



उत्पाद मैनुअल
CARTAP HYDROCHLORIDE SP
IS 14183 : 1994 के अनुसार

PRODUCT MANUAL
FOR CARTAP HYDROCHLORIDE SP
ACCORDING TO IS 14183 : 1994

विभिन्न उत्पादों के लिए भारतीय मानक ब्यूरो (अनुरूपता मूल्यांकन) विनियम 2018 की योजना- I के तहत प्रमाणन के संचालन में अभ्यास और पारदर्शिता के संचालन में पारदर्शिता सुनिश्चित करने 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 लाइसेंस/प्रमाणपत्र 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 coherence 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 licence/certificate.

1.	उत्पाद Product	:	IS 14183 : 1994
	शीर्षक Title	:	Cartap Hydrochloride SP
	संशोधनों की संख्या No.of amendments	:	02
2.	नमूना दिशानिर्देश Sampling Guidelines:		
a)	कच्चा माल Raw material	:	Cartap Hydrochloride technical employed in the formulation of Cartap Hydrochloride SP shall conform to IS 14159.
b)	समूहीकरण दिशानिर्देश Grouping Guidelines	:	NA (No varieties for the product mentioned in IS)
c)	नमूने का आकार Sample Size	:	500 g
3.	परीक्षण उपकरणों की सूची List of Test Equipment	:	Please refer ANNEX – <u>A</u>
4.	निरीक्षण और परीक्षण की स्कीम	:	Please refer ANNEX – <u>B</u>

	Scheme of Inspection and Testing		
5.	एक दिन में संभावित परीक्षण Possible tests in a day		
	i. Description ii. Cartap hydrochloride content iii. pH of 10 percent extract iv. Material insoluble in water		
6.	लाइसेंस का दायरा /Scope of the Licence:		
	“Licence is granted to use Standard Mark as per IS 14183 : 1994 with the following scope:		
	Name of the product	Cartap Hydrochloride (50%) SP	

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ANNEX - A

TO PRODUCT MANUAL
FOR CARTAP HYDROCHLORIDE SP ACCORDING TO IS 14183 : 1994

LIST OF TEST EQUIPMENT

Major test equipment required to test as per the Indian Standard

Sl. No.	Tests used in with Clause Reference	Test Equipment
1.	Cartap Hydrochloride Content Cl 3.3.1 (Annex A of IS 14159)	Spectrophotometer Method (Refree method): Spectrophotometer, Mechanical Shaker, Cartap Hydrochloride reference standard of Known purity, 5,5 dithiobis (2-Nitrobenzoic acid, Buffer Solution (Phosphoric acid, Methanol ,Boric acid, acetic acid, Sodium hydroxide solution), Standard glass ware, Analytical balance (0-200 gm, LC-0.01 mg). Iodimetric method: Standard Glass wares, Titration Flask 250 ml with glass stopper, Burette 50ml, Potassium hydroxide solution, Sulphuric acid, Starch reagent, Iodine solution, Potassium Iodide solution, Disodium or tetrasodium salt of EDTA, Methanol, Dil HCl, Analytical balance (0-200 gm, LC-0.01 mg).
3	Material Insoluble in water, Cl 3.3 & Table 1 (Cl 9 of IS 6940)	Analytical balance (0-200 gm, LC-0.01 mg), Standard glass wares, Erlenmeyer flask 250 ml with a ground glass joint, Heating Mantle (1000 ml), Sintered Glass crucible Reflex Condenser, Vacuum Pump, Oven (capable of operating at 110°C, Water.
4	pH of 10 percent extract Cl 3.3 & Table 1 (Annex B of IS 14159)	Arrangement for boiling water, Analytical balance (0-200 gm, LC-0.01 mg), pH meter, Glass rod, Beaker 100 ml.

The above list is indicative only and may not be treated as exhaustive.

ANNEX - B

SCHEME OF INSPECTION AND TESTING FOR CARTAP HYDROCHLORIDE SP ACCORDING TO IS 14183 : 1994

1. LABORATORY - A laboratory shall be maintained which shall be suitably equipped (as per the requirement given in column 2 of Table 1) and staffed, where different tests given in the specification shall be carried out in accordance with the methods given in the specification.

1.1 The manufacturer shall prepare a calibration plan for the test equipments.

2. TEST RECORDS – The manufacturer shall maintain test records for the tests carried out to establish conformity.

3. PACKING AND MARKING – The Standard Mark as given in Schedule of the licence shall be stenciled/printed on each container of Cartap Hydrochloride SP or printed on the labels applied to the container, as the case may be, provided always that the material in each container to which this mark is thus applied conforms to every requirement of the specification.

3.1 Packing and Marking shall be done as per clause 4 and 5 of IS 14183. In addition, the following details shall be mentioned on each container legibly and indelibly:

- a) BIS Licence No. CM/L_____.
- b) BIS website details i.e – “For details of BIS certification please visit www.bis.gov.in”.
- c) The minimum cautionary notice as worded in Insecticides Act, 1968 and Rules framed thereunder.

4. CONTROL UNIT – For the purpose of this scheme, the entire quantity of the material finally blended in a blended at a time in one operation in case of batch process (BP) and every 100 containers of 50 kg each of the material or part thereof, manufactured by a continuous process not exceeding a day’s production in case of continuous process (CP) shall constitute a control unit.

5. LEVELS OF CONTROL - The tests as indicated in column 1 of Table 1 and the levels of control in column 3 of Table 1, shall be carried out on the whole production of the factory which is covered by this plan and appropriate records maintained in accordance with paragraph 2 above.

5.1 All the production which conforms to the Indian Standards and covered by the licence should be marked with Standard Mark.

5.2 On the basis of test results, decision regarding conformity or otherwise of a control unit to the given requirements shall be made as follows.

5.2.1 A sample shall be drawn from each control unit and shall be tested for all the requirements of the specification. If any of the sample fails in the requirements other than Cartap Hydrochloride content requirement, the entire quantity of the material in the control unit shall be considered as unfit for the purpose of marking.

5.2.2 In case the sample fails in cartap hydrochloride content the control unit shall be suitably reprocessed and defect rectified. Such reprocessed material, when tested again shall satisfy all the requirements of the specification.

6. RAW MATERIAL – Cartap Hydrochloride technical used in the formulation of Cartap Hydrochloride SP shall conform to IS 14159. A test certificate to that effect shall be obtained from the supplier for each consignment of Cartap Hydrochloride technical received. Alternatively, a sample from each consignment shall be tested for its conformity to the Indian Standard mentioned above and a record maintained. However, no testing or test certificate may be required if the material is ISI marked.

7. REJECTIONS – 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
LEVELS OF CONTROL

(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
3.2	Description	3.2	IS 14183	R	One	Each Control unit	See clause 5 of SIT
3.1	Cartap hydrochloride content	Annex A	IS 14159	R	Five for CP One for BP	-do-	
3	Material insoluble in water (% by mass)	9	IS 6940	R	Two for CP One for BP	-do-	
3	pH of 10% extract in the water	Annex B	IS 14159	R	Five for CP One for BP	-do-	

Note-1: Whether test equipment is required or sub-contracting is permitted in column 2 shall be decided by the Bureau and shall be mandatory. Sub-contracting is permitted to a laboratory recognized by the Bureau or Government laboratories empaneled by the Bureau.

Note-2: Levels of control given in column 3 are only recommendatory in nature. The manufacturer may define the control unit/batch/lot and submit his own levels of control in column 3 with proper justification for approval by BO Head.