PRODUCT MANUAL
FOR INDIGO CARMINE, FOOD GRADE ACCORDING TO IS 1698 : 1994

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

1.	**Product**	**:**	IS 1698 : 1994
	Title	**:**	Indigo Carmine, Food Grade
	No. of amendments	**:**	01
2.	**Sampling Guidelines**		
a)	**Raw material**	**:**	No specific requirement
b)	**Grouping Guidelines**	**:**	NA
c)	**Sample Size**	**:**	**50 g**
3.	**List of Test Equipment**	**:**	Please refer Annex – A
4.	**Scheme of Inspection and Testing**	**:**	Please refer Annex - B
5.	**Possible tests in a day**	**:**	
	i. Total dye content (if done by "Titanium Trichloride Method) ii. Loss on Drying at 135ºC iii. Water-Insoluble Matter iv. Combined Ether Extracts v. Subsidiary Dyes vi. Isatin sulphonic acid vii. Lead viii. Arsenic ix. Heavy Metal		
6.	**Scope of the Licence :**		
	Licence is granted to use Standard Mark as per IS 1698 : 1994 with the following scope		
	Name of the product	:	Indigo Carmine, Food Grade

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ANNEX –A
TO PRODUCT MANUAL
FOR INDIGO CARMINE, FOOD GRADE ACCORDING TO IS 1698 : 1994

LIST OF TEST EQUIPMENT

Major test equipment required to test as per Indian Standard

Sr. No.	Tests used in with Clause Reference (Cl. 3.1 and Table)	Test Equipment/Chemicals/Glassware
1	Total Dye Content Cl 3.1 & Table 1, Sr. no (i) (Annex A of IS 1698)	**Spectrophotometric Method:** spectrophotometer, Ammonium acetate solution, Analytical balance (L.C- 1 mg), volumetric flask, Air oven (L.C- 1°C) **Titanium Trichloride Method**: Sodium Citrate, Standard potassium dichromate solution (0.1 N), Standard titanium trichloride, Measuring cylinder, weighing balance, ferrous ammonium sulphate, measuring flask, carbon dioxide, heater, sulpuric acid, potassium dichromate solution, ammonium thiocyanate, Erlenmeyer flask.
2	Loss on drying at 135ºC and chlorides and sulphates expressed as sodium salt Cl 3.1 & Table 1, Sr. no. (ii) (Cl 6, 13 and 14 of IS 1699)	**Determination of loss of drying:** weighing machine, weighing bottle fitted with a ground glass lid, heater, timer, Air oven, desiccator. **Determination of chloride as sodium chloride:** Potentiometric titration apparatus with silver electrode, weighing balance, water, measuring cylinder, nitric acid solution, silver electrode, glass electrode. **Determination of sulphate as sodium sulphate:** Weighing balance, conical flask, heater water bath, sulphate free sodium chloride, timer, measuring flask, beaker, hydrochloric acid, 0.25 N barium chloride solution, timer, filter, crucible, Hotplate, Barium Sulphate
3	Water Insoluble Matter, Cl 3.1 & Table 1, Sr. no. (iii) (Annex B of IS 1698)	Weighing machine, prepared gooch crucible, hot water, cold water, oven (L.C- 1°C), timer, desiccator.
4	Combined Ether Extracts Cl 3.1 & Table 1, Sr. no. (iv) (Annex C of IS 1698)	Weighing machine, separator or continuous extractor of 250 ml, Isopropyl ether, sodium hydroxide solution (10 % m/v), sodium hydroxide solution (0.1 N), dilute hydrochloric acid (1:1), hydrochloric acid wash solution, neutral ether extract, alkaline ether extract, acid ether extract.
5	Subsidiary Dyes Cl 3.1 & Table 1, Sr. no. (v) (Annex D of IS 1698)	Chromatography tank and auxillary equipment, micro syringe capable of delivering 0.1ml with a tolerance of ±0.002ml, spectrophotometer, chromatography

