MANUAL FOR INTEGRATED MILK CERTIFICATION
ACCORDING TO IS 13688:1999 and IS/ISO 22000

This Manual shall be used as reference material by all Regional/Branch Offices & licensees to ensure coherence of practice and transparency in operation of certification under Integrated Milk Certification Scheme (Scheme-I of Bureau of Indian Standards (Conformity) Assessment Regulations, 2018 and Food Safety Management System. The document may also be used by prospective applicants desirous of obtaining BIS certification licence/certificate under Integrated Milk Certification Scheme:

This Manual, as such, would not be applicable for Packaged Milk certification as per IS 13688 when applied as standalone i.e. only product certification without integration with FSMS. For standalone product certification, there would be separate SIT covering additional checks from procurement to retail level.

1.	**Product and Systems Integrated**	**:**	IS 13688:1999 and IS/ISO 22000
	Titles	**:**	Packaged Pasteurized Milk and Food Safety Management System
	No. of amendments	**:**	Nil (in both standards)
2.	**Sampling Guidelines**	:	
a)	**Raw material**	**:**	a) **Milk** –One sample shall be drawn at the receiving point of the factory for testing as per Cl 4.1 of IS 13688 b) **Milk Powder and Skimmed Milk Powder** – One sample each shall be drawn be at the receiving point of the factory for testing as per Cl 4.2 of IS 13688. However, no testing required if material is ISI marked. c) **Butter and Butter Oil** – One sample each shall be drawn at the receiving point of the factory for testing as per Cl 4.3 of IS 13688. However, no testing required if material is ISI marked or accompanied with test certificate of supplier or Test report from NABL accredited lab indicating compliance. d) **Water - One** sample shall be shall drawn at the receiving point of the factory for testing as per Cl 4.4 of IS 13688 . No testing would be required if Test report from NABL accredited lab indicating compliance to 4.4 of IS 13688 is available.
b)	**Packing Material**		Sample of each type of packing material (glass container/polyethylene pouches) shall be drawn and tested for compliance to Cl 9.1 of IS 13688 provided complete in-house test facilities are available and declared to BIS for verification. In case in-house testing facilities are not available, compliance shall be ensured through supplier's test certificate or Test report from NABL accredited lab.
c)	**Grouping Guidelines**	**:**	Sampling and testing of only one type of milk would be adequate to cover all the types of milk for which application is submitted and infrastructure for manufacturing and testing is available.

d)	**Sample Size**	:	Two pouches of minimum 250 ml capacity each
6.	**List of Test Equipment**	:	Please refer Annex - A
7.	**Scheme of Inspection and Testing**	:	Please refer Annex - B
8.	**Testing guidelines**	:	This scheme will be operated on factory testing basis since no BIS Labs or BIS recognized third party labs are available. Accordingly, all tests are required to be done during the inspection-cum-audit. The standard prescribes requirement, the testing of which involves long duration tests i.e. 72 hours. Therefore, the inspection-cum-audit should be planned in a manner to witness such long duration tests also. In future when BIS labs or BIS recognized third party testing as per IS 13688 are available and arrangement for maintaining cold chain for delivery of sample to the lab is made, then possible tests in a day will be carried out in factory testing.
9.	**Guidelines for operation of integrated milk certification scheme**		Please refer Annex - C

10. **Scope of the Licence :**

Licence shall be granted with scope specifying the type(s) permitted to be used for packing the product. Licence shall not be granted with “open scope”. Type of packing and the material shall be mentioned in the scope oflicencebased on proof of conformity to the relevant Indian Standard. The grant of licence letter and the Licence Document shall clearly indicate the following:

	Name of the product	Packaged Pasteurized Milk as per IS 13688:1999
	Type	Type of Packaged Pasteurized Milk (Standardized milk / Full Cream milk /Toned milk /Double Toned milk / Skimmed milk / Recombined milk)
	Material	Material of packing to be specified as per Cl. 9.1 of IS 13688:1999 (Polyethylene pouches/Glass containers)
	Food Safety Management System	Food Safety Management System certification as per IS/ISO 22000

