



उत्पाद मानुयल
मीठा संघनित दूध, मीठा संघनित आंशिक मलाईरहित दूध, मीठा संघनित मलाईरहित दूध एवं मीठा
संघनित उच्च वसायुक्त दूध- विशिष्टि
1166: 2022 के अनुसार

PRODUCT MANUAL FOR
SWEETENED CONDENSED MILK, SWEETENED CONDENSED PARTLY SKIMMED
MILK, SWEETENED CONDENSED SKIMMED MILK AND SWEETENED CONDENSED
HIGH FAT MILK — SPECIFICATION ACCORDING TO IS 1166:2022

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.	:	1166: 2022
	शीर्षक Title	:	Sweetened Condensed Milk, Sweetened Condensed Partly Skimmed Milk, Sweetened Condensed Skimmed Milk and Sweetened Condensed High Fat Milk
	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. 4.1 of IS 1166:2022 b) Manufacturer to submit declaration/undertaking in compliance to Cl. 4.3 of IS 1166:2022 and also maintain test records/test reports for Sugar as per IS 1151. c) Manufacturer to maintain test records/test reports for Potable Water as per IS 10500. d) In case, the manufacturer opts for addition of any Food Additives, it is required to submit declaration/undertaking in compliance to Cl. 4.5 of IS 1166:2022 e) In case of addition of pesticide residue, antibiotic and veterinary drug residues, the manufacturer is required to submit declaration/undertaking in compliance to Cl. 4.8 of IS 1166:2022
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	कृपया Annex-ए देखें Please see Annex – A

c)	नमूने का परिमाण Sample Quantity	:	2X500 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 Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	कृपया Annex-B देखें Please see Annex – B
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	कृपया Annex-C देखें Please see Annex – C
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	i) Description (a) Flavour and Taste; (b) Free from lumps and extraneous matter) ii) Total Milk Solids iii) Milk Fat iv) Milk solid not fat v) Milk protein in milk solids not fat vi) Lead (<i>if the manufacturer has in-house test facilities</i>) vii) Arsenic (<i>if the manufacturer has in-house test facilities</i>) viii) Aflatoxin M ₁ (<i>if the manufacturer has in-house test facilities</i>) ix) Melamine (<i>if the manufacturer has in-house test facilities</i>) 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 1166: 2022 with the following scope:		
	उत्पाद का नाम Name of the product		Sweetened Condensed Milk, Sweetened Condensed Partly Skimmed Milk, Sweetened Condensed Skimmed Milk and Sweetened Condensed High Fat Milk
	Type		a) Sweetened Condensed Milk, and/or b) Sweetened Condensed Partly Skimmed milk, and/or c) Sweetened Condensed Skimmed Milk, and/or d) Sweetened Condensed High Fat Milk

ANNEX – A
GROUPING GUIDELINES

1. There are four types of the product:

i	Sweetened Condensed Milk
ii	Sweetened Condensed Partly Skimmed Milk
iii	Sweetened Condensed Skimmed Milk
iv	Sweetened Condensed High Fat Milk

2. The manufacturer shall declare the type, 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. Scope of licence shall be restricted based on the manufacturing and testing facilities available.

4. During operation of licence, samples of each variety covered in the scope of licence, shall be tested in rotation, to the extent possible.

ANNEX-B
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl No.	Tests used in with Clause Reference	Test Equipment/Chemical
1.	Size of Lactose Crystals, Clause 4.6	Microscope, Depression slide
2.	Total milk solids, Cl. 4.1 and 4.7, Table 1, Sl. No. (i)	<u>Method as per IS 11622</u> – Weighing Balance – Water bath – Drying Oven – Desiccator – Flat Bottom Dishes – Quartz sand or Sea Sand <u>Method as per IS 11764</u> – Zinc acetate – Potassium hexacyanoferrate(II) solution – Dilute hydrochloric acid – Ammonium hydroxide solution – Dilute acetic acid – Analytical balance – Potarimeter tube – Filter funnel – Polarimeter or saccharimeter – Water bath <u>Method as per IS 4079 (C-2)</u> – Sodium Hydroxide Solution – Methylene Blue indicator – Fehling's solution – Sucrose – Zinc acetate – Potassium Ferricyanide – Conc. Hydrochloric acid – Conc. Ammonia solution – Acetic Acid solution
3.	Milk Fat, Cl. 4.1 and 4.7, Table 1, Sl. No. (ii)	<u>As per IS 19396</u> – Ammonia solution, containing a mass fraction of NH₃ of approximately 25 % – Ethanol (C₂H₅OH), or ethanol denatured by methanol, containing a volume fraction of ethanol of at least 94% – Indicator solution (optional) – Bromocresol purple solution – Patent blue V – Diethyl ether, free from peroxides – Light petroleum, with any boiling range between 30 °C and 60 °C – Analytical balance (capable of weighing to the nearest 1 mg, with a readability of 0.1 mg) – Centrifuge (capable to produce a radial acceleration of around 80g to 90g at the outer end of the flasks or tubes) – Distillation or evaporation apparatus – Drying oven (electrically heated, with ventilation)

