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Mazdoor Kisan Shakti Sangathan
"The Right to Information, The Right to Live"

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Jawaharlal Nehru
"Step Out From the Old to the New"

IS 16011 (2012): Aluminium and Aluminium Alloy Foil for Pharmaceutical Packaging - Specification [MTD 7: Light Metals and their Alloys]

"ज्ञान से एक नये भारत का निर्माण"
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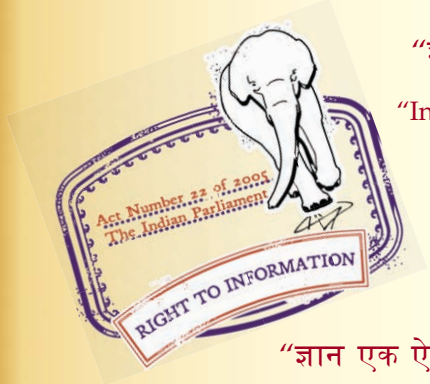

"ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है"
Bhartṛhari—Nītiśatakam
"Knowledge is such a treasure which cannot be stolen"

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भारतीय मानक

औषधि पैकेजबन्दी के लिए एल्यूमिनियम एवं एल्यूमिनियम मिश्रधातु की पन्नी — विशिष्टि

Indian Standard

ALUMINIUM AND ALUMINIUM ALLOY FOIL FOR PHARMACEUTICAL PACKAGING — SPECIFICATION

ICS 11.120.01; 55.040; 77.150.10

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

November 2012 **Price Group 3**

Light Metals and Their Alloys Sectional Committee, MTD 7

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Light Metals and Their Alloys Sectional Committee had been approved by the Metallurgical Engineering Division Council.

The aluminium and aluminium alloy foil play an important role in pharmaceutical packaging due to their unique barrier properties. Packaging with these foils exclude moisture, oxygen and other gases, micro-organisms and light, thus maintaining sensitive products in peak condition for long periods. Their various properties provide a convenient, safe and versatile packaging format for tablets, creams, liquids and powders covering an enormous variety of pharmaceutical products. On the request of stakeholders, the Committee decided to formulate an Indian Standard to cover the various technical requirements.

The composition of the Committee responsible for the formulation of this standard is given in Annex A.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

ALUMINIUM AND ALUMINIUM ALLOY FOIL FOR PHARMACEUTICAL PACKAGING — SPECIFICATION

1 SCOPE

This standard covers the requirements of aluminium and aluminium alloy-bare / coated / laminated foil for pharmaceutical packaging applications. It is applicable for 0.020 mm (20 µm) to 0.040 mm (40 µm) foil thicknesses.

2 REFERENCES

The following standards contain provisions, which through reference in this text constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

IS No.	*Title*
737 : 2008	Wrought aluminium and aluminium alloy sheet and strip for general engineering purposes (*fourth revision*)
5047 (Part 1) : 1986	Glossary of terms relating to aluminium and aluminium alloys: Part 1 Unwrought and wrought metals (*second revision*)
10259 : 1982	General conditions for delivery and inspection of aluminium and aluminium alloy products

3 TERMINOLOGY

For the purpose of this standard, the definitions given in IS 5047 (Part 1) and the following shall apply.

3.1 Bare Blister Pack Foil — Bare foil (of thickness 20-25 µ without any lamination or coating) used for blister pack application for pharmaceutical packaging usually after coating.

3.2 Coated Blister Pack Foil — Bare foil (of thickness 0.20-25 µ) with one side coated with heat seal lacquer and the other side with primer or printed, used for blister pack application in pharmaceutical packaging.

3.3 Bare Pharma Strip Pack Foil — Bare foil (of thickness 30-40 µ without any lamination or coating) used for strip pack application for pharmaceutical packaging.

3.4 Pharma Laminate — Laminated foil (with foil thickness of 30-40 µ) with one side laminated and other side coated with primer or printed used for strip pack application for pharmaceutical packaging.

4 MANUFACTURE

Unless otherwise specified, the production and manufacturing processes shall be left to the discretion of the manufacturer.

5 PINHOLE COUNT

Pinhole count shall be mutually agreed upon between the purchaser and the supplier. However, a guideline for pinhole count is given in Table 1.

