



उत्पाद मैनुअल

इंडिगो कारमीन, खाद्य ग्रेड— विशिष्टि

1698: 2024 के अनुसार

**PRODUCT MANUAL FOR
INDIGO CARMINE, FOOD GRADE – SPECIFICATION
ACCORDING TO IS 1698: 2024**

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 1698 : 2024
	शीर्षक Title	:	Indigo Carmine, Food Grade
	संशोधनों की संख्या No. of amendments	:	0
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	No specific requirement Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	Not Applicable

c)	नमूने का परिमाण Sample Quantity	:	100 g 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 (incase of market surveillance, effort may be made to procure therequired quantity of product sample, as far as possible since raw material sample may not be available in market)
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	Please refer to Annex-A देखें
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	Please refer to Annex-B देखें
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	i. Total Dye content ii. Water Insoluble Matter iii. Combined ether extracts iv. Subsidiary dyes v. Isatin sulphonic acid vi. Dye Intermediates vii. Unsulphonated primary aromatic amines viii. Lead ix. Arsenic x. Mercury xi. Copper xii. Chromium xiii. Cadmium 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:		
	1698:2024 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है “ Licence is granted to use Standard Mark as per IS 1698:2024 with the following scope:		
7.	Name of the product		Indigo Carmine, Food Grade

ANNEX – A
LIST OF TEST EQUIPMENTS
(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sr. No.	Tests used in with Clause Reference (Cl. 3.1 and Table)	Test Equipment/Chemicals/Glassware
1	Total Dye Content Cl 3.3 & 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), distilled water 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, sulphuric acid, potassium dichromate solution, ammonium thiocyanate, Erlenmeyer flask.
2	Loss on drying at 135°C and chlorides and sulphates expressed as sodium salt Cl 3.3 & 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, arrangement for temperature at 20 °C
3	Water Insoluble Matter, Cl 3.3 & 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, dilute hydrochloric acid, glass filter, desiccator.
4	Combined Ether Extracts Cl 3.3 & 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., beaker, water bath,
5	Subsidiary Dyes Cl 3.3 & Table 1, Sr. no. (v) (Annex D of IS 1698)	Chromatography Tank & Ancillary apparatus, Micro syringe, Chromatography solvents, Extracting solvents (Acetone & water), Sodium bicarbonate, Spectrophotometer, Filter papers, Test tubes, Drying cabinet.

6	Isatin Sulphonic Acid CI 3.3 & Table 1, Sr. no. (vi) (Annex E of IS 1698)	Chromatograph tank with auxillary equipment, micro syringe, spectrophotometer, atmosphere saturating solvent (water), measuring cylinder, timer, dryer, ultraviolet light arrangement, sodium chloride, ammonium sulphate
7	Dye Intermediates CI 3.3 & Table 1, Sr. no. (vii) (Annex F of IS 1698)	<u>Ascending paper chromatographic method</u> Chromatography Tank and Ancillary Equipment, Microsyringe — capable of 0.2 ml, Ultraviolet Lamp, Filter Paper, Spectrophotometer for Use in the Ultra violet range, ammonium sulphate, beaker, Ammonium Hydroxide Solution, Developing Solvent, 2-Naphthol-6-Sulphonic Acid, Aniline-4-Sulphonic Acid, Sodium Nitrite — crystals, Hydrochloric Acid, Chromotropic Acid Solution, Sodium Acetate Solution <u>Column chromatographic method</u> Chromatographic tube, Spectrophotometer with UV range, Whatman powdered cellulose (or equivalent), ammonium sulphate.
8	Unsulphonated primary aromatic amines CI 3.3 & Table 1, Sr. no. (viii) (Annex G of IS 1698)	Visible range spectrophotometer, Toluene, Hydrochloric Acid - 1 N, Potassium Bromide - 50%, Sodium Carbonate - 2 N, Sodium Hydroxide - 1 N, Sodium Hydroxide - 0.1, N Sodium Nitrite 0.5 N weighing balance, beaker, volumetric flask, ice/water bath, pipette 10 ml
9	Lead Arsenic Mercury Copper Chromium Cadmium CI. 3.3 & Table 1 (CI ix of IS 1699)	Instrumental method: Atomic absorption spectrophotometer Inductively coupled plasma-atomic emission spectrophotometer (Cadmium, Chromium, Copper, Lead and Zinc) Apparatus as per CI 15.1.10.4 of IS 1699 potentiometric recorder Nitric acid Perchloric acid Sulphuric acid Hydrochloric acid distilled water Sodium sulphate Sodium borohydride pellets Potassium chloride Standard copper solution Standard zinc solution Standard chromium solution Standard antimony solution Standard lead solution Standard barium solution Standard arsenic solution Standard cadmium solution hydroxylamine hydrochloride solution stannous chloride solution

