



**PRODUCT MANUAL  
FOR SYNTHETIC FOOD COLOUR- PREPARATIONS AND MIXTURES  
ACCORDING TO IS 5346 : 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.	<b>Product</b>	:	IS 5346 : 1994
	<b>Title</b>	:	Synthetic Food Colour - Preparations and Mixtures
	<b>No. of Amendments</b>	:	04
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	Permitted synthetic food colours used in the colour preparations or in mixtures shall conform to the relevant specifications prescribed by BIS. Declaration as per Clause 4.4 and 4.7 shall be obtained from applicants. Declaration on % Total Dye Content and Synthetic Colours present shall be obtained during the drawl of sample.
b)	<b>Grouping guidelines</b>	:	NA
c)	<b>Sample Size</b>	:	i) 100 g (for Solid preparations or mixtures). ii) 100 ml (for Liquid preparations)
3.	<b>List of Test equipment</b>	:	Please refer ANNEX – <a href="#">A</a>
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX – <a href="#">B</a>
5.	<b>Possible tests in a day:</b>		
	(i) % Total Dye Content (ii) Heavy metals (iii) Water insoluble matter		
6.	<b>Scope of the Licence:</b>		
	“Licence is granted to use Standard Mark as per IS 5346 : 1994 with the following scope:		
	Name of the product	Synthetic Food Colour - Preparations and Mixtures	
	Any other aspect required as per the standard	i. Solid preparations ii. Solid mixtures iii. Liquid preparations	

**ANNEX A**  
**TO PRODUCT MANUAL**  
**FOR SYNTHETIC FOOD COLOUR- PREPARATIONS AND MIXTURES**  
**ACCORDING TO IS 5346 : 1994**

**LIST OF TEST EQUIPMENT**

Major test equipment required to test as per Indian Standard

Sr. No.	Tests used in with Clause Reference	Test Equipments/Chemicals
1.	% Total Dye Content  Cl. 4.5 of IS 5346 (Annex B of IS 5346)	<p><b><u>Chromatographic Separation method:</u></b></p> <ul style="list-style-type: none"> <li>i) Chromatographic Paper of Whatman Filter Paper No 1 (32cm x 19.5cm)</li> <li>ii) Isobutanol</li> <li>iii) Ammonium hydroxide</li> <li>iv) Ethanol</li> <li>v) Glacial acetic acid</li> <li>vi) Trisodium Citrate</li> <li>vii) Hydrochloric acid</li> <li>viii) Sodium hydroxide</li> <li>ix) All glass Chromatographic tank (50 x 30 x 25cm)</li> <li>x) Spectrophotometer with 10mm cuvettes</li> <li>xi) Micropipettes/micro syringe</li> <li>xii) Standard Food Colours</li> <li>xiii) Distilled water or water distillation apparatus</li> </ul> <p><b><u>Direct estimation</u></b></p> <ul style="list-style-type: none"> <li>i) Hydrochloric acid</li> <li>ii) Sodium hydroxide</li> <li>iii) Spectrophotometer with 10mm cuvettes</li> <li>xiv) Distilled water or water distillation apparatus</li> </ul>
2	Water Insoluble matter  Cl 4.6 & Table 1 (i)  (Cl.7 of IS 1699)	<ul style="list-style-type: none"> <li>i) Gooch or sintered glass filter</li> <li>ii) Hot plate</li> <li>iii) Hot air oven</li> <li>iv) Analytical Balance (LC = 0.0001g)</li> <li>v) Distilled water or water distillation apparatus</li> <li>vi) Desiccator</li> </ul>

		<ul style="list-style-type: none"> <li>vii) Filtration flask</li> <li>viii) Vacuum pump/ Aspirator</li> </ul>
3	<p>Lead in mg/kg</p> <p>Cl 4.6 &amp; Table 1 (ii)</p> <p>(Cl.15 of IS 1699)</p>	<p><b><u>Atomic Absorption Spectrophotometric method</u></b></p> <ul style="list-style-type: none"> <li>i) Lead nitrate</li> <li>ii) Nitric acid</li> <li>iii) Distilled water or water distillation apparatus</li> <li>iv) Kjeldahl flask</li> <li>v) Perchloric acid</li> <li>vi) Hydrochloric acid</li> </ul> <p>Atomic Absorption Spectrophotometer with air &amp; acetylene flame and hollow cathode lamp of wavelength of 283.3nm</p> <p><b><u>Chemical method</u></b></p> <ul style="list-style-type: none"> <li>i) Digestion Funnel</li> <li>ii) Separatory Funnel</li> <li>iii) Nitric acid</li> <li>iv) Sulphuric acid</li> <li>v) Ammonium citrate</li> <li>vi) Ammonium acetate</li> <li>vii) Ammonia solution, concentrated</li> <li>viii) Dithizone</li> <li>ix) Carbon tetrachloride</li> <li>x) Potassium cyanide</li> <li>xi) Hydroxylamine hydrochloride</li> <li>xii) Potassium chloride</li> <li>xiii) Lead nitrate</li> </ul>
4.	<p>Arsenic in mg/kg</p> <p>Cl 4.6 &amp; Table 1 (iii)</p> <p>(Cl.15 of IS 1699)</p>	<p><b><u>Atomic Absorption Spectrophotometric method</u></b></p> <ul style="list-style-type: none"> <li>i) Nitric acid</li> <li>ii) Distilled water or water distillation apparatus</li> <li>iii) Kjeldahl flask</li> <li>iv) Perchloric acid</li> <li>v) Hydrochloric acid</li> <li>vi) Arsenous oxide</li> <li>vii) Sulphuric acid</li> <li>viii) Phenolphthalein</li> <li>ix) Atomic Absorption Spectrophotometer with argon &amp; acetylene flame and hollow cathode lamp of wavelength of 193.7nm and hydride generator</li> </ul> <p><b><u>Chemical method</u></b></p> <ul style="list-style-type: none"> <li>i) Guitzeit apparatus consisting of Distillation apparatus and conical flask Or Modified Guitzeit apparatus</li> </ul>

