

**PRODUCT MANUAL
BRILLIANT BLUE FCF, FOOD GRADE
According to IS 6406 : 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 6406 : 1994
	Title	:	Brilliant Blue FCF, Food Grade - Specification
	No. of Amendments	:	Nil
2.	Sampling Guidelines:		
a)	Raw material	:	No specific requirement
b)	Grouping guidelines	:	NA
c)	Sample Size	:	50 g
3.	List of Test Equipment	:	ANNEX - A
4.	Scheme of Inspection and Testing	:	ANNEX - B
5.	Possible tests in a day :		
	i. Total Dye Content ii. Loss on Drying iii. Water Insoluble matter iv. Heavy Metals (as Pb)		
6.	Scope of the Licence :		
	“Licence is granted to use Standard mark as per IS 6406 : 1994 with the following scope:		
	Name of the product	Brilliant Blue FCF, Food Grade	

ANNEX-A

TO PRODUCT MANUAL
BRILLIANT BLUE FCF, FOOD GRADE ACCORDING TO IS 6406 : 1994

LIST OF TEST EQUIPMENTS

Major test equipment required to test as per the Indian Standard

Sr. No.	Tests used in with Clause Reference	Test Equipment/Chemicals/Glassware
1.	Total dye content Cl. 3.1 & Table 1 (Annex A of 6406).	Suitable spectrophotometer with properly calibrated scale for both wavelength and optical density (alternatively suitable spectrophotometer, calibrated against spectrophotometer may be used), Weighing balance (least count 1 mg), Volumetric flask (Range 300 ml, least count 10 ml), Glass cell (cuvette) with 10 mm light path, Air oven (Range 150 °C, least count 1 °C). REAGENTS: Ammonium acetate solution (200 mg of chemical in one litre of distilled water).
2.	Loss on drying drawing at 135°C, and chlorides and sulphates expressed as sodium salt. Cl. 3.1 & Table 1 (Cl. 6, 13 & 14 of IS 1699)	Weighing balance as above, Weighing bottle fitted with a ground glass lid (a squat bottle with about 50 mm dia and 30 mm height is suitable), An air oven as above, Desiccator, Potentiometer titration apparatus with silver indicator electrode, calomel reference electrode and saturated potassium sulphate bridge, 250 ml conical flask, Suitable water bath, 500 ml beaker, hundred ml pipette hot plate thermometer range 100 °C least count 1 °C , tared crucible. REAGENTS: 1.5 N nitric acid solution, 0.1 N silver nitrate solution, Sulphate free sodium chloride, Hydrochloric acid, 0.25 N barium chloride solution.
3.	Water insoluble Cl. 3.1 & Table 1 (Cl. 7 of IS 1699)	Prepared Gooch crucible, Retentive asbestos, Air oven and desiccator as above, Alternatively sintered glass filter grade 4 may be used. Reagents Hydrochloric acid.

4.	<p>Combine ether extract Cl. 3.1 & Table 1 (Cl. 8 of IS 1699)</p>	<p>Separator or continuous extractor, Weighing balance, Beaker, Timer, Water bath or steam bath, Evaporated dish, Volumetric flask, Stopwatch. Reagents Isopropyl ether, Sodium hydroxide solution, Ferrous sulphate, Sodium hydroxide wash solution, Dilute hydrochloric acid, Hydrochloric acid wash solution, Concentrated hydrochloric acid, Aqueous solution, Sodium hydrochloric acid</p>
5.	<p>Subsidiary dyes Cl. 3.1 & Table 1 (Annex B of IS 6406)</p>	<p>Chromatography tank & Ancillary equipment as per Fig 1 of IS 1699 consisting of ,A glass tank & glass cover, Supporting frame for chromatography grade paper sheets, Tray, Secondary frame supporting drapes of filter paper, Sheets of chromatography grade paper, Microsyringe, Spectrophotometer, Drying cabinet, Stopwatch, Timer, Scale, Measuring tape. Reagents Sodium bicarbonate, Chromatography solvent - butan-2-one: acetone : water : ammonia</p>
6.	<p>Dyes intermediates Cl. 3.1 & Table 1 (Annex C and D of IS 6406 and Cl. 12 of IS 1699)</p>	<p>Chromatography tank & Ancillary equipment, Thermometer, Volumetric flask, Tared gooch / sintered glass filter, Microsyringe, Ultraviolet lamp, Filter paper, Desiccator, Weighing balance, Stopwatch, Volumetric flask, Burette, Spectrophotometer. REAGENTS Ammonium hydroxide solution, O, sulpho-benzaldehyde, N-N' ethyl-benyl-aniline-3-sulphonic acid, Ammonium sulphate, 2 : 4 dinitrophenyl-hydrazine-hydrochloride, Ethanol, Ethanol, Dimethylformamide.</p>