Table 1 Pinhole Count

Sl No.	Nominal Thickness		Pinhole Count No./m²
	Dimensions in mm	Dimensions in µm	
(1)	(2)	(3)	*Max* (4)
i)	0.020	20	25
ii)	0.025	25	20
iii)	0.030	30	10
iv)	≥ 0.040	≥ 40	5

6 FREEDOM FROM DEFECTS

The foil shall be well finished, uniform in quality, free from splits, slivers, wrinkles, ragged edges and oil staining. If supplied in coated/laminated condition the coating/lamination shall be uniform. There shall be no delaminated areas.

7 MATERIAL

7.1 The material used for aluminium and aluminium alloy foil shall conform to the chemical composition of the Grades 19000, 19500, 19600, 31000 or 40800 of IS 737.

7.2 Unless otherwise specified by the purchaser, bare blister pack foil shall be supplied in 'as rolled' condition without a final annealing treatment.

7.3 Unless otherwise specified by the purchaser, bare pharma strip pack foil shall be supplied in fully annealed condition.

7.4 Unless otherwise specified by the purchaser, coated

blister pack foil shall be supplied with one side of as rolled foil (without a final anneal) coated with heat seal lacquer and the other side coated with shellac or printed.

7.5 Unless otherwise specified by the purchaser, pharma laminate shall be supplied with one side of fully annealed foil laminated with 35 gsm LDPE and other side coated with shellac or printed.

8 SUPPLY OF MATERIAL

General requirements relating to the supply of aluminium and aluminium alloy foil shall conform to IS 10259.

9 LUBRICANTS

As the foils are to be used in pharmaceutical applications they shall be produced with rolling oils/ lubricants which do not contain substances which are injurious to health or have any deleterious effect on the flavour, odour or appearance of pharmaceutical products.

10 PREFERRED THICKNESSES

Unless otherwise stated, the preferred thickness shall be as given in Table 2.

Table 2 Preferred Thicknesses

Sl No.	Nominal Thickness		Nominal Covering Area
	Dimensions in mm	Dimensions in µm	m^2/kg
(1)	(2)	(3)	(4)
i)	0.020	20	18.5
ii)	0.025	25	14.8
iii)	0.030	30	12.3
iv)	0.040	40	9.26

11 AVERAGE THICKNESS OF BARE FOIL

11.1 The determination of average thickness shall be carried out using a method giving accurate and repeatable results.

11.2 In case of dispute, the average thickness may be determined by the gravimetric method, based on weighing a sample of 100 mm × 100 mm area, shall be dried and weighed on a balance, accurate to at least 0.5 mg

$$\text{Thickness of the foil, in mm} = \frac{W}{27.1}$$

where W is the mass of the foil sample (100 mm × 100 mm), in g.

12 COATING/LAMINATION

12.1 Pharma Laminate

It shall have one side laminated with 35 gsm LDPE. Non-laminated side shall have primer coating with Shellac or shall be printed as desired by the purchaser.

12.2 Coated Blister Pack Foil

It shall have one side of the aluminium foil coated with heat sealant lacquer with a coating weight in the range of either 4-6 gsm or 6-8 gsm depending on mutual agreement between the purchaser and the supplier. Primer coating with Shellac or printing shall be done on the non-heat seal side.

12.3 Winding

Coated blister pack foil shall be so wound so that the primer-coated side is on the outside surface.

13 DIMENSIONS AND TOLERANCES

13.1 Unless otherwise agreed, the thickness tolerance for bare foil shall be ±8 percent and the thickness tolerance for laminated products (including the foil and lamination together) shall be ± 8 percent.

13.2 Unless otherwise stated, the width tolerances shall be as given in Table 3.

Table 3 Width Tolerances

Sl No.	Product	Tolerance on Width for Width	
		<1 000 mm	≥1 000 mm
(1)	(2)	(3)	(4)
i)	All	0.5	1.0

14 MECHANICAL PROPERTIES

14.1 Bursting Strength

Bursting strength for bare strip pack foil and pharma laminate shall be as per Table 4.

NOTE — Bursting strength is only applicable for bare strip pack foil or pharma laminate. It is not applicable for bare blister pack foil or coated blister pack foil.

14.1.1 *Description of Test Method*

The material is submitted to a uniform pressure distributed over a known surface area and the bursting pressure is measured to give an indication of the suitability of the material.

14.2 Peel Strength (for Pharma Laminate)

Peel strength is only applicable for pharma laminate and shall be as per Table 5.

