitric acid solution (HNO_3), Element stock solutions of Ca, P, K, Standard working solution of Fe, Internal standard solution H_2O_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 bath, Appropriate grinding device, Sampler tubes, Cyclonic spray chamber, Concentric nebulizer

Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 21424

Methanol, Nitric acid (HNO_3) concentrated ultrapure reagent grade, Nitric acid (HNO_3), trace metal grade H_2O_2 , 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

15	Iron, Cl. 5.11, Table1, Sl.No. (xiv)	<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
16	Zinc, Cl. 5.11, Table1, Sl.No. (xv)	<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</u>

		<u>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
17	Copper, Cl. 5.11, Table 1, Sl.No. (xvi)	<u>Method as per IS 1599</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

18	Selenium, Cl. 5.11, Table1, Sl.No. (xvii)	<u>Method as per IS 15303</u> Atomic Absorption Spectrometer, Source Lamps, Graphite Furnace, Readout Sample Dispensers, Vent, Cooling Water Supply, Membrane Filter Apparatus, Metal-Free-Water, Hydrochloric Acid, Nitric Acid, Magneisum Nitrate, Nickel, Nitrate, Phosphoric Acid, Palladium Nitrate, Citric Acid, Stock Selenium Solution, Chelating Resin, General Glasswares, 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 Se, 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>Determination by Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 20649</u> Purified water, Concentrated nitric acid (HNO₃), Hydrogen peroxide (H₂O₂), Methanol, Potassium solution, Standard Solutions and Reference Materials, Microwave oven, ICP-MS, Various plasticware and pipettes, Analytical balance
19	Manganese, Cl. 5.11, Table1, Sl.No. (xviii)	<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

20	Iodine, Cl. 5.11, Table1, Sl.No. (xix)	KOH pellets, Ammonium hydroxide, Sodium thiosulfate, Surfactant, Concentrated nitric acid, Perchloric acid (HClO ₄), Purified water(18 MΩ/cm), Iodide standard solution, triethylamine (TEA), Praseodymium (Pr) standard solution, Polypropylene tubes, capacity 50 ml and 100 ml, Oven (105 °C ± 5 °C), Open-vessel microwave digestion unit(optional), Analytical balance(LC=0.0001 g), Top-loader balance (LC= 0.01 g), ICP-MS system, Autosampler for ICP-MS, Adjustable volumetric pipets, Re-pipet volumetric dispensers, Polypropylene or polytetrafluoroethylene (PTFE) bottles, Disposable plastic syringes, Syringe filters, Beakers, Pump tubing
21	Chromium, Cl. 5.11, Table1, Sl.No. (xx)	<u>Determination by Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 20649</u> Purified water, Concentrated nitric acid (HNO ₃), Hydrogen peroxide (H ₂ O ₂), Methanol, Potassium solution, Standard Solutions and Reference Materials, Microwave oven, ICP-MS, Various plasticware and pipettes, Analytical balance
22	Molybdenum, Cl. 5.11, Table1, Sl.No. (xxi)	<u>Determination by Inductively coupled plasma mass spectrometry (ICP-MS) method as per ISO 20649</u> Purified water, Concentrated nitric acid (HNO ₃), Hydrogen peroxide (H ₂ O ₂), Methanol, Potassium solution, Standard Solutions and Reference Materials, Microwave oven, ICP-MS, Various plasticware and pipettes, Analytical balance
23	Thiamin, Cl. 5.11, Table1, Sl.No. (xxii)	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 column ²) or equivalent, UHPLC system, Waters Acquity Classic ²), or equivalent, Tandem quadrupole mass spectrometer with ESI probe, Waters Xevo TQ-S ²), 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.