		port(s) fully open, capable of being maintained at a temperature of $102\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ throughout its working space. The oven shall be fitted with a suitable thermometer.) – Water bath (capable of being maintained at a temperature of $37,5\text{ }^{\circ}\text{C} \pm 2,5\text{ }^{\circ}\text{C}$, $50\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$, $65\text{ }^{\circ}\text{C} \pm 5\text{ }^{\circ}\text{C}$ and at boiling point) – Fat-extraction flasks: ○ Mojonnier-type fat-extraction flasks ○ Extraction tubes-type fat extraction flask ○ Stoppers – Rack – Wash bottle – Fat-collecting vessels – Measuring cylinders or delivering systems – Pipettes or delivering systems – Tongs – Blender – Boiling aids
4.	Milk protein in milk solids not fat, Cl. 4.1 and 4.7, Table 1, Sl. No. (iv)	– Potassium sulfate – Copper (II) sulfate pentahydrate solution – Sulfuric acid – Sodium hydroxide (NaOH) solution – Boric acid solution – Ammonium sulfate – Tryptophan or lysine hydrochloride – Sucrose – Water bath – Analytical balance – Grinding device – Digestion flasks (Kjeldahl) – Boiling aids – Centrifugal scrubber apparatus or filter pump or aspirator
5.	Accelerated Storage test, Cl. 4.1 and 4.7, Table 1, Sl. No. (iv)	– Incubator
6.	Aerobic Plate Count, Cl. 4.7, 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
7.	Coliform count, Cl. 4.7, Table 2, 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
8.	<i>Staphylococcus aureus</i> (Coagulase positive), Cl. 4.7, Table 2, 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
9.	Yeast and mould count, Cl. 4.7, Table 2, Sl. No. (iv)	– Diluent (0.1 % (mass concentration) peptone water broth) – Culture medium (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
10.	<i>Salmonella sp.</i> , Cl. 4.7, Table 2, 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
11.	<i>Listeria monocytogenes</i> , Cl. 4.7, Table 2, 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
12.	<i>E. Coli</i> , Cl. 4.7, Table 2, Sl. No. (vii)	– 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 × 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
13.	Lead, Cl. 4.9, Table 3, 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
14.	Arsenic, Cl. 4.9, Table 3, Sl. No. (ii)	<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

15.	Aflatoxin, Cl. 4.9, Table 3, Sl. No. (iii)	<u>Clean-up by immunoaffinity chromatography and determination by high-performance liquid chromatography method as per ISO 14501</u> – Acetonitrile, pure HPLC grade – Acetonitrile solution – Nitrogen gas – Aflatoxin M1 standard solutions – Disposable syringes of capacities 10 ml and 50 ml – Vacuum system, e.g. Büchner flask, Vac-Elut system or peristaltic pump – Centrifuge – Pipettes – Water baths – Filter paper (Whatman No. 42) – HPLC apparatus – Reversed phase HPLC analytical column, Fluorescence detector – Spectrophotometer – Analytical balance <u>Clean-up by immunoaffinity chromatography and determination by thin-layer chromatography method as per ISO 14674</u> – Chloroform – Acetonitrile – Diethyl ether – Methanol – Toluene, – Acetone – Isopropanol – Aflatoxin M1 standard solutions – Volumetric pipettes – Hamilton-like microsyringes – Laboratory glassware – One-mark volumetric flask – Measuring cylinder – Disposable syringes, of capacities 10 ml and 100 ml – Evaporation system – Spectrometer – Water bath – Centrifuge – Filter paper (Whatman No. 42) – Analytical balance – Magnetic stirrer – Vortex type stirrer – Oven, Vacuum system – Thin-layer chromatography (TLC) container and plates, UV lamp, Densitometer (optional)
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16.	Melamine, Cl. 4.9, Table 3, Sl. No. (iv)	<u>Simultaneous quantitative determination of melamine by liquid chromatography electrospray ionization tandem mass</u> – spectrometry 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
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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 equipment.
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 or 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 5 of IS 1166: 2022.
 - 3.2 The information as mentioned under clause 6.1 of IS 1166:2022 shall be legibly and indelibly marked on each container. 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 Sweetened Condensed Milk, Sweetened Condensed Partly Skimmed Milk, Sweetened Condensed Skimmed Milk and Sweetened Condensed High Fat Milk 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 of Table 1, shall be carried out on the whole production of factory covered by this Scheme and appropriate records maintained in accordance with paragraph 2 above. A separate record shall be maintained for requirement mentioned in clause 4.3 and 4.4 of IS 1166:2022.
 - 5.1 All the production which conforms to the Indian Standard 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 4.10 of IS 1166: 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 the provisions of BIS Act, 2016.