ANNEX- A
LIST OF TEST EQUIPMENTS
MAJOR TEST EQUIPMENTS REQUIRED AS PER INDIAN STANDARD

Sl. No.	Test	Clause no. of IS 13688	Equipments and Glassware	Chemicals
1	Milk (Adulterants)			
	a) Starch test		General laboratory glasswareslikeTest Tubes, pipettes	1.0% Iodine Solution
	b) Sugar test		1. General laboratory glasswares like Test Tubes, pipettes 2. Water bath 3. Weighing Balance	1. Concentrated Hydrochloric Acid 2. Resorcinol
	c) Urea		General laboratory glasswares like Test Tubes, pipettes	1. Dimethyl Aminobenzaldehyde 2. Concentrated Hydrochloric Acid 3. Ethyl Alcohol
	d) Formalin		General laboratory glasswares like Test Tubes, pipettes	1. Ferric Chloride 2. Sulphuric Acid 90%
	e) Pond Water (Fertilizer test)	4.1	General laboratory glasswares like Test Tube, pipettes	1. Diphenylamine Solution 2. Sulphuric Acid
	f) Ammonia Compound		General laboratory glasswares like Test Tubes, pipettes	1. Nessler reagent
	g) Glucose		1. General laboratory glasswares like Test Tubes, pipettes 2. Water bath	1. Barfoed's reagent 2.Phosphomolybdic acid
	i) Ionic Detergent		General laboratory glasswares like Glass Cylinder, pipettes	1. Methylene Blue Solution 2. Chloroform
	g)Boric Acid and Borates		General laboratory glasswares like pipettes, Beaker	1. N/10 Sodium Hydroxide 2. Phenolphthalein indicator 3. Glycerol
	h) Soya Powder		1. General laboratory glasswares like Test Tubes, pipettes 2.Filter paper	1. Urea crystals 2. Phenol red solution
2	Milk powder and Skimmed Milk Powder	4.2	If used, shall conform to PM of IS 1165, IS 13334(Part I) and IS I3334 (Part 2) respectively.	

3	Butter and Butter oil	4.3		
4	Water supply	4.4		
5	Colour and Appearance	7.1 and Table 1	---	---
6	Odour	-do-	---	---
7	Flavour	-do-	---	---
8	Body	-do-	---	---
9	Total plate count	7.3	1. Autoclave, 2. Hot Air Oven, 3. Conical Flask 4. pH meter 5. Weighing Balance, 6. Biosafety cabinet 7. Micropipette 8. Petri Dish	Plate count Agar, Buffer peptone Water
10	Coliform	-do-	1. Autoclave, 2. Hot Air Oven, 3. Conical Flask 4. pH meter 5. Weighing balance 6. Biosafety cabinet 7. Micropipette 8. Petri Dish	Violet Red Bile Agar
11	Methylene blue reduction test	-do-	1. General laboratory glasswares like Test Tubes, pipettes 2. Water bath, 3. Hot air oven, 4. Spirit lamp &comparator	Methylene Blue Solution
12	Milk Fat	7.4 and Table 2	1.mojonniier Fat-extraction tube, 2.General laboratory glasswares like pipettes, cylinder	1. Conc. Ammonia solution (sp-gr 0.88), 2. Ethyl Alcohol, 3. Diethyl Ether (sp. Gr 0.720), 4. Petroleum Ether (boiling range-40 to 60°C)
13	Milk solids-not-fat (SNF)	-do-	1. Aluminum Dish 2. Water Bath 3. Oven well-ventilated	N.A.
14	Phosphatase Test	-do-	General laboratory glasswares like Test Tubes	1. Buffer Solution 2. Disodium p-Nitro phenyl phosphatase
15	Neutralizer	-do-	General laboratory glasswares like Test Tubes	0.05 percent rosolic acid in 60% Ethyl Alcohol Solution

ANNEX-B
SCHEME OF INSPECTION AND TESTING
FOR MANUAL FOR INTEGRATED MILK CERTIFICATION
ACCORDING TO IS 13688:1999 and IS/ISO 22000

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 to carry out the different tests in accordance with the methods given in the Indian Standards.

2. **TEST RECORD:** The manufacturer shall maintain test records for the tests carried out to establish conformity. **In addition, records may be maintained for raw material, packaging etc. for which an indicative list is as under and suggested formats are given in Annex D:**

i. **Raw material records**
ii. **Packing/packaging material records**
iii. **Cleaning, plant hygiene and sanitation records**
iv. **Pest Control records**
v. **Health record of the employees (involved in milk handling operations)**.

