



उत्पाद मैनुअल
आइसो प्रोपाइल अल्कोहल - विशिष्ट
IS 2631:2020 के अनुसार

Product Manual Isopropyl Alcohol - Specification
According to IS 2631:2020

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम, 2018 की योजना -I 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। दस्तावेज़ का 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.	मानक संख्या IS No.	:	IS 2631:2020
	शीर्षक Title	:	ISOPROPYL ALCOHOL - Specification
	संशोधनों की संख्या No. of amendments	:	2
2.	नमूना दिशानिर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	No specific requirements.
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	NA
c)	नमूने का आकार Sample Size	:	100 ml
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	Please refer Annex-A
4.	निरीक्षण और परीक्षण की स्कीम Scheme of Inspection and Testing	:	Please refer Annex-B

5.	एक दिन में संभावित परीक्षण Possible tests in a day All tests can be done in a day.		
6.	लाइसेंस का दायरा /Scope of the Licence: “Licence is granted to use Standard Mark as per IS 2631:2020 with the following scope:		
	Name of the product	ISOPROPYL ALCOHOL	

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ANNEX – A

**LIST OF TEST EQUIPMENT
(INDICATIVE LIST, FOR GUIDANCE ONLY)**

Sl.No	Tests Used In With Clause Reference	Test Equipment/Chemical
1.	Description, Cl. 3.1	Visual
2.	Odour, Cl.3.2	Filter paper (Organoleptic requirement)
3	Relative Density at 27/27°C, Cl: 3.3., Table-1, Sl. No. i) Annex A of IS :229	50ml Capacity Relative Density bottle.of Regnault type, Pycnometer, Thermometer (0 to 50°C), Water Bath, Filter Paper, Weighing balance
4	Distillation Range, Cl: 3.3., Table-1, Sl. No. ii) IS 1448(Part 18) : 2020	Apparatus: • Distillation Flasks ; Distillation flask, 125 mL, borosilicate glass • Condenser and Cooling Bath: 560 mm length, 14 mm in outside diameter, • Metal Shield or Enclosure for Flask: 480 mm high, 280 mm long, 200 mm wide, made of sheet metal of approximately 0,8 mm. • Heat Source: Gas burner/Electric heater • Thermometer or temperature indicator Flask Support: type1(for burner)/type2for electric heater • Graduated Cylinder: Measuring cylinder, 100 mL, complete with metal base, without Schell bach strip Graduated cylinder, 5 mL, for measuring distillation residue with funnel-shaped opening • Pt100 sample temperature sensor Centering holder for Pt100 sample temperature sensor. Holder for Pt100 sample temperature sensor. • Cleaning Cleaning wire with grip, 100 cm Cleaning felt. • Stopper Silicone stopper 22/55, bore 6 mm Boiling stones against boiling retardation Barometer, levelling device, centering device
5	Residue on evaporation Cl: 3.3., Table-1, Sl. No. iii) Annex-A-1 of IS 2631:2020	• Platinum or borosilicate or silica crucible of 150 ml capacity. • Water –bath with controlling temperature • Oven with controlling temperature • Measuring cylinder 100 ml capacity • Desiccators, • weighing balance
6	Acidity (as CH ₃ COOH), Cl: 3.3., Table-1, Sl. No. iv) Annex C of IS :229	• Rectified Spirit 95% • Phenolphthalein Indicator • Standard Sodium Hydroxide Solution – 0.1N • Burette,1 ml Graduate Pipette • 100 ml Measuring cylinder • Weigh balance

7	Aldehydes and Ketones (as acetone), Cl: 3.3., Table-1, Sl. No. v) Annex-A-2 of IS 2631:2020	Reagent • Standard Sodium Hydroxide Solution – 0.01N • Carbonyl Free Ethanol • 2,4 Di nitro phenyl hydrazine • Hydrochloric acid • Bromophenol Blue APPARATUS • Weigh balance • 50 ml measuring cylinder • 5 ml Graduate pipette • Reflux Column (300*25 mm) • 100 ml volumetric flask • 20 ml pippete • 5 ml Volumetric Pippete • 200 ml Volumetric flask • Water Bath • 25 ml Volumetric Pippete • 250 ml conical flask Alternate: Capillary Gas chromatograph
8	Water Content, Cl: 3.3., Table-1, Sl. No. vi) IS 2362	APPARATUS • Automatic Burette • 10 to 25 ml capacity with a fine pointed tip and graduations of 0.05 • Titration Vessel : 100 ml capacity • Electrode : Double platinum • Magnetic stirrer with PTFE coated stirring bar. • Electrometric end point detection device utilizing a micrometer • Glass syringe, Suitable capacity. • Aluminum Sodium Silicate/Activated Silica Gel • Silicone Base Grease Methanol • 2-Methoxyethanol (Ethylene Glycol Monomethyl Ether) • Iodine • Pyridine • Karl Fischer Reagent • Sodium Tartrate Crystalline
9&10	Purity as Propane-2-ol (Isopropyl alcohol) and Benzene Content, Cl: 3.3., Table-1, Sl. No. vii) Annex-A-3/A-4 of IS 2631:2020	Reagent - Isopropyl alcohol • Acetone • Di isopropyl alcohol • 2-Butanol • Cyclohexane • Standard Benzene solution APPARATUS • Gas Chromatography with Flame ionization Detector. • Capillary Column (60 m * 0.25 mm * 0.5 µ) • Syringe (10 ul) Utility Gases • Air (Pure Grade) • Nitrogen/Helium (Pure Grade) • Hydrogen (Pure Grade)

ANNEX C

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 **the quantity of the Iso Propyl Alcohol produced in a single batch at a time 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 the container transporting Iso Propyl Alcohol, 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 the container transporting Iso Propyl Alcohol:

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 requirementR: required (or)S:Sub-contracting permitted	Levels of Control		
Cl.	Requirement	Test Methods Clause Reference			No. of Sample	Frequency	Remarks
3.1	Description	3.1	IS 2631:2020	R	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		
3.2	Odour	3.2	IS 2631:2020	R	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		
3.3 & Table 1	i)Relative Density; 27°C/27°C	Annex-A	IS 229: 1993	R	1	Each Control Unit	-
	ii)Distillation Range;	Part 18	IS 1448: 2020	R	1	Each Control Unit	-
	iii) Residue on evaporation g/100ml	A-1	IS 2631:2020	R	1	Each Control Unit	-
	iv) Acidity (As acetic acid); % by Mass;	Annex-C	IS 229: 1993	R	1	Each Control Unit)	-
	v) Aldehydes & Ketones (As acetone); % by Mass;	A-2	IS 2631:2020	R	1	Each Control Unit	-
	vi)Water Content; % by Mass	--	IS 2362: 1993	R	1	Each Control Unit	-
	vii) Purity as Propane-2-ol(Isopropyl alcohol)	A-3	IS 2631:2020	R	1	Each Control Unit)	-
	viii) Benzene Content,	A-3/A-4	IS 2631:2020	R	1	Each Control Unit	-