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उत्पाद मानुयल
एच एसिड विशिष्टि

IS 8637:2020 के अनुसार
PRODUCT MANUAL FOR
H-Acid-SPECIFICATION
ACCORDING TO IS 8637:2020

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.	उत्पाद Product:	:	IS 8637:2020
	शीर्षक Title	:	H Acid - SPECIFICATION
	संशोधनों की संख्या No. of Amendments	:	2
2.	नमूना दिशानिर्देश Sampling Guidelines:		
a)	कच्चा माल Raw material	:	No specific requirement
b)	समूहिकरण दिशानिर्देश Grouping guidelines		Not Applicable
c)	नमूने का परिमाण Sample Size		1Kg
3.	परीक्षण उपकरणों की सूची List of Test Equipment		Please refer ANNEX – A

4.	निरीक्षण व परीक्षण 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.	लाइसेन्स का कार्यक्षेत्र Scope of the Licence :		
IS 8637:2020 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेन्स निम्नलिखित कार्यक्षेत्रके लिए प्रदान किया जाता है “Licence is granted to use Standard Mark as per IS 8637:2020 with the following scope:			
	Name of the product		H-Acid

BUREAU OF INDIAN STANDARDS

Manak Bhawan, 9, Bahadur Shah Zafar Marg, New Delhi-110002

ANNEX A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	<i>Test Used in With Clause Reference</i>	<i>Test Equipment/Chemical</i>
1	Assay (by nitrite value), %by mass ODB Annex A-2 of IS 8673: 2020	Oven, wide-mouthed bottle with stopper, 1 litre beaker, burette, pipette Concentrated Hydrochloric Acid, Potassium Bromide Standard Sodium Nitrite Solution — 0.1 N Potassium Starch Iodide Indicator Papers, washed ice
2	Difference between nitrite-value and coupling value Annex A-3 of IS 8673: 2020	one-litre beaker, burette, washed ice, pipette Whatmanpaper Sodium carbonate solution — 20 percent (m/v). P-chloroanilinediazo solution — 0.1 N, Common salt
3	Matter insoluble in sodium carbonate solution, %by mass Annex A-4 of IS 8673: 2020	Oven, 500-ml beaker, Hot plate, weighing balance Sodium carbonate solution — 20 percent (m/v). Brilliant Yellow Indicator Papers Whatman filter paper
4	Purity By HPLC, %by area ODB Annex B of IS 8637: 2020	Binary Gradient Liquid chromatography system with UV detector C18 100A 250 x 4.6mm, 5µm or equivalent column Acetonitrile –HPLC grade Water – HPLC Grade Sodium di hydrogen orthophosphate – HPLC grade, Tetra n-Butyl Ammonium Bromide – HPLC grade H Acid (Known Purity) 100 ml and 1 litre vol. flask
5	Chromotropic acid content & Koch's acid content, %by mass(on 100 % basis) Annex C of IS 8637: 2020	Binary Gradient Liquid chromatography system with UV detector C18 100A 250 x 4.6mm, 5µm or equivalent column Acetonitrile –HPLC grade, Water – HPLC grade Sodium di hydrogen orthophosphate – HPLC grade Tetra n-Butyl Ammonium Bromide – HPLC grade Koch Acid – Known Purity Chromotropic Acid – Known Purity 100 ml and 1 litre vol. flask, 1ml pipette

ANNEXURE 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 the product produced in a 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/empanelled 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. The polyethylene sheets, if used for packaging shall not be less than 0.05mm in thickness.

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:Subcontracting permitted	Levels of Control		
Cl.	Requirement	Test Method			No. of Sample	Frequency	Remarks
		Clause	Reference				
3.1	Description	3.1	IS 8637	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, Table 1	i)Assay (By Nitrite Value)	A-2 of ANNEX A	IS 8637	R	One	Each Control Unit	NA
	ii)Difference between nitrite value and coupling value	A-3 of ANNEX A	IS 8637	R	One	Each Control Unit	NA
	iii)Matter insoluble in sodium carbonate solution	A-4 of ANNEX A	IS 8637	R	One	Each Control Unit	NA
	iv)Purity by HPLC	ANNEX B	IS 8637	R	One	Each Control Unit	NA
	v)Chromotropic acid content,	ANNEX C	IS 8637	R	One	Each Control Unit	NA
	vi)Koch’s acid content	ANNEX C	IS 8637	R	One	Each Control Unit	NA