PRODUCT MANUAL
FOR BROMADIOLONE RB ACCORDING TO IS 12912 : 1990

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.	**Product**	:	IS 12912 : 1990
	Title	:	Bromadiolone RB
	No. of Amendments	:	01
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	Bromadiolone technical used in the formulation of Bromadiolone RB shall conform to IS 12914.
b)	**Grouping guidelines**	:	NA
c)	**Sample Size**	:	500 g
3.	**List of Test Equipment**	:	Please refer ANNEX – A
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX – B
5.	**Possible tests in a day :**		
	(i) Description (ii) Bromadiolone content.		
6.	**Scope of the Licence :**		
	"Licence is granted to use Standard Mark as per IS 12912 : 1990 with the following scope:		
	Name of the product	Bromadiolone (0.005 %) RB	

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	Bromadiolone content Clause 3.2	HPLC with profile as per Annex-A of IS12914, Analytical Balance (0-200 gm LC 0.001g), Sohxlet Apparatus, Heating Mantle, Refrigerator, Micro-syringe, Air-conditioner, Bromadiolone Refrence Standard, Water-HPLC Grade, Methanol-HPLC Grade, Acetic acid, Karl Fisher Reagent, N-Butyl Phthalate (AR Grade), Silica gel, Volumetric Flask (50 ml, 100 ml), Pipette (01 ml,02 ml,10 ml), Measuring Cylinder (100 ml , 200 ml), Sintered Crucible (G-5).

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 Bromadiolone RB 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 Marking – The material shall be marked as per 5 of the Indian Standard IS 12912. 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)

3.2 Packing - The material shall be packed in laminated glassine paper/LDPE pouch of 100 g capacity or alternatively the product may also be packed in BOPP pouch or laminated pouch made from 12-microns polyester coated with 38-microns LDPE. It shall be free from pinholes, fine eye patches, tears and blisters and any other visible defects. These pouches are heat sealed and shall be further packed in duplex skillet cartons and in CFB boxes. The container shall also meet the general requirements given in IS 8190 (Part 3).

4. CONTROL UNIT – For the purpose of this scheme, the entire quantity of material mixed together in a single operation 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 the test results, decision regarding the conformity or otherwise of a control unit of the Wheat Atta with the requirement of the specification shall be taken as follows:

5.2.1 One sample shall be drawn from each control unit and tested for Description and Bromadiolone content. It shall satisfy the corresponding requirements of specification.

5.2.2 If the sample fails in any requirement, the control unit shall be considered unfit for the purpose of marking. The material may however, be suitably reprocessed and defect(s) rectified. Such reprocessed material, when tested again shall satisfy all the requirements of the specification.

6. RAW MATERIAL - Bromadiolone technical employed in manufacture of this material shall conform to IS 12914. Each consignment of Bromadiolone technical shall be covered by test certificate from the supplier guaranteeing its conformity to IS 12914. Alternatively, a sample from each consignment of the material received, shall be tested for its conformity to IS 12914 and 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**
3.1	Description	3.1	IS 12912	R	One	Each control unit	
3.2	Bromadiolone content	6.3 & 6.4 Annex-A	IS 12912 IS 12914	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.