



उत्पाद मैनुअल

IS 4603: 1991 के अनुसार

**PRODUCT MANUAL FOR PHENYL
ETHYL ALCOHOL
ACCORDING TO IS 4603: 1991**

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना 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। इस दस्तावेज़ के 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.	Product	:	IS 4603: 1991
	Title	:	Phenyl Ethyl Alcohol
	No. of Amendments	:	01
2.	Sampling Guidelines:		
a)	Raw material	:	No specific Requirement
b)	Grouping guidelines	:	NA
c)	Sample Size	:	1 kg
d)	Parameters to be Declared in Test Request	:	i) Name of the product Note: Apart from the above, any other requirements/parameters may also be declared as per the standard, as applicable.
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	:	All tests
6.	Scope of the Licence		
	Licence is granted to use Standard Mark as per IS 4603:1991 with the following scope:		
	Name of the product	:	Phenyl Ethyl Alcohol

BUREAU OF INDIAN STANDARDS

Manak Bhawan,

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New Delhi – 110002

ANNEX A**List of Test Equipment*****(INDICATIVE LIST, FOR GUIDANCE ONLY)***

Sl. No.	Tests used in with Clause Reference	Test Equipment/Chemicals
1	Solubility- In Alcohol, Cl.4.2,	- Ethanol, Distilled Water, Silver Nitrate, Sodium Chloride, Nitric Acid - Burette, Pipettes (1ml), Analytical Balance, Measuring cylinder/ flask - Air conditioner - Thermometer
2	Solubility- In Water Cl.4.2	- Barium Chloride solution, sulphuric acid, hydrochloric acid - Glass stoppered Graduated cylinder
3	Colour and appearance Cl.4.3, Table 1, Sl.No.i)	Visual
4	Odour and Taste Cl.4.3, Table 1, Sl.No.ii)	- Standard sample, ethyl alcohol, diethyl phthalate, smelling strips, strip stand - Refrigerator - Temperature and Humidity Controller
5	Refractive Index Cl.4.3, Table 1, Sl.No.iii)	- Standard products, distilled water, p-Cymene, Benzyl benzoate, 1-Bromonaphthalene - Refractometer with apparatus for temperature maintenance and light source - Plate of glass
6	Relative density Cl.4.3, Table 1, Sl.No.iv)	- Distilled water - Glass pycnometer - Water bath - Thermometer - Analytical balance
7	Freedom from chlorinated compounds Cl.4.3, Table 1, Sl.No.v)	- Copper wire and strip - Dropper - Bunsen Burner
8	Alcohol content Cl.4.3, Table 1, Sl.No.vi)	- Gas chromatograph with FID detector

ANNEX D

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 phenyl ethyl alcohol manufactured under similar conditions of production in a day shall constitute a control unit.

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 incorporated legibly and indelibly on each packaging provided always that the material so marked conforms to each 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 each packaging:

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		
Cl.	Requirement	Test Methods			No. of Sample	Frequency	Remarks
		Clause	Reference				
4.1	Description	4.1	IS 4603	R	One	Each Control Unit	-
4.2.1	Solubility- In Alcohol	4.2.1	IS 326 (part 6)	R	One	Each Control Unit	-
4.2.2	Solubility- In Water	Annex A	IS 4603	R	One	Each Control Unit	-
4.3, Table 1	Colour and Appearance	-	IS 326 (part 2)	Firm to have adequate in-process controls to check compliance of this parameter as given in the Indian Standard. However, appropriate records shall be maintained by the manufacturer for evidence of conformity			-
4.3, Table 1	Odour and Taste	-	IS 2284	R	One	Each Control Unit	-
4.3, Table 1	Refractive Index	-	IS 326 (part 5)	R	One	Each Control Unit	-
4.3, Table 1	Relative Density	-	IS 326 (part 3)	R	One	Each Control Unit	-
4.3, Table 1	Freedom from chlorinated compounds	Annex B	IS 4603	R	One	Each Control Unit	-
4.3, Table 1	Alcohol Content	Annex C	IS 4603	S	One	Every Month	-