		Potassium permanganate solution Chromic acid mixture Magnesium perchlorate Mercury chloride Kjeldahl flask, Chemical Methods A. Lead (Pb) Digestion funnel; Separating funnel, Nitric acid, Sulphuric acid, Ammonium acetate-citrate solution, Ammonia solution, Carbon tetrachloride, Ammonium hydroxide, Potassium cyanide, Hydroxylamine hydrochloride solution, Dithizone solution, Buffer pH 2, hot plate B. Arsenic (As) 1. <u>Distillation method (routine)</u> Distillation apparatus, water bath, Conical flask, Sulphuric acid, Potassium permanganate solution, Ferrous sulphate, Hydrochloric acid, Potassium bromide solution, Aluminium strips, Tin chloride solution, Test paper, hot plate, micro burner, water bath 2. <u>modified Gutzeit method (IS 2088)</u> Apparatus for modified Gutzeit method as per Fig. 1 of IS 2088, Lead Acetate Solution, Lead Acetate Paper Strips, Absorbent Cotton Wool Impregnated with Lead Acetate, Mercuric Bromide Solution, Sensitized Mercuric Bromide Paper Strips, Dilute Sulphuric Acid, Concentrated Hydrochloric Acid, Potassium Iodide Solution, Stannous Chloride Solution, Zinc, Standard Arsenic Stock Solution (arsenic trioxide and sodium hydroxide solution), C. Copper (Cu) Citric acid, Ammonium hydroxide solution, Concentrated hydrochloric acid, Dithizone (diphenyl thiocarbazone) solution, Concentrated nitric acid, Concentrated sulphuric acid, Gum arabic solution, Standard strong solution of copper, hot plate D. Chromium (Cr) Magnesium nitrate solution, Strong sulphuric acid solution, Potassium permanganate solution, Sodium azide solution, Sodium dihydrophosphate, Diphenylcarbazide solution, Standard chromium solution, Sucrose, quartz dish, oven, water bath, hot plate, Vis-spectrophotometer
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ANNEX B

SCHEME OF INSPECTION AND TESTING

1. QUALITY ASSURANCE PLAN

1.1 It is expected that manufacturers (licensees/applicants) will implement a Quality Assurance Plan i.e. a plan of regular testing and in-process controls, designed to ensure that the product bearing the Standard Mark conforms to all requirements of the Indian Standard.

1.2 The manufacturers shall define a Quality Assurance Plan defining the control unit (i.e. lot/batch etc.) and the levels of control (i.e. the frequency and number of samples for conducting the different tests as per the Indian Standard) and submit the same to BIS Branch Office for information. The manufacturer shall comply with the same and maintain test records in accordance with para 2.4.

1.3 RECOMMENDED LEVELS OF CONTROL/CONTROL UNIT:

1.3.1 For the guidance of manufacturers, the recommended definition of control unit is: Entire quantity of Indigo Carmine, Food Grade produced continuously at a time in each reaction vessel

1.3.2 For the guidance of manufacturers in preparing the Quality Assurance Plan, recommended levels of control are given in **Table 1**.

1.3.3 The manufacturer shall ensure inspection and testing as per the Quality Assurance Plan submitted by them on the whole production of the factory which is covered by this plan. Alternatively, the manufacturer has the option of adherence to the quality plan as per levels of control recommended in column 3 of Table 1.