24	Riboflavin, Cl. 5.11, Table1, Sl.No. (xxiii)	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.
25	Niacin equivalent, Cl. 5.11, Table1, Sl.No. (xxiv)	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.
26	Pantothenic acid, Cl. 5.11, Table1, Sl.No. (xxv)	Calcium d-pantothenate, Calcium pantothenate- [13 C 6, 15 N 2], α-Amylase, Acetonitrile, Ammonium acetate, Acetic acid, Formic acid, 1 % Formic acid in water, Balances, pH-meter, Homogenizer, Stir plate with magnetic stirrers, Filters, UHPLC-MS/MS system

27	Pyridoxine, Cl. 5.11, Table1, Sl.No. (xxvi)	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.
28	Cobalamin, Cl. 5.11, Table1, Sl.No. (xxvii)	<u>Determination by Reversed Phase High Performance Liquid Chromatography (RP-HPLC) as per IS 16640:2018</u> <u>Reagents</u> Glacial acetic acid, Acetonitrile(HPLC grade), Drierite (anhydrous calcium sulfate), Ethanol, Formic acid, Potassium cyanide, Riboflavin, Sodium acetate anhydrous or sodium acetate trihydrate, Taka-Diastase, Triethylamine(HPLC grade), Vitamin B12 (cyanocobalamin) primary reference standard <u>Apparatus</u> HPLC system, Oven(capable of maintaining temperatures of 95 °C ± 5 °C and 105 °C ± 5 °C), pH-meter, Analytical balance(LC= 0.00001 g), Beakers, glass, Bottle top dispenser, Cylinders, Desiccator, Filter paper, Whatman 2V²) or equivalent OR <u>Ultra-High-Performance Liquid Chromatography method as per AOAC 2014.02</u> Balances, Sonicator, Oven, water bath, Rotary shaker, Heating block with nitrogen evaporation, Vortex, Homogeniser, Erlemmeyers flask, Whatman filter paper 602 ½ or 597 ½, Amber vials, Chromatographic system, Methanol, Acetonitrile, Acetic acid glacial, Sodium cyanide puriss, TFA for spectroscop, Sodium acetate tri hydrate, Vitamin B,, (cyanacabalamin), Sodium hypachloride, α-Amylase from Bacillus subtilis

29	Folic acid, Cl. 5.11, Table1, Sl.No. (xxviii)	<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 filter paper, Solid-phase extraction cartridges, Amber vials, L-ascorbic acid, Ammonium acetate, Disodium hydrogen phosphate powder, α-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
30	L-Ascorbic acid (vitamin C), Cl. 5.11, Table1, Sl.No. (xxix)	<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
31	Biotin, Cl. 5.11, Table1, Sl.No. (xxx)	Laboratory reagent grade water, Sodium dihydrogen phosphate dihydrate (CAS # 13472-35-0), Disodium hydrogen phosphate dihydrate, Sodium hydroxide, Methanol, HPLC grade, Acetonitrile, HPLC grade, Ortho-phosphoric acid, PBS, Biotin, Biocytin, Sodium hydroxide, Sodium phosphate buffer, Phosphoric acid, HPLC system, Column, Kinetex Phenyl-Hexyl Glass microfibre filters, Immunoaffinity column pack, SPE manifold, Autoclave, Centrifuge, analytical balance, Amber glass screw-cap bottle, Horizontal shaker, Volumetric flasks, Pipettors, Measuring cylinder, Reaction vial, Heating block, Ultrasonic bath, Centrifuge tubes, Vortex mixer, Syringe filter, Disposable syringes, HPLC vials, HPLC System
32	Vitamin A, retinol equivalents, Cl. 5.11, Table1, Sl.No. (xxxi)	Methyl-t-butyl ether, n-Hexane, Ethanol Methanol, Iso-octane (2,2,4-trimethylpentane), Papain (from Carica papaya), Hydroquinone, 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
33	Vitamin D, Cl. 5.11, Table1, Sl.No. (xxxii)	Vitamin D ₂ (ergocalciferol), Vitamin D ₃ (cholecalciferol), d6-Vitamin D ₂ , d6-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 μ m), Cryogenic vials
34	Vitamin E, α -tocopherol, Cl. 5.11, Table1, Sl. No. (xxxiii)	Methyl-t-butyl ether, n-Hexane, Ethanol Methanol, Iso-octane (2,2,4-trimethylpentane), Papain (from Carica papaya), Hydroquinone, 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
35	Vitamin K, Cl. 5.11, Table1, Sl. No. (xxxiv)	Acetic acid(glacial), Helium or nitrogen, Hexane(HPLC grade), Iso-octane (2,2,4-trimethylpentane)(HPLC grade), Isopropanol (isopropyl alcohol)(HPLC grade), Methanol(HPLC grade),Phytonadione/ phyloquinone (vitamin K1), primary reference standard, distilled water, Ethanol, Sodium acetate(anhydrous), Zinc, Zinc chloride, HPLC system, Analytical balance(LC= 0.000 01 g),Beakers, Centrifuge, Centrifuge tubes and caps, Gas regulator, compatible with helium or nitrogen, Gas sparge, tubing and filtering assembly, Magnetic stirrer and stir bar, centrifuge tubes, Pipet, Spectrophotometer, Volumetric flasks, Volumetric pipets, Vortex mixers.
36	Choline, Cl. 5.11, Table1, Sl.No. (xxxv)	Water, purified, MS grade or equivalent purity, Acetonitrile, Ammonium formate, Formic acid, Nitric acid, Isopropanol, Desiccant L-carnitine, inner salt, Choline bitartrate, L-carnitine-d3 HCL,Choline-1,1,2,2-d 4 chloride, HPLC system MS/MS system, Microwave, Microwave turntable, Vortex mixer, Analytical balance, Horizontal shaker, Magnetic stir plate, Positive displacement pipets, Repeater positive displacement pipette, Polypropylene tubes, Digestion vessels for microwave digestion, Graduated polypropylene tube, Glass containers, Syringe filters, Disposable syringes, Graduated cylinders,

