



उत्पाद मैनुअल
हेक्सामेथैलिनटेट्रामिन (हेक्सामिन) - विशिष्टि
आईएस 4306:1987 के अनुसार

PRODUCT MANUAL FOR
Specification for Hexamethylenetetramine (Hexamine)
As per IS 4306:1987

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.	:	IS4306:1987
	शीर्षक Title	:	Specification for Hexamethylenetetramine(Hexamine)
	संशोधन संख्या No.ofamendments	:	01
2.	नमूनाकरण दिशा निर्देश Sampling Guidelines		
a)	कच्चा माल Raw material	:	No requirement.
b)	समूहीकरण दिशा निर्देश Grouping Guidelines	:	Not Applicable
c)	नमूने का परिमाण Sample Size	:	01kg approx.
3.	परीक्षण उपकरणों की सूची ListofTestEquipment	:	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
7.	लाइसेंस का कार्यक्षेत्र/Scope of the Licence:		
	IS4306:1987 के अनुसार मानक मुहर का उपयोग करने के लिए लाइसेंस निम्नलिखित कार्यक्षेत्र के लिए प्रदान किया जाता है। Licence is granted to use Standard Mark as per IS4306:1987 with the following scope:		
	Name of the product	Specification for Hexamethylenetetramine(Hexamine)	
	Type	Hexamethylenetetramine (Hexamine)	

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Zafar Marg, New Delhi – 110002

AnnexureA**LIST OF TEST EQUIPMENTS****(INDICATIVE LIST FOR GUIDANCE ONLY)**

Sl. No.	Tests Used in with Clause Reference	Test Equipment and Chemicals
1.	Description(Cl. 2.1)	Visual and sensory
2.	Solubility(Cl. 2.1.2)	Water, rectified spirit and chloroform, Beaker.
3.	Size of the material(Cl. 2.1.3)	Sieve Shaker, Mesh of various sizes
4.	Assay (Cl. 2.2, Table 1, SI No. i)	Glass calomel Electrode, Burettes, Beaker, Stirring bar Glacial acetic acid, Perchloric acid Weighing Balance
5.	pH of aqueous extract(Cl. 2.2, Table 1, SI No. ii)	pH meter with Glass Electrode, Hot plate Distilled water, Weighing balance, Beaker
6.	Water Insolubles (Cl. 2.2, Table 1, SI No. iii)	Sintered glass crucibles, Hot Air Oven Distilled water, weighing balance, Beakers
7.	Loss on Drying (Cl. 2.2, Table 1, SI No. iv)	Glass Petri Dish, Desiccators, Muffle furnace Dry Silica Gel or Sulphuric Acid, Weighing Balance
8.	Sulphated Ash (Cl. 2.2, Table 1, SI No. v)	Platinum, Silica or Porcelain Dish, Sulphuric acid, weighing balance Muffle Furnace, Desiccator
9.	Ammonia (as NH_3) (Cl. 2.2, Table 1, SI No. vi)	Nessler's cylinders, Beakers, Pipettes, Stopper bottle, Stop watch Potassium iodide, Mercuric Chloride solution, Potassium Hydroxide, Ammonium Chloride, Distilled water
10.	Arsenic (As_2O_3) (Cl. 2.2, Table 1, SI No. vii)	Volumetric flask, Gutzeit bottle, Apparatus for modified gutzeit bottle, weighing balance, Mercuric Bromide, Arsenic trioxide, Distilled water, Dry lead acetate paper, Cotton wool, Lead Acetate, Mercuric Bromide Paper, Rubber stopper, Dilute sulphuric acid, Stannous chloride, Potassium Iodide solution, Zinc Metal, Tweezers, Distilled water
11.	Chloride(as Cl) (Cl. 2.2, Table 1, SI No. viii)	Nessler's cylinders, Beakers, Pipettes, Stop watch, Weighing Balance, Dilute nitric acid, Silver nitrate solution, Std Sodium chloride solution, Distilled water
12.	Sulphate (as SO_4) (Cl. 2.2, Table 1, SI No. ix)	Nessler's cylinders, weighing balance, Steam bath, Barium chloride solution, Dilute hydrochloride acid, Potassium sulphate, Distilled water, Beaker.
13.	Iron (as Fe) (Cl. 2.2, Table 1, SI No. x)	Nessler's cylinders, weighing balance, Ammonium Persulphate Butanolic Potassium thiocyanate, Dilute sulphuric acid Hydrochloride acid, Butanolic potassium thiocyanate, Ferric Ammonium Sulphate, Distilled water.
14.	Heavy Metals (as Pb) (Cl. 2.2, Table 1, SI No. xi)	Nessler's cylinders, Beakers, weighing balance, Steam bath Porcelain dish, Glass containers free from soluble lead salts White surface/tiles, Nitric acid, Hydrochloric acid, Hydrogen sulphide Solution, Dilute acetic acid, Lead, Lead nitrate solution Distilled water, Pipettes,
15.	Organic Impurities (Cl. 2.2, Table 1, SI No. xii)	weighing balance, Desiccator, Concentrated Sulphuric acid cooling arrangement

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 :A single batch of Hexamethylenetetramine(Hexamine) produced from same raw materials and under similar conditions of production.

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.

TABLE1
(Only for Guidance Purpose)

(1)				(2)	(3)		(4)
TEST DETAILS					LEVELSOFCONTROL		REMARK S
Clause	Requirements	TestMethod		Test equipment requirement R:required (or)S:Sub- contracting permitted	No. of Samples	Frequency	
		Clause	Reference				
2.1	Description	2.1	IS4306	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.		
2.1.2	Solubility	2.1.2	IS 4306	R	01	Each Control Unit	----
2.1.3	Size of the Material	2.1.3	IS 4306	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.		
2.2	Assay(on dry basis)	2.2, Table 1	A-2, IS 4306	R	01	Each Control Unit	---
2.2	pH of Aqueous Extract	2.2, Table 1	A-3, IS 4306	R	01	Each Control Unit	---
2.2	Water Insolubles	2.2, Table 1	A-4, IS 4306	R	01	Each Control Unit	---
2.2	Loss on Drying	2.2, Table 1	A-5, IS 4306	R	01	Each Control Unit	---
2.2	Sulphated Ash	2.2, Table 1	A-6, IS 4306	R	01	Each Control Unit	---

2.2	Ammonia(as NH ₃)	2.2, Table 1	A-7, IS 4306	R	01	Each Control Unit	---
2.2	Arsenic(as As ₂ O ₃)	2.2, Table 1	A-8, IS 4306	R	01	Each Control Unit	---
2.2	Chloride(as Cl)	2.2, Table 1	A-9, IS 4306	R	01	Each Control Unit	---
2.2	Sulphate(as SO ₄)	2.2, Table 1	A-10, IS 4306	R	01	Each Control Unit	---
2.2	Iron(as Fe)	2.2, Table 1	A-11, IS 4306	R	01	Each Control Unit	---
2.2	Heavy Metals(as Pb)	2.2, Table 1	A-12, IS 4306	R	01	Each Control Unit	---
2.2	Organic Impurities	2.2, Table 1	A-13, IS 4306	R	01	Each Control Unit	---