1.4 However, all manufacturers shall ensure compliance of their products to all the requirements of the Indian Standard.

2. ENSURING COMPLIANCE THROUGH TESTING- It is expected that manufacturers (licensees/applicants) will establish a suitably equipped and staffed in house laboratory (In house testing facility) for testing at least those parameters of the Indian Standard which require routine testing for ensuring quality of the product. This includes in-process controls as may be defined and put in place by the manufacturer and testing parameters/requirements which can only be performed in the factory.

2.1 For the guidance of manufacturers, Table 1 giving the recommended levels of control is given below. Column 2 of Table 1 indicates routine tests where test equipment is required in house as "R" or other tests which can be subcontracted as "S". Subcontracting is permitted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.2 For MSME manufacturers, the requirement of maintaining a laboratory/in-house testing facility for routine tests (indicated as "R" in Column 2 of Table 1) is also optional.

2.2.1 MSME manufacturers may utilize common cluster based facilities as per guidelines for the utilization of cluster based test facilities by MSMEs or the provisions of Sharing of testing facilities or get testing done from BIS recognized/empaneled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025.

2.3 Large Scale manufacturers shall maintain an in-house laboratory equipped at least with test facilities for routine tests (indicated as "R" in Column 2 of Table 1), where different tests given in the specification shall be carried out in accordance with the method given in the specification. They

shall also implement a calibration plan for the in-house test equipment.

2.3.1 Alternatively, in lieu of an in-house laboratory, large scale manufacturers can also utilize the provisions of Sharing of testing facilities as per the Guidelines for Grant of Licence available on BIS website www.bis.gov.in. (Under Conformity Assessment>Product Certification Process). Even for subcontracted tests, provisions for sharing of testing facilities can be utilized.

2.4 TEST RECORDS- The manufacturers maintaining an in-house laboratory or utilizing common cluster based facilities or shared test facilities shall maintain test records for the tests carried out to establish conformity. For the tests being subcontracted to BIS recognized/empanelled laboratory or any other laboratory having valid NABL accreditation as per IS/ISO/IEC 17025, test reports issued by the laboratories shall be available for inspection by BIS.

3. PACKING AND MARKING - The Standard Mark, as given in the Schedule of the licence shall be clearly and indelibly marked on each container of Indigo Carmine, Food Grade or printed on the labels 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 Packing and Marking shall be done as per the Indian Standard.

3.2 **Additional Marking requirements:** The material shall also be marked with the following additional requirement on shall be marked on each piece of float glass,

a) "For BIS certification details please visit www.bis.gov.in"

4. REJECTION - All the production which conforms to the Indian Standard and covered under the scope of this licence shall be marked with the Standard Mark. 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
(ONLY FOR GUIDANCE PURPOSE)

(1)				(2)	(3)		
Test Details				Test equipment requirement R: required (or) S: Sub-contracting permitted	Levels of Control		
Clause	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Cl. Ref.	Test Method IS				
3.1	Colour	3.1	IS 1698	R	Manufacturer shall maintain adequate inspection and in process control, to ensure product meets specified requirements and maintain test records		
Cl. 3.3 and Table 1, Sr No. i)	Total Dye content	Annex A	IS 1698	R	One	Each control unit	-
ii)	Loss on drying at 135°C and chlorides and sulphates expressed as sodium salt.	6, 13 & 14	IS 1699	R	-do-	-do-	
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)	Dye Intermediates	Annex F	-do-	R	-do-	-do-	
viii)	Unsulphonated primary aromatic amines	Annex G	-do-	R	-do-	-do-	
ix)	Lead	15	IS 1699	S	-do-	Once a month	
x)	Arsenic	15	IS 1699	R	-do-	Each control unit	
xi)	Mercury	15	IS 1699	S	-do-	Once a month	
xii)	Copper	15	IS 1699	R	-do-	Each control unit	
xiii)	Chromium	15	IS 1699	R	-do-	-do-	
xiv)	Cadmium	15	IS 1699	S	-do-	Once a month	