		solvents, extracting solvent, sodium bicarbonate (0.50 N), measuring apparatus, drying cabinet.
6	Isatin Sulphonic Acid Cl 3.1 & Table 1, Sr. no. (vi) (Annex E of IS 1698)	Chromatograph tank with auxillary equipment, micro syringe, spectrophotometer, atmosphere saturating solvent, measuring cylinder, timer, dryer, ultraviolet light arrangement.
7	Lead Cl 3.1 & Table 1, Sr. no. (vii) (Cl 15 of IS 1699) Arsenic Cl 3.1 & Table 1, Sr. no. (viii) (Cl 15 of IS 1699)	**Instrument method**: Kjeldahl flask, Atomic absorption spectrophotometer, hydrochloric acid, water, sodium sulphate, sodium borohydride pellets, potassium chloride, measuring cylinder/ beaker, volumetric flask, Analytical balance, heater. **Chemical method: For Lead**; Nitric acid, sulphuric acid, ammonium acetate- citrate solution, ammonium solution, carbon tetrachloride, ammonium hydroxide, potassium cyanide, hydroxylamine hydrochloride solution, duluzone solution, buffer pH2. **For Arsenic:** Distillation apparatus, conical flask, sulphuric acid, potassium permanganate solution, ferrous sulphate, Hydrochloric acid, potassium bromine solution, aluminium stripes, tin chloride solution, test paper.
8	Heavy Metal Cl 3.1 & Table 1, Sr. no. (ix) (Cl 16 of IS 1699)	Ammonium solution, acetic acid solution, standard lead solution, lead nitrate stock solution, measuring beaker/cylinder, weighing balance, hydrogen sulphide, pH indicator paper.

The list above is indicative only and may not be treated as exhaustive.

ANNEX - B

SCHEME OF INSPECTION AND TESTING FOR INDIGO CARMINE, FOOD GRADE ACCORDING TO IS 1698 : 1994

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test 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 stenciled/printed on each container of Indigo Carmine, Food Grade or printed on the label applied to it, as the case may be, provided always that the material in each container to which the Mark is thus applied conforms to every requirement of the specification.

3.1 Marking – Each container shall be legibly and indelibly marked with the information provided under clause 4.2.1 of IS 1698. In addition, the following information shall be clearly and indelibly marked on each container:

a) The words "Synthetic Food Colour";
b) Names of the major dye intermediates present;
c) Name and address of the manufacturer;
d) BIS Licence No. CM/L_.
e) BIS website details i.e – "For details of BIS Certification please visit www.bis.gov.in".

3.2 Packing – The material shall be packed in glass containers, polyethylene containers, metal containers, or cardboard containers suitably lined with polyethylene. Subject to agreement between the purchaser and the vendor any other suitable container may also be used.

4. CONTROL UNIT – For the purpose of this Scheme, Indigo Carmine, Food Grade blended at a time from different filter pressed batches 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.

5.2 On the basis of test results, the decision regarding conformity or otherwise of a control unit to a given requirement shall be made as follows:

5.2.1 Two independent samples drawn from each control unit or batch and tested for pure dye content, shall individually satisfy the requirements given in the specification. If any one of the

sample fails, the entire material in the control unit shall be considered as unfit for the purpose of marking.

5.2.2 A composite sample made from the two independent samples drawn under 5.2.1 and tested for all the remaining characteristics of the specification shall satisfy the corresponding requirements. If it fails in any one or more of these requirements, the entire material of the control units shall be considered as unfit for the purpose of marking.

5.2.3 Precaution shall be taken to ensure that the material is free from mercury, copper, and chromium in any form; aromatic amines; aromatic nitro compounds, aromatic hydrocarbons and cyanides.

6 RAW MATERIALS - Routine analysis of various raw materials going into the manufacture of Indigo Carmine, Food Grade shall be made on each lot received in the factory or alternatively raw materials of known composition may be used.

7. HYGIENIC CONDITIONS - The material shall be processed, packed, stored and distributed under hygienic conditions (See IS 2491). All the processing equipments should be properly cleaned and care should be taken to prevent infestation**.**

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

TABLE 1
LEVELS OF CONTROL

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Clause	**Requirement**	**Test Method Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
Cl. 3.1 and Table 1							
Sr No. i)	Total Dye content	Annex A	IS 1698	R	Two	Each control unit	-
ii)	Loss on drying at 135°C and chlorides and sulphates expressed as sodium salt.	6, 13 & 14	IS 1699	R	One	-do-	See clause 5.2.2 of SIT
iii)	Water Insoluble Matter	Annex B	IS 1698	R	-do-	-do-	
iv)	Combined ether -extracts	Annex C	-do-	R	-do-	-do-	
v)	Subsidiary dyes	Annex D	-do-	R	-do-	-do-	
vi)	Isatin sulphonic acid	Annex E	-do-	R	-do-	-do-	
vii)	Lead	15	IS 1699	R	-do-	-do-	
viii)	Arsenic	15	-do-	R	-do-	-do-	
ix)	Heavy Metals	16	-do-	R	-do-	-do-	

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.