PRODUCT MANUAL

FOR ALUMINIUM AND ALUMINIUM ALLOY FOILS FOR PHARMACEUTICAL PACKAGING

ACCORDING TO IS 16011:2012

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 16011:2012
	Title	:	Aluminium and Aluminium Alloy Foil for Pharmaceutical Packaging
	No. of Amendments	:	Nil
2.	**Sampling Guidelines:**		
a)	**Raw material**	:	The material used shall conform to the chemical composition of the Grades 19000, 19500, 19600, 31000 or 40800 of IS 737.
b)	**Grouping guidelines**	:	Please refer ANNEX –A
c)	**Sample Size**	:	10 pieces/sheets of A 4 size
3.	**List of Test Equipment**	:	Please refer ANNEX –B
4.	**Scheme of Inspection and Testing**	:	Please refer ANNEX –C
5.	**Possible tests in a day : All**		
6.	**Scope of the Licence :**		
	Licence is granted to use Standard Mark as per IS 16011:2012 with the following scope:		
	Name of the product	Aluminium and Aluminium Alloy Foils for Pharmaceutical Packaging	
	Type/Variety	Bare Blister Pack Foil/Coated Blister Pack Foil/Bare Pharma Strip Pack Foil/Pharma Laminate	
	Nominal Thickness (to be given type-wise)	From …… up to and including …… mm or µm	
	Width(to be given type-wise)	Up to and including ……. mm	
	Delivery Condition	*As rolled/Fully Annealed etc.*	
	Coating/Lamination (to be given type-wise for each side)	e.g. *Pharma Laminate with one side laminated with 35 gsm LDPE and non laminated side with primer coating with shellac*	

ANNEX A

GROUPING GUIDELINES

1. IS 16011 covers the following varieties of Aluminium and Aluminium Alloy Foils for Pharmaceutical Packaging:

a. Bare Blister Pack Foil
b. Coated Blister Pack Foil
c. Bare Pharma Strip Pack Foil
d. Pharma Laminate

2. Samples of highest and lowest Nominal Thickness of each variety must be tested to cover entire range of nominal thickness. Separate samples of each type of delivery condition (As rolled/annealed etc.), coating/lamination shall be tested. Sample of any width may be tested.

3. While considering grant of licence/ inclusion of new varieties, it shall be ensured that the firm has necessary manufacturing and testing facilities for all the varieties proposed to be covered under the scope of BIS Certification.

4. During the operation of licence, BOs shall ensure testing of different varieties covered in the licence in rotation, so that all varieties are tested over a period of time.

ANNEX B
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.	Pin Hole Count (Clause 5)	Dark Room, Light Box with Glass Top Table, Frame of size 1 m x 1 m.
2.	Freedom from Defects (Clause 6)	Visual inspection
3.	Average Thickness of Bare Foil (Clause 11 & 13)	Sample cutter (area 10000 mm square), Vernier Caliper, Analytical Weighing Balance Drying Oven
4.	Coating/Lamination (Clause 12)	Sample cutter, Vernier Caliper, Analytical Weighing Balance Drying Oven
5.	Width Tolerance (Clause 13)	Vernier Caliper/Tape/Scale
6.	Bursting Strength (Clause 14.1)	Bursting Strength Tester
7.	Peel Strength (Clause 14.2)	Suitable Sample Preparation arrangement, Peel Strength Tester
8.	Sealing Strength (Clause 14.3)	Blistering Machine or any other Suitable Sample Preparation arrangement, Sealing Strength Tester

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

ANNEX B

Scheme of Inspection And Testing

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. LABELLING AND MARKING – The Standard Mark as given in Schedule of the license shall be incorporated, on each foil package and the labeling/ marking and packing shall be done as per the provision of the Indian Standard, provided always the Safety product thus marked conforms to all the requirement of the specification. In addition, details of BIS website shall be marked on each package as follows: "For details of BIS certification please visit www bis.gov.in"

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4. CONTROL UNIT – For the purpose of the Scheme of Testing and Inspection, all the rolls/sheets of same type, width and thickness manufactured in a shift 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.

6. HYGIENIC CONDITIONS –Wherever applicable**,** hygienic conditions shall be complied in day to day production and quality control activities. Schedule for each activity for this purpose shall be displayed prominently in the factory premises and records of compliance shall be 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

(1)				(2)	(3)		
Test Details				**Test equipment requirement R: required (or) S: Sub-contracting permitted**	**Levels of Control**		
Cl.	**Requirement**	**Test Method**			**No. of Sample**	**Frequency**	**Remarks**
		Clause	**Reference**				
7	Material	7.1	IS 737	S	One	Each Consignment of up to 4 Ton	In case a supplier's test certificate is received with each consignment of raw materials, or the material is ISI marked, further testing would not be necessary.
5	Pin Hole Count	5	IS 16011	R	One	Every Fifth Finished Roll/Coil	The lot shall be passed if samples pass. In case of failure of one or more samples, 100% inspection (i.e. one sample from each finished coil) should be done and those conforming to the requirement be marked.
6	Freedom From Defects	6	IS 16011	R	One		
11	Average Thickness of bare foil	11 & 13.1	IS 16011	R	Five	Each Control Unit	
12	Coating/Lamination	12	IS 16011	R	Five		
13.2	Width	13.2	IS 16011	R	Five		
14.1	Bursting Strength	14.1	IS 16011	R	Five		
14.2	Peel Strength	14.2	IS 16011	R	One	One Control Unitp	If any sample fails to comply with the requirements, two additional samples one from the same rolls/ sheets and one from other rolls/sheets shall be selected and tested. If both the samples pass the lot shall be accepted.
14.3	Sealing Strength	14.3	IS 16011	R	One		
9	Lubricants	9	IS 16011	S	One	Each consignment	In case a supplier's test certificate is received with each consignment of lubricant indicating conformity to the standard, no testing is required

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 to BO Head