PRODUCT MANUAL
FOR ANNATTO COLOUR FOR FOOD PRODUCTS
ACCORDING TO IS 2557 : 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 2557 : 1994
	Title	:	Annatto Colour for Food Products
	No. of Amendments	:	02
2.	**Sampling Guidelines:**		
a)	Raw material	:	No specific requirement
b)	Grouping guidelines	:	NA
c)	Sample Size	:	50 ml
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) Colour (ii) Identification (iii)Purity Tests		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 2557 : 1994 with the following scope:		
	Name of the product		Annatto Colour for Food Products
	Type		(a) Solution in oil for use in butter and other food products (b) Solution in water for use in cheese and other food products.

ANNEX – A
TO PRODUCT MANUAL
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LIST OF TEST EQUIPMENT

Major test equipment required to test as per Indian Standard

S. No.	Tests used in with Clause Reference	Test Equipment / Chemicals / Glassware
1.	**Colour** **Clause 4.2.3 and 4.3.3**	Lovibond Tintometer, cell length= 1 cm, Amyl actetate (solvent), 0.1 N Sodium hydroxide or potassium hydroxide.
2.	**Identification Tests** **Clause 4.4**	**Spectrophotometry** U.V-Visible Spectrophotometer, Cuvettes.
		Column Chromatography and Carr- Price Reaction **Preparation of Column** Glass Tube (7×200mm internal diameter) stoppered with glass wool, Beakers, Alumina, to prepare slurry for column packing, Benzene. ***Annatto Extract in oil*** 0.1% potassium dichromate, Dry chloroform, Carr- Price Reagent, Calibrated Burettes. ***Water Soluble Annatto*** 50 ml Separating Funnel, 2 N sulphuric acid, pH Test Paper, Centrifuge Apparatus.
		Thin Layer Chromatography TLC Plates, Silica Gel, 12% $CaSO_4$, Acetic acid: Chloroform: Acetone(1:50:5)
3.	**Purity Tests** **Clause 5** ***Carotenoids*** **(Annex B of IS 2557)**	**Annatto extract in oil** U.V- Visible Spectrophotometer, 100 ml volumetric flask, Calibrated Analytical balance of L.C. 0.01 g, Burettes, Measuring cylinders, Chloroform **Water soluble Annatto** U.V-Visible Spectrophotometer, Calibrated Analytical balance of L.C. 0.01g, 100ml volumetric flask, 250ml Separating funnel, Burettes, 10% NaCl solution, 0.01N NaOH, Benzene, Dil.H_2SO_4

