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उत्पाद मैन्युअल
फिनोलिक टाइप रोगाणुनाशी द्रव विशिष्टि
IS 1061: 2017 के अनुसार

PRODUCT MANUAL FOR
Disinfectant Fluids, Phenolic Type — Specification
ACCORDINGTO IS 1061: 2017

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 1061: 2017
	शीर्षक **Title**	:	Disinfectant Fluids, Phenolic Type **फिनोलिक टाइप रोगाणुनाशी द्रव विशिष्टि**
	संशोधनों की संख्या **No. of amendments**	:	02
2.	नमूना दिशानिर्देश **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	No specific requirement for raw material Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be establishedduring Grant of Licence/Change in Scope of Licence /Factory Surveillance
b)	समूहीकरण दिशानिर्देश **Grouping Guidelines**	:	Each class, grade and type is required to be tested to be covered in the scope of licence

c)	**नमूने का परिमाण** **Sample Quantity**	:	3x500ml of Disinfectant Fluid, Phenolic Type Note: This section indicates the quantity of the sample of the product and/or the raw material (if applicable), required to be sent to the laboratory for testing, for the purpose of Grant of Licence/Change in Scope of Licence/ Factory Surveillance (incase of market surveillance, effort may be made to procure therequired quantity of product sample, as far as possible since raw material sample may not be available in market)
3.	**परीक्षण उपकरणों की सूची** **List of Test Equipment**	:	कृपया Annex-A देखें Please refer to Annex – A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	कृपया Annex-B देखें Please refer to Annex – B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	Composition and Description (Cl. 4.1), Stability after dilution (Cl.4.4), Mercury compounds (Cl.4.4) Detection of phenolic compounds (Cl.4.6) Note: This section is for the guidance of BIS Certification Officers/Technical Auditors of BIS Authorized Outside Surveillance Agencies (OSAs) during factory inspection to provide readyreference regarding the tests which can be witnessed during the inspection in the factory by the officer/auditor.		
6.	**लाइसेंस का दायरा /Scope of the Licence:**		
	"Licence is granted to use Standard Mark as per IS IS 1061 : 2017 with the following scope: IS 1061: 2017 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्रके लिए प्रदान किया जाता है		
	Name of the product		Disinfectant Fluids, Phenolic Type **फिनोलिक टाइप रोगाणुनाशी द्रव**
	Class		Black or White
	Grade		1, 2, 3, 1A, 2A or 3A
	Type		Normal or Winter

ANNEX – A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No	Test used in with clause Reference	Test Equipment/Chemical
1.	Composition and Description (Cl. 4.1)	Glass beaker, Glass rod, water
2.	Stability after dilution (Cl. 4.2)	Artificial hard water- Hydrochloric acid, Calcium carbonate, Reagent grade water, filtration arrangement, 100ml stoppered measuring cylinder Artificial sea water- (see IS 8770) stoppered measuring cylinder, Pipettes, Arrangement for maintaining extremes of temperature as per A-3.4
3.	Germicidal Value (Cl. 4.3),	Test organism: Salmonella typhi (NCTC 786) cultures, Staphylococcus aureus (MTCC 3160) cultures –For Grade 1A,2A and 3A Phenol (Carbolic Acid), crystalizing point not less than 40.5^0C Media: Standard Rideal Walker Broth dehydrated media available commercially with composition as per B.2.1, Standard Staphylococcal Broth dehydrated media available commercially with composition as per C.2.1 for grades 1A,2A,3A, Or microbiological grade Meat extract, Peptone, Sodium chloride, Sodium hydroxide solution, phenolphthalein indicator, phenol red, Titration apparatus, and filter paper, if prepared by mixing. Equipment: Weighing balance, pH meter(LC 0.1 Range 0-14), Autoclave (capable of 15 psi/ 121 ºC), Inoculating loop (as in B1.1), Incubator L.C. 1^0C capable to maintain 37±1ºC, Hot plate, Water bath (with temperature control), Distilled water, Stoppered measuring cylinder 100 ml Cap. Pipettes 1 ml, 5ml, 10 ml., Dropping pipette, Medication tubes 125 mm x 20 mm size made of hard neutral glass, Broth tubes, Stoppered and graduated measuring cylinders- 500 graduated in 10 ml and 100 ml and 1 ml, , Flask 1000 ml Cap., Air conditioner, refrigerator (for stock agar slope culture),
4.	Mercury Compound (Cl. 4.4),	Measuring cylinder, Beaker 100 ml, distilled water, hot plate, Bright clean copper rod (100 mm length x 3 mm diameter), Hydrochloric acid
5.	Stability on storage (Cl. 4.5)	Arrangement to maintain storage temperatures 15^0C and 45^0C for Normal type and 5^0C and 30^0C for Winter type.

		All the equipment and Chemicals as mentioned at Sl.No. 2 & 3 above.
6.	Detection of Phenolic Compounds (Cl. 4.6)	Conical flask 250 ml cap., Graduated pipettes 5 ml and 10 ml cap., Measuring cylinder, 2N Folin and Ciocalteu's reagent (Phosphomolybdic-Phosphotungstic phenol reagent), Sodium Carbonate, Standard Phenol AR Grade Distilled water

ANNEX B

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 disinfectant fluid, phenolic type homogenized at a time in one tank

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 container provided always that the material in each container on which this Mark is thus applied, 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 container:

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.	**Requirements**	**Test Methods**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
4.1	Composition and Description	4.1.1 or 4.1.2	IS 1061 : 2017	R	One	Each Control Unit	
4.2	Stability after dilution	Annex A	-do-	R	One	-do-	
4.3	Germicidal Value	Annex B & C	-do-	R	One	-do-	
4.4	Mercury Compound	Annex D	-do-	R	One	Once in a month	
4.5	Stability on storage	4.2, 4.3 & 4.5	-do-	R	One	Once in a month	
4.6	Detection of Phenolic Compounds	Annex E	-do-	R	One	Each Control Unit	