7.	Heavy metals (as Pb) Lead Arsenic & Chromium Cl. 3.1 & Table 1 (Cl. 16 and 15 of IS 1699)	Instrument method for Lead, Arsenic and Chromium - Kjedahl flasks (refer fig 4 of IS 1699), Atomic absorption spectrophotometer. (wavelength range 180-600 nm), A hydride generation vessel accessory, Potentiometer recorder (multirange type covering range 1-20 mV). REAGENTS Nitric acid special grade 1.42, Perchloric acid 60% m/m solution, Sulphuric acid 98%, Hydrochloric acid special grade 1.16 to 1.18, Hydrochloric acid 5 N solution, Water - metal free, Sodium sulphate, Sodium borohydride pellets, Potassium chloride, Standard Solutions of Lead, Arsenic and Chromium (Alternately, chemical method as given in 15.2 of IS 1699 may be used.) For Heavy metals (as Pb): pH Meter, Crucible, Muffle furnace, Steam bath, Nessler Tube Reagents: Ammonium Hydroxide, Hydrochloric Acid, Lead Nitrate, Nitric Acid, Sulphuric Acid, Hydrogen Sulphide.
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Above list is indicative only and may not be treated as exhaustive.

ANNEX B

SCHEME OF INSPECTION AND INSPECTION BRILLIANT BLUE FCF, FOOD GRADE - SPECIFICATION ACCORDING TO IS 6406 : 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 Schedule of the licence shall be stenciled/printed on each container of Brilliant Blue FCF, Food Grade or printed on the labels applied to the container, as the case may be, provided always that the material in each container to which this mark is thus applied conforms to every requirement of the specification.
 - 3.1 **Packing** – The material shall be packed in glass containers, metal containers, polyethylene containers or cardboard containers suitably lined with polyethylene, subject to agreement between the purchaser and the vendor, other suitable containers may also be used.
 - 3.2 **Marking** - Each container shall be legibly and indelibly marked with the details mentioned under clause 4.2.1 of IS 6406. In addition, the following details shall be mentioned on each container legibly and indelibly:
 - a) BIS Licence No. CM/L_____.
 - b) BIS website details i.e – “For details of BIS Certification please visit www.bis.gov.in”
4. **CONTROL UNIT-** For the purpose of this Scheme, Brilliant Blue FCF, Food Grade recrystallized at one time from the Mother Liquor shall constitute a control unit.
5. **LEVELS OF CONTROL** – The analysis tests as indicated in Table 1 and at the levels of control specified therein, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records and charts 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.
 - 5.2.1 Two independent samples drawn from each control unit and tested for pure dye content, shall individually satisfy the requirement 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 and tested for the remaining characteristics of the specification shall satisfy the corresponding requirements. It fails in any one or more of these requirements, the entire material in the control unit shall be considered as unfit for the purpose of marking.
5. **RAW MATERIAL** – Routine analysis of various raw materials going into the manufacture of Brilliant Blue FCF, Food Grade shall be made on each lot received in the factory or alternatively raw materials of known composition may be used. Precaution shall be taken to ensure that the material is free from aromatic amines, aromatic nitro compounds, aromatic hydrocarbons and cyanides.
6. **HYGIENIC CONDITION** -The product shall be processed, packed; stored and distributed under hygienic conditions in licensed premises (see IS 2491). All the processing equipments should be properly cleaned and care should be taken to prevent infestation.
7. **REJECTION**- 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 Methods Cl. Ref.	Test Method IS		No. of Sample	Frequency	Remarks
3.1 & Table 1	Total dye content	Annex A	IS 6406	R	Two	Each control unit	See clause 5.2.1 of SIT
-do-	Loss on drying at 135°C and chlorides and sulphates expressed as sodium salt.	6, 13 & 14	IS 1699	R	One	Each control unit	See clause 5.2.2 of SIT
-do-	Water insoluble matter	7	IS 1699	R	-do-	Each control unit	-do-
-do-	Combined ether extract	8	IS 1699	R	-do-	Each control unit	-do-
-do-	Subsidiary dyes	Annex B	IS 6406	R	-do-	Each control unit	-do-
-do-	Dyes intermediates	Annex C, D Clause 12	IS 6406 IS 1699	R	-do-	Each control unit	-do-
-do-	Heavy metals (as Pb)	16	IS 1699	R	-do-	Each control unit	-do-
-do-	Lead, Arsenic and Chromium	15	IS 1699	R	-do-	Each control unit	-do-

Note-1: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control and submit his own levels of control in column 3 with proper justification for approval by BO Head.

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.