		<ul style="list-style-type: none"> <li>ii) Sulphuric acid — sp gr 1.84.</li> <li>iii) Potassium permanganate solution— 0.1 N.</li> <li>iv) Ferrous sulphate — freshly powdered.</li> <li>v) Hydrochloric acid — 38 percent.</li> <li>vi) Potassium bromide solution — 20 percent.</li> <li>vii) Aluminium strips — 8 mm × 8 mm × 1 mm.</li> <li>vii) Tin chloride</li> <li>viii) Test paper —dried strips of filter paper soaked in saturated ethanolic solution of mercuric bromide.</li> </ul>
5.	<p>Heavy metals (as Pb) in mg/kg</p> <p>Cl 4.6 &amp; Table 1 (iv)</p> <p>(Cl.16 of IS 1699)</p>	<ul style="list-style-type: none"> <li>i) Ammonia Solution - 28%</li> <li>ii) Hydrochloric acid – 10%</li> <li>iii) Lead nitrate</li> <li>iv) Nitric acid</li> <li>v) Sulphuric acid</li> <li>vi) Hydrogen sulphide (to be made by reaction of iron sulphide with hydrochloric acid in Kipp's Apparatus)</li> <li>vii) Kipp's Apparatus</li> <li>viii) Muffle furnace capable of a temperature of 500oC to 600°C</li> <li>ix) Silica crucible</li> <li>x) Steam bath</li> <li>xi) pH indicator strip of about 2 pH</li> </ul>

**The list above is indicative only and may not be taken as exhaustive**

## ANNEX B

### SCHEME OF INSPECTION AND TESTING FOR SYNTHETIC FOOD COLOUR - PREPARATIONS AND MIXTURES ACCORDING TO IS 5346 : 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 a given in the Schedule of the licence shall be stencilled with indelible ink or printed on labels applied to the container of Synthetic Food Colour preparations and mixtures, provided always that the material in each container to which this mark is thus applied conforms to every requirement of the specification subject to the provisions of the Food Adulteration Act, 1954.

**3.1 Marking** – Each container shall be legibly and indelibly marked with the information given under clause 5.2.1 of IS 5346. In addition, the following information shall be given legibly and indelibly on each container.

a) BIS Licence No. CM/L\_\_.

b) BIS website details i.e – “For details of BIS Certification please visit [www.bis.gov.in](http://www.bis.gov.in)”

**3.2 Packing** – The material shall be packed as per clause 5.1 of IS 5346.

**4. CONTROL UNIT**- For the purpose of this Scheme, the entire quantity of all ingredients mixed and taken out of the homogenizer at a time 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.

**6. RAW MATERIAL**- The Synthetic food colour preparations and mixtures shall conform to the relevant Indian Standard specifications. If food colours are purchased from the synthetic food colour manufacturers the same bear BIS Certificate Mark.

**6.1 Diluants** – Only permitted diluants and filler material of the quality mentioned in the specification shall be used in the colour preparations.

**6.2 Freedom from contaminants-** Precaution shall be taken to ensure that the material is free from mercury, copper and chromium in any form.

6.3 Appropriate records shall be maintained regarding the receipt and issue of the basic food colours as per proforma at Table 2.

**7. HYGIENIC CONDITIONS** – The product shall be processed, packed, stored and distributed under hygienic conditions in licensed premises as per 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		
Cl.	Requirement	Test Method Cl. Ref.	Test Method IS		No of Sample	Frequency	Remarks
4	Description	4.1 to 4.4	IS 5346	R	One	Control Unit	
4.5	Total Dye Content	Annex B	IS 5346	R	One	* One sample from every control Unit every week	
4.6 & Table 1	i) Water insoluble matter	7	IS 1699	R	One	Control Unit	
-do-	ii) Lead	15	IS 1699	R	One	Control Unit	
-do-	iii) Arsenic	15	IS 1699	R	One	Control Unit	
-do-	iv) Heavy metals	16	IS 1699	R	One	Control Unit	

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.

Note-3: \* For the requirement of total dye content, one sample shall be taken from a control unit at weekly intervals and conformity checked. Samples shall be taken from every control unit and kept till the result of the weekly sample is known. In case of non – conformity of this sample in total dye content, all the samples taken for the week shall be tested for total dye content. Till such time six consecutive control units pass, this procedure shall be followed.