Table 1 LEVELS OF CONTROL
(Scheme of Inspection and Testing)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Clause	Requirements	Test Method			No. of Samples	Frequency	Remarks
		Clause Ref.	IS				
4.2	Description: a) Shall be whitish to light brown in colour, pleasant in taste and flavor shall be pleasant and clean. Free from lumps and coarse particles; uniform in appearance; free from dirt and extraneous matte	4.2	IS 1166	R	One	Every half an hour	See Note 3 below
	Free from rancid, fruity moldy, tallowy, cooked, sour, sandy and any other objectionable odour and taste	--	IS 5126	R	One	Every half an hour	See Note 3 below
4.6	Size of Lactose Crystals	Annex-A	IS 1166	R	One	Each Control Unit	See note 6 below
4.1 and 4.7, Table 1, Sl. No. (i)	Total milk solids	Annex-B	IS 1166	R	Two	Each Control Unit	See note 4 below
4.1 and 4.7, Table 1, Sl. No. (ii)	Milk Fat	--	IS 19396	R	Two	Each Control Unit	See note 4 below
4.1 and 4.7, Table 1, Sl. No. (iii)	Milk solid not fat	--		R	---	Each Control Unit	See note 4 below (By Calculations)
4.1 and 4.7, Table 1, Sl. No. (iv)	Milk Protein in milk solids not fat	--	IS 11917	R	Two	Each Control Unit	See note 4 below
4.1 and							

4.7, Table 1, Sl. No. (v)	Accelerated Storage test	Annex-C	IS 1166	R	One	Each seventh control unit	See note 5 below
4.7, Table 2, Sl. No. (i)	Aerobic Plate Count	--	IS 5402 (Part-1)	R	One	Each Control Unit	See note 6 below
4.7, Table 2, Sl. No. (ii)	Coliform count	--	IS 5401 (Part-1)	R	One	Each Control Unit	See note 6 below
4.7, Table 2, 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 7 below
4.7, Table 2, Sl. No. (iv)	Yeast and mould count	--	IS 16069 (Part 1)	R	One	Each control unit	See note 6 below
4.7, Table 2, Sl. No. (v)	<i>Salmonella sp.</i>	--	IS 5887 (Part 3/ Sec 1)	S	One	Once in a month	See note 7 below
4.7, Table 2, Sl. No. (vi)	<i>Listeria monocytogenes</i> ,	--	IS 14988 (Part-1)	S	One	Once in a month	See note 7 below
4.7, Table 2, Sl. No. (vii)	<i>E. Coli</i>	--	IS 16424	S	One	Once in a month	See note 7 below
4.9, Table 3, Sl. No. (i)	Lead	--	IS 12074	S	One	Once in a month	See note 7 below
4.9, Table 3, Sl. No. (ii)	Arsenic	--	IS 11124	S	One	Once in a month	See note 7 below
4.9, Table 3, Sl. No. (iii)	Aflatoxin M ₁	--	IS 18108 or IS 18110*	S	One	Once in a month	See note 7 below
4.9, Table 3, Sl. No. (iv)	Melamine	--	IS 16195	S	One	Once in a month	See note 7 below

* In case of dispute, the method indicated in IS 18110 shall be the referee method.

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.

Note 3: A sample shall be taken at the packing/repacking stage after every half an hour which shall be examined visually for appearance, colour, absence of lumps and extraneous matter; examined by organoleptic methods for flavour and taste. 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 drawl of sample shall either 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 Total Milk Solids, Milk Fat, Milk solid not fat (by calculations) and Milk protein in milk solids not fat. If any one or both the samples fail to conform to anyone or more of these requirements(s) as given in the specification, the entire material of the control unit shall not be marked.

Note 5: One sample from every seventh control unit shall be tested for Accelerated Storage test. If the sample fail to satisfy the requirement, the corresponding control unit shall not be marked. One sample from every subsequent control unit shall be tested for the characteristic, till seven consecutive control units are found meeting the specification requirements, whereupon the original frequency of testing may be resumed.

Note-6: One sample from every control unit shall be tested for the requirements of Size of Lactose Crystals, Aerobic Plate Count, Coliform Count and Yeast & Mould count as laid down in the Indian Standard. If the sample 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: A sample shall be tested every month for *Staphylococcus aureus*, *Salmonella*, *Listeria monocytogenes*, *E. coli*, Lead, Arsenic, Aflatoxin M₁ and 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.