		Magnetic stir bars, Autosampler vials and caps, Microcentrifuge tubes, Bottle top dispenser, Desiccator
37	Inositol, Cl. 5.11, Table 1, Sl. No. (xxxvi)	Acetic acid, glacial, Chloroform, Diethyl ether, Drierite, Helium, Hexane, Hydrochloric acid, Metaphosphoric acid, Methanol, Myo-inositol, Sodium chloride, Sodium hydroxide, Analytical balance, Centrifuge, Desiccator, Nitrogen evaporator, Oven, pH-meter, Stir plate, Vacuum manifold, Vortex mixer, System HPLC Columns, Beakers, Centrifuge tubes, Syringe filters, Filter paper, Conical flasks, Volumetric flasks, Funnels, Pipettes, Solid-phase extraction (SPE) cartridge, Syringes
38	Aerobic Plate count, Cl. 5.12, Table 2, 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
39	Staphylococcus aureus (Coagulase Positive), Cl. 5.12, Table 2, Sl. No. (ii)	Diluent, Baird-parker Agar Medium, Potassoum 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
40	Yeast and Mould count, Cl. 5.12, Table 2, Sl. No. (iii)	<u>HORIZONTAL METHOD FOR THE ENUMERATION OF YEASTS AND MOULDS as per IS 16069(Part 1) and IS 16069(Part 2)</u> Diluent (0.1 % (mass concentration) peptone water broth), Culture medium (Dichloran 18 % (mass concentration) glycerol agar (DG18)), Dichloran-rose bengal chloramphenicol agar (DRBC), 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
41	Salmonella sp., Cl. 5.12, Table 2, Sl. No. (iv)	Buffered peptone water, Rappaport-Vassiliadis medium with soya (RVS broth) or Modified Semi-solid Rappaport-Vassiliadis (MSRV) agar and Muller-Kauffmann tetrathionate-novobiocin broth (MKTTn 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
42	Listeria Monocytogenes, Cl. 5.12, Table 2, Sl. No. (v)	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
43	Bacillus cereus, Cl. 5.12, Table 2, Sl. No. (vi)	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
44	Sulphite reducing clostridia, Cl. 5.12, Table 2, Sl. No. (vii)	Iron sulfite agar, Saline peptone diluents, Homogenization equipment, Water bath, Anaerobic jars, Incubator, Test tubes

