

**PRODUCT MANUAL
FOR PONCEAU 4R, FOOD GRADE
ACCORDING TO IS 2558 : 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 2558 : 1994
	Title	:	Ponceau 4R, Food Grade
	No. of Amendments	:	01
2.	Sampling Guidelines:		
a)	Raw material	:	No specific requirement
b)	Grouping guidelines	:	Not Applicable
c)	Sample Size	:	50 g
3.	List of Test Equipment	:	Please refer ANNEX – <u>A</u>
4.	Scheme of Inspection and Testing	:	Please refer ANNEX – <u>B</u>
5.	Possible tests in a day :		
	i. Total dye content ii. Loss on drying at 135 ⁰ C iii. Water insoluble matter iv. Combined ether extracts v. Subsidiary dyes vi. Dye intermediates vii. Lead viii. Arsenic ix. Heavy Metals		
6.	Scope of the Licence :		
	“Licence is granted to use Standard Mark as per IS 2558 : 1994 with the following scope:		
	Name of the product	:	Ponceau 4R, Food Grade

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ANNEX A
TO PRODUCT MANUAL
FOR PONCEAU 4R, FOOD GRADE ACCORDING TO IS 2558 : 1994

LIST OF TEST EQUIPMENT

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Total dye content Cl 3.1 & Table 1 (Annex A of IS 2558)	<p>Spectrophotometric method (Reference method)</p> <p>Spectrophotometer (with properly calibrated scales for both wave length and optical density) or Spectrocolorimeter, Volumetric flasks of varying capacities, weighing balance, drying oven, 0.1 N Hydrochloric acid</p> <p>Titanium Trichloride method</p> <p>Weighing balance, heating mantle or water bath, Volumetric flasks of varying capacities, sodium citrate, 0.1 N standard potassium dichromate solution, 0.1 N standard Titanium trichloride solution, concentrated Hydrochloric acid, Ferrous ammonium sulphate, carbon dioxide, sulphuric acid, ammonium thiocyanate</p>
2.	Loss on drying at 135°C and Chlorides and sulphates expressed as sodium salt. Cl 3.1 & Table 1 (Cl 6, 13 & 14 of IS 1699)	<p>Weighing balance, weighing bottle fitted with a ground-glass lid, hot air oven, desiccator</p> <p>Potentiometric titration apparatus, with silver indicator electrode, calomel reference electrode, saturated potassium sulphate bridge or glass electrode, weighing balance, 1.5 N Nitric acid, 0.1 N silver nitrate solution</p> <p>weighing balance, water bath, Hot plate, muffle furnace, ignition crucible, sulphate-free sodium chloride, saturated sodium chloride solution, filter funnel, filter paper, pipettes, flasks of varying capacities, Hydrochloric acid, 0.25 N Barium chloride solution.</p>
3.	Water-insoluble matter Cl 3.1 & Table 1 (Cl 7 of IS 1699)	Prepared Gooch crucible or sintered glass funnel Grade 4, weighing balance, hot plate, drying oven.

4.	Combined ether extracts Cl 3.1 & Table 1 (Cl 8 of IS 1699)	Separators or continuous extractor of 250 ml capacity, water /steam bath, weighing balance, evaporating dish, desiccator, Isopropyl ether, 0.5 N sodium hydroxide, saturated ferrous sulphate solution, 10% sodium hydroxide solution, Dilute Hydrochloric acid.
5.	Subsidiary Dyes Cl 3.1 & Table 1 (Annex B of IS 2558)	Chromatography Tank & Ancillary apparatus, Microsyringe, Chromatography solvents, Extracting solvents (Acetone & water), Sodium bicarbonate, Spectrophotometer, Filter papers, Test tubes, Drying cabinet.
6.	Dye intermediates Cl 3.1 & Table 1 (Annex C of IS 2558)	<p>Routine method</p> <p>Chromatography Tank and Ancillary Equipment (as per clause 9.2.1 of IS 1699), Microsyringe, Ultraviolet Lamp (at 365.5 nm), Drying oven, Whatman No. 1 filter paper, ammonium hydroxide solution, 1-Naphthylamine-4-Sulphonic Acid, 2-Naphthol : 6 Disulphonic Acid, Developing Solvent [sodium bicarbonate solution (10 percent m/v)]</p> <p>Reference Method</p> <p>Chromatographic tube, Spectrophotometer with UV range, Whatman powdered cellulose (or equivalent), ammonium sulphate</p>
7.	Lead Cl 3.1 & Table 1 Arsenic Cl 3.1 & Table 1 (Cl 15 of IS 1699)	<p>Instrumental Method (Referee method)</p> <p>Weighing balance, hot plate 50 ml one-mark graduated flask, 100 ml one-mark volumetric flasks, Modified Kjeldahl flask (as per Fig 4 of IS 1699), Atomic absorption spectrophotometer (with Hydride generation vessel accessory and potentiometric recorder), nitric acid, Perchloric acid, Sulphuric acid, Hydrochloric acid, metal-free Distilled water, Sodium sulphate, Sodium borohydride pellets, Potassium chloride, standard lead solution, Standard Arsenic solution.</p> <p>Note: Reagents shall be of an order of purity higher than accepted analytical reagent grade quality.</p> <p>Chemical Method</p> <p>For Lead-</p> <p>Digestion funnel, separatory funnel, Hot plate, Nitric acid, Sulphuric acid, Ammonium acetate-citrate solution, ammonia solution, Carbon tetrachloride, Ammonium hydroxide, Potassium</p>