3. **PACKING & MARKING**

3.1 Packing: The Pasteurized milk shall be packed in clean, sound and sanitary containers made of glass (see IS 1392), polyethylene pouches (conforming to IS 11805), properly sealed so as to prevent contamination.

3.2 Standard Mark: The Standard Mark as given in the Schedule of the licence shall be printed legibly and indelibly to the container of Packaged Pasteurized Milk Specification.

3.3 Other Marking– The container, pouches shall bear legibly and indelibly the following information:

a) Name of the material 'Pasteurized Milk'.
b) Type of milk 'full cream', 'toned', 'standardized skimmed', 'double toned', 'recombined' as applicable
c) Batch or Code number;
d) Date of packingand/or time;
e) Name of the processor;
f) Net volume in ml or litre
g) Best before (*date*)_____,(when stored at temperature of milk not exceeding 8˚C)
h) Fat ____percent, Solid-not-fat_____percent
i) Any other requirements under the Legal Metrology (Packaged Commodities) Rules,2011 and Food Safety and Standards (Food Products Standards and Food Additives) Regulation, 2011

4. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 4 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.

4.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

4.2 Control Unit – For the purpose of this Scheme, the entire quantity of milk manufactured continuously at a time in a period of 24 hours or a part **in one silo** shall constitute a Control Unit.

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

4.3.1 A sample shall be taken at the packing stage after every half an hour which shall be examined visually for appearance, colour, examined by organoleptic methods for flavour and taste and body. If the sample does not conform to the specification in anyone or more of these requirements, the material manufactured during the half an hour prior to the drawl of sample shall either be rejected or reprocessed and the defect(s) rectified. Such reprocessed material when tested again shall conform to all the requirements of the specification.

4.3.2 Two samples shall be drawn from every Control Unit, one during the first half of the packing period and other during the second half of the packing period. These samples shall be individually tested for Milk Solids-not-fat (SNF),Milk fat, phosphate, Total plate count, Coliform, neutralizer and Methylene Blue reduction test. If any one or both the samples fail to conform to anyone or more of these requirements, the production should be stopped. The production should be initiated only after carrying out Root-Cause Analysis for the failure, Corrective Actions taken and its effectiveness verified by the conformance of the product at testing.

5 Hygienic Conditions

5.1 The milk shall be processed, pasteurized, packed and handled under strict hygienic conditions as prescribed in Cl.6 of IS 13688 and various clauses of IS 7005.

5.2 In respect of all the above clauses of the specification, the factory shall maintain appropriate controls and checks to ensure that the product conforms to the various requirements of the specification.

Note: In case firm is having valid FSMS licence from any accredited agency and has applied for only product certification licence as per IS 13688, it may not be possible to verify compliance to IS 7005 since it covers hygienic conditions and practices from the cattle shed to the Milk distribution, which will not be possible to verify in the plant itself. In such a case, hygienic conditions may be verified in the plant only as per Cl 6.1 to 6.7 of IS 13688.

6 Rejection

6.1 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.Any rejected material which is potentially re-saleable be sheared or cut or deformed in such a manner that it cannot be used for any other purpose. A separate record shall be maintained giving information on quantity and batch number/control unit number, as applicable, relating to all such rejections/defective/sub-standard material of the production not conforming to the requirements of the Specification and the method of its disposal. Such material shall in no case be stored together with that conforming to the Specification. The Standard Mark (if already applied) on rejected material should be defaced.

IS 13688:1999
PACKAGED PASTEURIZED MILK SPECIFICATION
Table 1 LEVELS OF CONTROL
(Scheme of Inspection and Testing)