45	Enterobacteriaceae, Cl. 5.12, Table 2, Sl. No. (viii)	Oven, Incubator, Water bath, Tubes, flasks or bottles pH-meter, Petri dishes, Graduated pipettes or automatic pipettes, Homogenizer, Buffered peptone water, Violet red bile glucose agar, Nutrient agar, Oxidase discs/Oxidase reagent, Glucose OF medium
46	Enterobacter sakazakii (Cronobacter sp.), Cl. 5.12, Table 2, Sl. No. (ix)	Apparatus for dry sterilization (oven) or wet sterilization (autoclave), Incubators, pH meter, Tubes (plugged or with caps) or culture bottles, Spectrophotometer, Pestle and mortar, Water baths, Refrigerators, Drying cabinet (or oven ventilated by convection), Oxidase, Hydrolysis of 4-Nitrophenyl α -D-glucopyranoside substrate, L-Lysine decarboxylase, L-Ornithine decarboxylase, Methyl Red (optional), Voges-Proskauer (optional), D-Arabitol, D-Sorbitol, D-Sucrose, α -Methyl-D-glucoside (optional)
47	E.Coli, Cl. 5.12, Table 2, 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 $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$ and $44^{\circ}\text{C} \pm 1^{\circ}\text{C}$), Water bath (capable of being maintained at $44^{\circ}\text{C} \pm 1^{\circ}\text{C}$), Test tubes, of dimensions approximately 16 mm $\times$ 160 mm and 18 mm $\times$ 180 mm or 20 mm $\times$ 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
48	Lead, Cl. 5.14	<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_2O_2), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Internal Standard Solution, Certified Reference Materials, Analytical Balance
49	Arsenic, Cl. 5.14	<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 (HNO_3), Hydrogen peroxide (H_2O_2), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Certified Reference Materials, Analytical Balance

49	Tin, Cl. 5.14	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
50	Cadmium, Cl. 5.14	<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 (H₂O₂), Stock standard solution, Single-element standards, Second source standard, Multi Element Stock Standard Solution, Certified Reference Materials, Analytical Balance
51	Melamine, Cl. 5.14	<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
52	Bisphenol A(BPA), Cl. 6.1	<u>Gas chromatographic-mass spectrometric determination of Bisphenol A by ISO 18857-2</u> Hydrochloric acid or sulfuric acid, Acetone, Internal standard solutions, 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, Glass Beads, Food Cells, Thermostatically controlled ovens or incubators

ANNEX C
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 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.

3.1 The material shall be packed in suitable form of packing as per provisions of clause 6.1.1 of IS 17945: 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 Food for Special Medical Purpose Intended for Infants shall be packed in accordance with requirements under the Food Safety and Standards (Packaging) Regulations, 2018.

3.3 The information as mentioned under clause 6.2.1 of IS 17945:2022 shall be legibly and indelibly marked on each container. In case of flexible packs, a cautionary notice to the following effect shall be printed on the container: 'On opening, transfer the contents of the pack to a clean air tight container. After each use, replace the lid tightly and store in a cool dry place. In addition, the following shall be incorporated on each container:

i) BIS Licence No. (CM/L.....)

ii) For details of BIS certification details please visit www.bis.gov.in'.

4. CONTROL UNIT – For the purpose of this scheme, the entire quantity of the same type of Food for Special Medical Purpose Intended for Infants 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. STORAGE AND HYGIENIC CONDITIONS: The product shall be processed, packed, stored and distributed under strict hygienic conditions as per provisions of IS 2491, cross-referred in clause 5.15 of IS 17945: 2022