	Arsenic (Cl 15 of IS 1699)	**Atomic absorption Spectrophotometric Method** Nitric acid, Distilled water or water or water distillation apparatus, Kjeldahl flask, Perchloric acid, Hydrochloric acid Arsenous oxide, Sulphuric acid, Phenolphthalein, Atomic Absorption Spectrophotometer with argon acetylene flame and hollow cathode lamp of wavelength 193.7 nm and hydride generator. **Chemical method** Guitzeit apparatus consisting of Distillation apparatus and conical flask or Modified Guitzeit apparatus, Sulphuric acid — sp gr 1.84, Potassium permanganate solution- 0.1 N, Ferrous sulphate- freshly powdered, Hydrochloric acid — 38%, Potassium bromide solution- 20%, Aluminium strips — 8 mm × 8 mm × 1 mm, Tin chloride, Test paper.
	Lead (Cl 15 of IS 1699)	**Atomic Absorption Spectrophotometry** Lead nitrate, Nitric acid, Distilled water or water distillation Apparatus, Kjeldahl flask, Perchloric acid, Hydrochloric acid, Atomic Absorption Spectrophotometer with argon acetylene flame and hollow cathode lamp of wavelength 283.3 nm, **Chemical Method** Digestion Funnel, Separatory Funnel, Nitric acid, Sulphuric acid, Ammonium citrate, Ammonium acetate, Ammonia solution, Concentrated, Dithizone, Carbon tetrachloride, Potassium cyanide, Hydroxylamine Hydrochloride, Potassium chloride, Lead nitrate.
	Copper (Cl 15 of IS 1699)	**Atomic Absorption Spectrophotometry** Lead nitrate, Nitric acid, Distilled water or water distillation Apparatus, Kjeldahl flask, Perchloric acid, Hydrochloric acid, Atomic Absorption Spectrophotometer with argon acetylene flame and hollow cathode lamp of wavelength 324.8 nm. **Chemical Method** Citric Acid- solid, Ammonium hydroxide solution- sp. gr 0.92, Conc. HCl, Dithiazone (diphenyl thiocarbazone) solution -0.1% (m/v) in chloroform, Conc. Nitric acid, Conc. Sulphuric acid, Citirc acid solution-5% (m/v) aqueous, Gum Arabic solution- 1%, Sodium diethyl dithiocarbamate solution- 0.2% (m/v), aq., Standard strong solution of copper- Standard dilute solution of copper.
	Heavy Metals (Cl 16 of IS 1699)	Ammonia Solution - 28%, Hydrochloric acid – 10%, Lead nitrate, Nitric acid, Sulphuric acid, Hydrogen sulphide (to be made by reaction of iron sulphide with hydrochloric acid in Kipp's Apparatus), Kipp's Apparatus, Muffle furnace capable of a temperature of 500°C to 600°C, Silica crucible, Steam bath, pH indicator strip.

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

ANNEXE – B

SCHEME OF INSPECTION AND TESTING FOR ANNATTO COLOUR FOR FOOD PRODUCTS ACCORDING TO IS 2557 : 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 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 stenciled/printed on each container of Annatto colour 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 marked legibly and indelibly to give the information mentioned under clause 6.2.1 of IS 2557. In addition, the following information shall be clearly and indelibly marked on each container:

a. The words "Food Grade Colour";
b. BIS Licence No. CM/L___.
c. BIS website details i.e – "For details of BIS Certification please visit www.bis.gov.in"

3.2 Packing – The material shall be filled in suitable containers with as little air space as possible so as to preclude contamination of the contents with metals or other impurities, and should preferably exclude light.

4. CONTROL UNIT –For the purpose of this scheme, Annatto Colour processed in a mixer in one operation shall be considered as 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 A sample shall be drawn from each control unit and when tested shall satisfy all the requirements given in the specification. If the sample fails, the entire material in the control unit shall be considered as unfit for the purpose of marking.

6. RAW MATERIAL – The material shall be derived only from the plant Bixa Orellana L and shall not contain any extraneous colouring matter.

6.1 Solution of Annatto colour in oil for use in Butter and other food products shall be according to clause 4.2.1, 4.2.2 and 4.2.3 of IS 2557.

6.2 Solution of Annatto colour in water for use in cheese and other food products shall be according to clause 4.3.1, 4.3.2 and 4.3.3 of IS 2557.

7. HYGIENIC CONDITIONS – The material shall be processed, packed, stored and distributed under hygienic conditions in licenced premises (see IS 2491).

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**
4.2.3 & 4.3.3	Colour	4.2.3 & 4.3.3	IS 2557	R	One	Every Control Unit	
4.4	Identification	4.4	-do-	R	-do-	-do-	
5.1 & Table 1	Purity Test				-do-		
(i)	Carotenoids a) Annatto extract in oil, expressed as bixin b) Water soluble Annatto, expressed as norbixin	 Annexe B -do-	 -do- -do-	 R R	-do-	 -do- -do-	
(ii)	Arsenic	15	IS 1699	R	-do-	-do-	
(iii)	Lead	15	-do-	R	-do-	-do-	
(iv)	Copper	15	-do-	R	-do-	-do-	
(v)	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 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 for approval by BO Head.