(1)	(2)			(3)	(4)		(5)
	TEST DETAILS			**Test equipment requirement** R: required (or) S: Sub-contracting permitted	**LEVELS OF CONTROL**		**REMARKS**
Clause	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	
		Clause	**Reference**				
4	Raw Material	-	IS 1479(part 1)	S	One	Once in a month for each source (supplier)	No testing required if material is ISI marked or accompanied with test certificate of supplier or Test report from NABL accredited lab indicating compliance.
4.1	Raw Milk	-	IS 1479(part 1) and IS 7768				
4.2	Milk powder and Skimmed Milk Powder	-	Shall conform to IS 1165, IS 13334 (part1) and IS 13334(part 2)	S			
4.3	Butter and Butter oil	-	Shall conform to IS 13690 and IS 13689	S			
4.4	Water supply	-	IS 4251	S	One	Once in 6 months	-do-
7	Description	7.1 and Table 1	IS 13688	R	One	Every half an hour	See clause 4.3.1 of SIT
7.1 and Table 1	Colour and Appearance	7.1	--do--	R	One	-do-	-do-
-do-	Odour	-do-	do	R	One	-do-	-do-
-do-	Flavour	-do-	do	R	One	-do-	-do-
-do-	Body	-do-	do	R	One	-do-	-do-
7.3	Total plate count	-	IS 5402	R	Two	Each control unit	See clause 4.3.2 of SIT
-do-	Coliform	-	IS 5401	R	Two	-do-	-do-
-do-	Methylene blue reduction test	-	IS 1479(part 1)	R	Two	-do-	-do-
7.4 and Table 2	Milk Fat	Annex-B	IS 1479 (Pt-2)	R	Two	-do-	-do-
-do-	Milk solids-not-fat	-	IS 12333 and IS	R	Two	-do-	-do-

	(SNF)		1479(part 2)				
-do-	Phosphatase Test	-	IS 8479 (pt-1 and 2)	R	Two	-do-	-do-
-do-	Neutralizer	-	IS 1479(part 1)	R	Two	-do-	-do-

Note-1: Whether test equipment is required or sub-contracting is permitted in column 3 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 4 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 4 with proper justification.

Annex C
Guidelines for operation of integrated milk certification scheme

S. No.	Stage of Certification Process	Guidelines for Integrated Milk Certification
1.	Application for Grant of licence	Separate applications to be made for product certification and FSMS licences as per established procedure. In case the applicant is already holding FSMS Certification, it should be ensured that: i) The FSMS Certification is from an accredited agency. ii) The certification is valid and includes packaged milk under its scope. iii) Inputs are obtained from the certification agency regarding satisfactory performance of FSMS. (Note: The applicant on its part may submit the proof of satisfactory performance in any form generated/maintained by the certification agency) iv) The manufacturer undertakes to allow BIS to assess the systems and records as maintained by the applicant. v) The applicant to inform the schedule of surveillance assessment to BIS and inform the outcome of the surveillance to BIS.
2.	Sequence of application	**Applicant to apply first for FSMS certification to the concerned regional office.** Based on acceptance of application, the Stage I audit of FSMSshould be carried out, preferably within a week of recording of application. Generally, one man-day is adequate for Stage I audit but depending upon the processes involved, the man-days required could be more than one also. **If the plant is already certified for FSMS by an accredited certification body, he may directly apply for product certification by providing evidence of said FSMS certification**
3.	Application for IS 13688	**If Stage I Audit is satisfactory, the MSCO (R) to inform the concerned BO to accept and record the application for Product Certification**.
4.	Application and LicenceFee	Application and licencefee for both product certification and FSMS to be charged separately as per regulations
5.	Inspection/Audit Fee	The preliminary inspection will be of 3 days, Rs 12000 x 3 = Rs 36,000 to be charged as per Scheme III fee schedule as it is higher than the Scheme I fee applicable (i.e. Rs 7000 x 3 = 21000). **However, the payment to be received through payment module in Manakonline since otherwise Product Certification application cannot be processed.**
6.	Preliminary Inspection/Certification Audit	The preliminary inspection and FSMS Certification Audit**(Stage II Audit)** shall be combined (3 days) and the visit shall be paid by an officer who is conversant with food and dairy products and is FSMS auditor.(In case FSMS trained auditor is not available in the branch or region, the officer may be sourced from other branches/regions with the concurrence of the DDGRs concerned) For FSMS, the audit will include visit to milk procurement centres (village level centres and milk chilling centres) and retail points (on sampling basis). However, if the dairy has milk procurement centres located outside dairy premises, (which may or may not be with chilling centres), and it is intended to cover these centres in the scope of FSMS then all such centres will be visited and assessed during the audit. However, if these centres are not