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)
(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
		Cl. Ref.	IS				
5.1	Description	--	--	--	---		
	a) Shall be white/white with a greenish tinge to light cream to light yellow in colour, free from lumps and coarse particles; uniform in appearance; free from dirt and extraneous matter	5.1	IS 17945	--	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
	c) Free from preservatives, added colour and flavour and from any material which are harmful to infant's health	--	IS 17945	--	One	Every half an hour	Manufacturer to submit declaration / undertaking
5.4	Scorched Particles	-	IS 13500	R	Two	Every control unit	See Note 3 below
5.11, Table1, Sl. No. (i)	Energy	--	---	--	--	Every Control Unit	(Based on calculations)
5.11, Table1, Sl.No. (ii)	Total Protein	--	IS 7219	R	Two	Every Control unit	See Note 4 below
5.11, Table1, Sl.No. (iii, a)	Total Fat	--	IS 11721	R	Two	Every Control unit	See Note 4 below
5.11, Table1, Sl.No. (iii, a)	Linoleic acid	Annex-B	IS 14433 / ISO 16958	S	One	Once in a month	See Note 5 below

5.11, Table1, Sl.No. (ii)	α -Linolenic acid	-do-	-do-	S	One	Once in a month	See Note 5 below
5.11, Table1, Sl.No. (iv)	Docosahexaenoic acid (DHA)	--	ISO 16958	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
5.11, Table1, Sl.No. (v)	Eicosapentaenoic acid (EPA)	--	ISO 16958	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
5.11, Table1, Sl.No. (vi)	Arachidonic acid (ARA)	--	ISO 16958	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
5.11, Table1, Sl.No. (vii)	Carbohydrate	Annex- C	IS 1656	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
5.11, Table1, Sl.No. (viii)	Sodium	--	IS 12760/ISO 15151/ 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
5.11, Table1, Sl.No. (ix)	Potassium	--	IS 12760/ISO 15151/ 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
5.11, Table1, Sl.No. (x)	Calcium	--	IS 12760/ISO 15151/ ISO 21424	R	One	Every Control unit	See Note 6 below
5.11, Table1, Sl.No. (xi)	Phosphate	--	IS 12756/ ISO 15151/ ISO 21424	R	One	Every Control unit	See Note 6 below

5.11, Table1, Sl.No. (xii)	Chloride	--	IS 11763/ AOAC 2016.0 3	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
5.11, Table1, Sl.No. (xiii)	Magnesium	--	IS 12760/ ISO 15151/ 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
5.11, Table1, Sl.No. (xiv)	Iron	--	AOAC 985.35/ ISO 15151/ ISO 21424	S	One	Once in a month	See Note 5 below
5.11, Table1, Sl.No. (xv)	Zinc	15	IS 1699/ ISO 15151/ 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
5.11, Table1, Sl.No. (xvi)	Copper	-do-	-do-	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
5.11, Table1, Sl.No. (xvii)	Selenium	--	IS 15303/ ISO 15151/ ISO 20649	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
5.11, Table1, Sl.No. (xviii)	Manganese	---	ISO 1515 1/ 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
5.11, Table1, Sl.No. (xix)	Iodine	--	IS 17379	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

5.11, Table1, Sl.No. (xx)	Chromium	--	ISO 20649	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
5.11, Table1, Sl.No. (xxi)	Molybdenum	--	-do-	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
5.11, Table1, Sl.No. (xxii)	Thiamin	--	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
5.11, Table1, Sl.No. (xxiii)	Riboflavin	--	-do-	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
5.11, Table1, Sl.No. (xxiv)	Niacin equivalent	--	-do-	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
5.11, Table1, Sl.No. (xxv)	Pantothenic acid	--	IS 16642	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
5.11, Table1, Sl.No. (xxvi)	Pyridoxine	--	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
5.11, Table1, Sl.No. (xxvii)	Cobalamin	--	IS 16640 / AOAC 2014. 02	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

