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उत्पाद मैन्युअल

बीटा पिकोलिन विशिष्ट

IS 16112:2013 के अनुसार

PRODUCT MANUAL FOR

BETA PICOLINE- SPECIFICATION

ACCORDING TO **IS 16112:2013**

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 16112:2013
	शीर्षक **Title**	:	BETA PICOLINE- SPECIFICATION
	संशोधनों की संख्या **No. of amendments**	:	05
2.	**नमूना दिशानिर्देश** **Sampling Guidelines**		
a)	**कच्चा माल** **Raw material**	:	No specific requirement Note: This section indicates the requirements for raw material (if specified in the IS) for which compliance is to be established during Grant of Licence/Change in Scope of Licence/Factory Surveillance

b)	**समूहीकरण दिशानिर्देश** **Grouping Guidelines**	:	Not Applicable
c)	**नमूने का परिमाण** **Sample Quantity**	:	200 g 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 (in case of market surveillance, effort may be made to procure the required 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**	:	Please refer to Annex-A
4.	**निरीक्षण और परीक्षण की स्कीम** **Scheme of Inspection and Testing**	:	Please refer to Annex-B
5.	**एक दिन में संभावित परीक्षण** **Possible tests in a day**		
	All tests are possible in a day. 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 ready reference 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 16112:2013 with the following scope:		
	Name of the product	BETA PICOLINE	

ANNEX – A

LIST OF TEST EQUIPMENTS

(INDICATIVE LIST, FOR GUIDANCE ONLY)

Sl. No.	Tests Used In WithClause Reference	Test Equipment/Chemical
1	Solubility/Cl 3.2	General Glassware, distilled water
2	Beta picoline content /Cl 3.3 Table 1 Sl no.i)	Gas Chromatograph (with FID) with data acquisition system and integrating chromatographic peaks, General purpose nonpolar capillary GC column containing 100 percent dimethyl polysiloxane (PDMS) or capillary GC column containing high polarity polyethylene glycol (PEG) phase, 60 m long, 0.25 mm internal diameter, 0.25 µm film thickness (df). (The above gas chromatographic conditions are suggestive. However any GC having different columns and different carrier gas with different calibration technique (internal standard, external standard, area normalization) may be used,provided standardization/calibrations are done after setting up chromatographic conditions for required resolution) Certified Reference/Working Standard of 2-Ethylpyridine, Certified Reference/Working Standard of Alpha Picoline Certified Reference/Working Standard of Beta Picoline, Certified Reference/Working Standard of Gamma Picoline Internal Standard — Pentadecane, Methanol Electronic Balance with LC 0.1 mg General Glassware
3	2- Ethyl pyridine content /Cl 3.3 Table1, Sl no. ii))	Same as above
4	Alpha picoline content /Cl 3.3 Table1, Sl no. iii)	Same as above
5	Gamma picoline content /Cl 3.3 Table1, Sl no. iv)	Same as above
6	Other unknown impurities/Cl 3.3 Table1, Sl no. v)	Same as above
7	Moisture content/ Cl 3.3 Table 1 Sl no. vi)	Pyridine free Karl Fischer Reagent, Karl Fischer Titrator apparatus with electrometric end point detection, Analytical balance, Hot air oven, Distilled water,Ice Bath,Glass wares,Thermometer, Reagents:-Methanol, 2-Methoxyethanol, Iodine, Pyridine, Sulphur Di Oxide, Sodium Tartarate (Crystalline), Silicone Base Grease

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 the entire quantity of the product produced in a single batch 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 testingfacility 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 laboratoryor 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 Beta Picoline, 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 If material is supplied in tank cars, tank trucks, container ships etc. the Standard Mark as given in Schedule of the licence and Licence Number (i.e. CM/L .....) shall be incorporated on a test certificate to be provided along with each tank car/tank truck/container ship as per the format at Appendix-1 enclosed, provided always that the product thus marked conforms to all the requirement of the specification. Packing shall be done as per provisions of Indian Standard and the marking details as per IS 16112:2013 shall also be indicated on the test certificate.

3.3Additional Marking requirements: The material shall also be marked with the following additional requirement on the container transporting Beta Picoline:

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 Method Cl. Ref.**	**Test Method IS**		**No. of Sample**	**Frequency**	**Remarks**
3.1	Description	3.1	IS 16112	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	Solubility	3.2	-do-	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		
Cl 3.3 Table 1 Sl no. i)	Beta picoline content	Annex A	-do-	R	One	Each Control Unit	
Cl 3.3 Table 1 Sl no. ii)	2- Ethyl pyridine content	Annex A	-do-	R	One	Each Control Unit	
Cl 3.3 Table 1 Sl no. iii)	Alpha picoline content	Annex A	-do-	R	One	Each Control Unit	
Cl 3.3 Table 1 Sl no. iv)	Gamma picoline content	Annex A	-do-	R	One	Each Control Unit	
Cl 3.3 Table 1 Sl no. v)	Other unknown impurities	Annex A	-do-	R	One	Each Control Unit	
Cl 3.3 Table 1 Sl no. vi)	Moisture content	Annex B	-do-	R	One	Each Control Unit	

Appendix- 1

BIS Standard Mark

XYZ COMPANY
(Registered Office Address and works address)
TEST CERTIFICATE
Beta Picoline: as per IS 16112: 2013

TEST CERTIFICATE No. Date……

To M/s_____

We certified that the material described below fully conforms to **IS 16112:2013.** The properties of the product, as tested in accordance with the Scheme of Inspection and Testing contained in the BIS Certification Marks License No. CM/L_____ are as indicated below against each order No.

(PLEASE REFER TO IS 16112:2013 FOR DETAILS OFSPECIFICATION REQUIREMENTS)

TEST RESULTS

Month and year of mfg.	Batch No.	Quantity	Date of supply		Requirements						
				Description	Solubility	Beta picoline content	2- Ethyl pyridine content	Alpha picoline content	Gama picoline content	Other unknown impurities	Moisture content

REMARKS
Tanker No./Container No.

FOR XYZ COMPANY