		intended to be covered, then at least 2 of the centres shall be visited during the audit. In case firm is having valid FSMS licence from any accredited agency and has applied for only product certification licence as per IS 13688, it may not be possible to verify compliance to IS 7005 since it covers hygienic conditions and practices from the cattle shed to the Milk distribution, which will not be possible to verify in the plant itself. In such a case, hygienic conditions may be verified in the plant only as per Cl 6.1 to 6.7 of IS 13688.
7.	Grant of licence	Grant of licence to be considered for both Product Certification and FSMS subject to applicant satisfying requirements of Scheme I and III. Separate licence documents to be issued concurrently with the same validity. However, in cases where it becomes necessary to reject the application for either product certification or FSMS licence, licence may be granted for the other scheme (It will not be integrated milk certification in that case). However, manufacturer may be advised to re-apply after taking necessary corrective actions.
8.	Surveillance	Two visits to be paid during the year: i) The first visit would be for surveillance inspection for assessment of performance of the product certification licence only. ii) The next visit would be a combined audit for product certification and FSMS. This second visit would also serve as the re-certification audit for the FSMS licence. (Milk Procurement centres and retail points also to be visited) All surveillance visits to be so planned such that while proceeding for the inspection to a particular dairy, the market sample for that dairy may be drawn from the nearby market/source and transported to the plant whilst maintaining the necessary handling and storage requirements (cold chain). This market sample would then be tested in the factory during the surveillance visit in addition to factory sample testing. Surveillance audits to be done preferably by officer who is conversant with food and dairy products and is an FSMS auditor. However, the first visit which is only surveillance visit for product certification, may be done by an officer who may not be FSMS auditor. Efforts may be made to train such officers about food safety aspects and FSMS criteria, before deputing them for surveillance visits . The second visit, however, which serves as a re-certification audit, has to be done by an FSMS auditor only.
9.	Renewal/Re-certification	Renewal/recertification may be normally done for a period of 3 years for both PC/FSMS licences, to maintain concurrent validity for both Product Certification and FSMS Licence
10.	Suspension	Since prolonged suspension of licence may not be tenable for milk as it may affect the availability of milk to end users, the alternative approach to be followed is: If a non-conformity is observed in Product Certification during surveillance visit or testing of samples, the

		manufacturer shall be advised to investigate and identify the root cause and take corrective action immediately during the currency of the visit. During the same visit, the corrective actions taken may be verified by the officer. If the visit is prolonged beyond 1 day due to the above, the visit charges for the additional days to be borne by the licensee. However, for suspension in case of FSMS, it may be treated as per the defined procedure for the same.
11.	Complaint	Considering the importance of milk and health aspects involved, in case of consumer complaint, the concerned BO to complete investigation including factory visit and testing of samples in 3 days. Testing may be done on samples as per the following order of priority: 1. In case sample of the same batch as the complaint sample is available, same to be tested 2. In case sample of the same batch is not available, sample of the same type from the running batch may be tested. 3. In case sample of the same type is not available in the running batch, the sample of the type of the running batch may be tested. Complaint investigation visit at factory should done by an officer who is a trained FSMS auditor*

ANNEX D
RAW MILK RECORD

Form-I

Tanker No./MCC/ Date	Analysis of Raw Milk for Adulteration											
	Detection of skimming C-15.2	Detection of Mixed Separated Milk/ C-15.2	Detection of Extraneous/ C-15.4	Mineral oil/C-15.5	Starch/C-15.6	Cane Sugar/ C-15.7	Maltodextrine/ C-15.8	Glucose/ C-15.9	Urea/ C-15.10	Vegetative oils/ C-15.11	Sulphates/C-15.12	Anoinic Detergent/C-15.13

Form-II

Analysis of Raw Milk for Preservatives					
Boric Acid/C-16.1	Formaldehyde/C-16.2	Hydrogen peroxide/C-16.5	Detection of Salicylic Acid/C-16.4	Detection of Hypochlorite/C-16.6	Detection of Soya Powder/C-15.14

Form-III

Analysis of Raw Milk for Neutralizer			
Rosolic Acid/C-17.1	Sodium Salt/C-17.2	Acidity difference/C-17.3	TPC

Form-IV

Analysis of Raw Milk				
MBRT	Acidity	Coliform	Temperature	organoleptic