		<p>cyanide, Hydroxylamine hydrochloride solution, Dithizone solution, pH 2 buffer.</p> <p>For Arsenic - Method 1: Distillation apparatus (as per Fig 6 of IS 1699), conical flask (as per Fig 7 of IS 1699), micro burner, water bath, Sulphuric acid, potassium permanganate, ferrous sulphate, Hydrochloric acid. Potassium bromide solution, Aluminium strips, Tin chloride solution, Test paper (dried strips of filter paper in saturated ethanolic solution of mercuric bromide), nitric acid, distilled water</p> <p>Method 2 (Modified Gutzeit method)</p> <p>Distillation setup, Modified Gutzeit Apparatus/Spectrophotometer, Weighing balance, Distilled water, Concentrated Hydrochloric acid, Hydrazine Sulphate, Sodium Bromide, Lead Acetate, Filter paper strips, Absorbent Cotton Wool, Mercuric Bromide Paper, Dilute Sulphuric Acid, Potassium Iodide, Stannous Chloride, Zinc granules, Arsenic trioxide, Sodium hydroxide</p>
8.	Heavy metals Cl 3.1 & Table 1 (Cl 16 of IS 1699)	50 ml Nessler tubes, pH meter/pH indicator paper, Analytical balance, Igniting crucible, Muffle furnace, Steam bath, Litmus paper, Ammonia solution, Hydrochloric Acid, Lead nitrate, distilled water, Nitric acid, Sulphuric acid, Hydrogen sulphide, Acetic acid, Filter funnel, Filter paper.

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

ANNEX B
SCHEME OF INSPECTION AND TESTING
FOR PONCEAU 4R, FOOD GRADE ACCORDING TO IS 2558 : 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 Ponceau 4R, 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 2558. 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, Ponceau 4R, Food Grade blended at one time from different 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 total 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 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 the 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, selenium and chromium in any form; aromatic amines; aromatic nitro compounds, aromatic hydrocarbons and cyanides.

6. RAW MATERIAL – Routine analysis of various raw materials going into the manufacture of Ponceau 4R shall be made on each lot received in the factory or alternatively raw materials of known composition may be used.

7. HYGIENIC CONDITIONS – The product 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		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
3.1 & Table 1 (i)	Total Dye Content Percent by mass	Annex A	IS 2588	R	Two	Each control unit	See clause 5.2.1 of SIT
(ii)	Loss on drying at 135°C & chloride & sulphates expressed as sodium salt	6, 13 & 14	IS 1699	R	One	-do-	See clause 5.2.2
(iii)	Water insoluble matter	7	IS 1699	R	-do-	-do-	
(iv)	Combined ether extracts	8	IS 1699	R	-do-	-do-	
(v)	Subsidiary dyes	Annex B	IS 2588	R	-do-	-do-	
(vi)	Dye intermediates	Annex C	IS 2588	R	-do-	-do-	
(vii)	Lead	15	IS 1699	R	-do-	-do-	
(viii)	Arsenic	15	IS 1699	R	-do-	-do-	
(ix)	Heavy metals	16	IS 1699	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.