



**PRODUCT MANUAL  
FOR FIPRONIL SUSPENSION CONCENTRATE (SC)  
ACCORDING TO IS 16145 : 2013**

*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.	<b>Product</b>	:	IS 16145 : 2013
	<b>Title</b>	:	Fipronil Suspension Concentrate (SC)
	<b>No. of Amendments</b>	:	Nil
2.	<b>Sampling Guidelines:</b>		
a)	<b>Raw material</b>	:	Fipronil technical shall be employed in the formulation of the material.
b)	<b>Grouping guidelines</b>	:	NA
c)	<b>Sample Size</b>	:	500 ml
3.	<b>List of Test Equipment</b>	:	Please refer ANNEX – <u>A</u>
4.	<b>Scheme of Inspection and Testing</b>	:	Please refer ANNEX – <u>B</u>
5.	<b>Possible tests in a day :</b>		
	<ul style="list-style-type: none"> <li>i. Description</li> <li>ii. Spontaneity of Dispersion</li> <li>iii. Suspensibility</li> <li>iv. Wet Sieve Test</li> <li>v. Persistent Foam</li> <li>vi. pH of Suspension</li> <li>vii. Fipronil Content</li> <li>viii. Acidity / Alkalinity</li> </ul>		
6.	<b>Scope of the Licence :</b>		
	“Licence is granted to use Standard Mark as per IS 16145 : 2013 with the following scope:		
	Name of the product	:	Fipronil (5%) SC

ANNEX A

TO PRODUCT MANUAL  
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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.	Pourability Cl 3.2.2 (Annex A of IS 16145)	500 ml stoppered measuring cylinder as per following requirements: Volume equivalent to 1 subdivision of the scale = 5 ml, Capacity corresponding to lowest graduation mark = 50 ml Capacity corresponding to highest graduation mark = 500 ml, Length of scale = 250 mm, Overall height = 39 cm Diameter of base = 10 cm Stopper = B 34. Analytical balance, Distilled water.
2.	Spontaneity of Dispersion Cl 3.2.3 (Annex B of IS 16145)	Standard Hard Water (342 ppm), Graduated Cylinders — Glass stoppered, 250 ml capacity. Glass Suction Tubes — About 40 cm long, 5 mm internal diameter, drawn out at one end to 2-3 mm internal diameter. Magnetic Stirrer, Rotary Vacuum Evaporator, Standard Glassware, Stop watch, Vacuum pump.
3.	Suspensibility Cl 3.2.4 (Annex C of IS 16145)	A High Performance Liquid Chromatography (HPLC) system equipped with UV-VIS detector and chromatographic software/printer plotter-cum integrator or PC based data system, Analytical Balance, Microlitre Syringe — 25 µl capacity, Magnetic Stirrer, Ultrasonic Bath, Standard Glassware, Fipronil Reference Standard — of known purity, Acetonitrile — AR grade, or equivalent, Water — AR grade, or equivalent.
4.	Wet Sieve Test Cl 3.2.5 (Cl 11.1 of IS 6940)	Beaker of 6.0 to 6.5 cm and 250 ml capacity, Pressure assembly - a piston or disc, loosely fitting in the beaker and so formed or weighed as to exert an even pressure of 2.5 g/cm <sup>2</sup> , 45 micron IS Sieve prepared for the test by removing any film, grease or other water repellent material and then by drying, Rubber hose - of about 10 mm internal diameter.
5.	Persistent Foam Cl 3.2.6 (Annex D of IS 16145)	Standard Hard Water, Graduated Cylinder— Glass stoppered, 250 ml capacity with 2 ml graduations. The distance between the 0 mark and the 250 ml mark should be 20 cm to 21.5 cm. The distance between the 250 ml mark and the bottom of the stopper should be 6 cm to 8 cm, Stopwatch, Top pan balance.

6.	pH of Suspension CI 3.2.7 (Annex E of IS 16145)	pH Meter — Direct reading, with glass electrode and a calomel reference electrode or any other suitable electrode along with temperature compensation. Balance (Analytical) — Sensitive to 0.1 g, Standard Glassware, Wash Bottle — Containing distilled water, Standard Hard Water, Buffer Tablets — Tablets of pH 4.0, 7.0 and 9.2.
7.	Fipronil Content CI 3.3.1 (Annex F of IS 16145)	High Performance Liquid Chromatography system equipped with ultraviolet detector and chromatographic software/printer plotter-cum integrator or PC based data system, Analytical Balance, Microlitre Syringe — 25 µl capacity, Magnetic Stirrer, Ultrasonic Bath, Standard Glassware, Fipronil Reference Standard — of known purity, Acetonitrile — AR grade, or equivalent, Water — AR grade, or equivalent.
8.	Acidity / Alkalinity CI 3.3.2 (CI 13.5 of IS 6940)	Methyl red indicator solution - aqueous one percent ( m/v), Bromocresol purple indicator solution- one percent (m/v) in ethyl alcohol, Standard sodium hydroxide solution - 0.05 N. Standard hydrochloric acid -0.05 N.

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

**ANNEX B**

**SCHEME OF INSPECTION AND TESTING  
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**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 Fipronil SC 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 the Indian Standard IS 16145. 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](http://www.bis.gov.in)”.

**4. CONTROL UNIT** – For the purpose of this scheme, the entire quantity of Fipronil suspension concentrate mixed in a mixer at a time shall constitute one 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 tests and analysis results, the decision regarding conformity or otherwise of a control unit shall be taken as follows:

**5.2.1** A sample shall be drawn from each control unit and tested for all the requirements of the specification. If the sample fails in any one or more of the requirement tested, the entire control unit represented by the sample shall be considered unfit for the purpose of marking. However, the material may be suitably reprocessed and defect(s) rectified in case the material fails in technical content only. Such reprocessed material when tested again shall conform to all the requirements of the specification before it is used for marking.

**6. RAW MATERIAL** – Fipronil technical shall be used in the formulation of Fipronil SC. It is recommended that a test certificate be obtained from the supplier for each consignment of Fipronil technical received. It is also recommended that Routine analysis of each consignment of raw materials used in the manufacture of Fipronil SC be carried out and appropriate records maintained.

**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
3.2.1	Description	3.2.1	IS 16145	R	One	Each Control Unit	See clause 6 of SIT
3.2.2	Pourability	Annex A	IS 16145	R	-do-	-do-	
3.2.3	Spontaneity of Dispersion	Annex B	IS 16145	R	-do-	-do-	
3.2.4	Suspensibility	Annex C	IS 16145	R	-do-	-do-	
3.2.5	Wet Sieve Test	11.1	IS 6940	R	-do-	-do-	
3.2.6	Persistent Foam	Annex D	IS 16145	R	-do-	-do-	
3.2.7	pH of Suspension	Annex E	IS 16145	R	-do-	-do-	
3.3.1	Fipronil Content	Annex F	IS 16145	R	-do-	-do-	
3.3.2	Acidity / Alkalinity	13.5	IS 6940	R	-do-	-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.