5.11, Table1, Sl.No. (xxviii)	Folic acid	--	AOAC 2013.12	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
5.11, Table1, Sl.No. (xxix)	L-Ascorbic acid (vitamin C)	--	IS 5838/ IS 17176	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
5.11, Table1, Sl.No. (xxx)	Biotin	---	IS 17670	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
5.11, Table1, Sl.No. (xxxi)	Vitamin A, retinol equivalents	--	IS 16639	S	One	Once in a month	See Note 5 below
5.11, Table1, Sl.No. (xxxii)	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
5.11, Table1, Sl.No. (xxxiii)	Vitamin E, α -tocopherol	--	IS 16639	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
5.11, Table1, Sl.No. (xxxiv)	Vitamin K	--	IS/ISO 21466	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
5.11, Table1, Sl.No. (xxxv)	Choline	--	IS 17668	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

5.11, Table 1, Sl.No. (xxxvi)	Inositol	--	IS 16649	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
5.12, Table 2, Sl. No. (i)	Aerobic Plate count	--	IS 5402(Part- 1)	R	One	Each control unit	See Note 6 below
5.12, Table 2, Sl. No. (ii)	<i>Staphylococcus aureus</i> (Coagulase Positive)	--	IS 5887 (Part 8/Sec c 1 or 2)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (iii)	Yeast and Mould count	--	IS 16069- 1 for liquid product or IS 16069-2 for powdered product	R	One	Each control unit	See Note 6 below
5.12, Table 2, Sl. No. (iv)	<i>Salmonella sp.</i>	--	IS 5887 (Part- 3/Sec 1)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (v)	<i>Listeria</i> <i>Monocytogenes</i>	--	IS 14988(Part 1)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (vi)	<i>Bacillus cereus</i>	--	IS 5887 (Part 6)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (vii)	Sulphite reducing <i>Clostridia</i>	--	IS 18349 (Part 1)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (viii)	Enterobacteriaceae	--	IS 17112 (Part 1)	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (ix)	<i>Enterobacter</i> <i>sakazakii</i> (<i>Cronobacter sp.</i>)	--	IS 18357	S	One	Once in a month	See Note 5 below
5.12, Table 2, Sl. No. (x)	<i>E. Coli</i>	--	IS 16424	S	One	Once in a month	See note 5 below
Cl. 5.14	Lead		IS 12074 / AOAC 2015.01	S	One	Once in a month	See Note 5 below
Cl. 5.14	Arsenic		IS 11124 / AOAC 2015.01	S	One	Once in a month	See Note 5 below
Cl. 5.14	Tin		IS18843	S	One	Once in a month	See Note 5 below

Cl. 5.14	Cadmium	15	IS 1699 / AOAC 2015.01	S	One	Once in a month	See Note 5 below
Cl. 5.14	Melamine		IS 16195	S	One	Once in a month	See Note 5 below
6.1	Bisphenol A(BPA)	--	ISO 18857-2: 2009 or EN 13130- 13	S	One	Each consignment of raw material received	Manufacture r 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 empanelled 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 for colour, Free from lumps and coarse particles, 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. 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 either be rejected for its conformity to these requirements of the specification

Note-4: - 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 protein, Total fat content and carbohydrate. 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.

Note-5: A sample shall be tested every month for Linoleic Acid, α -Linolenic acid, Iron, Vitamin A, *Staphylococcus aureus*, *Salmonella*, *Listeria monocytogenes*, *Bacillus cereus*, Sulphite reducing *Clostridia*, Enterobacteriaceae, *Enterobacter sakazakii* (*Cronobacter sp.*), *E.Coli*, Lead, Arsenic, Tin, Cadmium, Melamine. 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-6: One sample from every control unit shall be tested for the requirements of Calcium, Phosphate, Aerobic Plate Count, Yeast & Mould count as laid down in the Indian Standard. 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.

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 Docosahexaenoic acid (DHA), Eicosapentaenoic acid (EPA), Arachidonic acid (ARA), Carbohydrate, Sodium, Potassium, Chloride, Magnesium, Zinc, Copper, Selenium, Manganese, Iodine, Chromium, Molybdenum, Thiamin, Riboflavin, Niacin equivalent, Pantothenic Acid, Pyridoxine, Cobalamin, Folic Acid, L-ascorbic acid(Vitamin C), Biotin, Vitamin D, Vitamin E, Vitamin K, Choline, Inositol 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