Table 4 Bursting Strength
(*Clause* 14.1)

Sl No.	Product		Nominal Thickness		Bursting Strength (kg/cm^2)
			Dimensions in mm	Dimensions in µm	*Min*
(1)	(2)		(3)	(4)	(5)
i)	For Bare foil:				
		a)	0.020	20	1.4
		b)	0.025	25	1.7
		c)	0.030	30	2.0
		d)	0.040	40	2.6
ii)	For laminated:				
		a)	0.030	30	2.2
		b)	0.040	40	2.8

Table 5 Peel Strength
(*Clause* 14.2)

Sl No.	Product		Nominal Thickness		Peel Strength (g/25 mm)
			Dimensions in mm	Dimensions in µm	*Min*
(1)	(2)		(3)	(4)	(5)
i)	For Bare foil:				
		a)	0.030	30	250
		b)	0.040	40	250

14.3 Sealing Strength (for Coated Blister Pack Foil and Pharma Laminate)

Sealing strength is only applicable for coated blister pack foil and pharma laminate and shall be as per Table 6.

Table 6 Sealing Strength

Sl No.	Product		Nominal Thickness		Sealing Strength (g/25 mm)
			Dimensions in mm	Dimensions in µm	*Min*
(1)	(2)		(3)	(4)	(5)
i)	For Bare foil:				
		a)	0.020	20	500
		b)	0.025	25	500
		c)	0.030	30	500
		d)	0.040	40	500

15 SURFACE CONDITION

15.1 For coated blister pack foil one of the foil surfaces is bright and the other surface is matte.

15.2 For pharma laminate either one of the foil surfaces is bright and the other surface matte or both the surfaces may be bright depending on requirements of the purchaser.

16 SAMPLING

16.1 Unless otherwise agreed to between the purchaser and the manufacturer the following procedure and the criteria for conformity shall apply.

16.2 In a consignment the foils of same width and thickness and of the same surface condition and manufactured by a single firm under essentially similar conditions of production shall be grouped together to constitute a lot.

16.2.1 Tests for determining the conformity of the lot to the requirement of this standard shall be carried out on each lot separately. The number of rolls of foils to be selected for this purpose at random over the whole lot shall be in accordance with col 2 and col 3 of Table 7.

Table 7 Scale of Sampling and Permissible Number of Defectives
(*Clauses* 16.2.1 *and* 16.2.2)

Sl No.	No. of Rolls in the Lot	No. of Rolls to be Selected	Permissible No. of Defectives
(1)	(2)	(3)	(4)
i)	Up to 15	5	0
ii)	16 to 25	8	1
iii)	26 to 50	13	1
iv)	51 to 100	20	2
v)	101 to 300	32	3
vi)	> 300	50	3

16.2.2 All the rolls shall be individually examined for manufacturing defects, surface defects and dimensional tolerances. A sample failing to meet any one of these requirements shall be called defective. The lot shall be considered as conforming to the corresponding requirements of this standard if number of defectives satisfy the freedom from defects and dimensions in less than or equal to the permissible number given in col 4 of Table 7.

17 ORDERING INFORMATION

The order shall include the following information:

a) Quantity, in kg;
b) Nominal thickness;
c) Foil size;
d) Dimensions of rolls (outside diameter, in mm);
e) Type and inside diameter of the core in mm; length of core (if different from the width of the rolls);
f) Surface condition; and
g) Packing mode.

18 MARKING

18.1 Each package of bare or converted aluminium foil may be suitably marked for identification with the name of manufacturer, grade, condition of the material, batch No. and date of manufacture.

18.1.1 The foil package may also be marked with the Standard Mark.

18.2 BIS Certification Marking

18.2.1 The use of the Standard Mark is governed by the provision of the *Bureau of Indian Standards Act,* 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

ANNEX A
(*Foreword*)

COMMITTEE COMPOSITION

Light Metals and Their Alloys Sectional Committee, MTD 7

Organization	*Representative(s)*
Hindalco Industries Ltd (R&D Centre) Taloja, Navi Mumbai	Shri Subhankar Gupta (***Chairman***)
Aluminium Association of India, Bangalore	Prof K. S. S. Murthy Shri N. C. Sud (*Alternate*)
Aeronautical Development Establishment, Bangalore	Shri G. S. Ravindra Shri T. Mohan Reddy (*Alternate*)
BEML Ltd, Bangalore	Shri H. S. Prakash Shri R. Nanda Nandan (*Alternate*)
Bharat Aluminium Co Ltd, Korba	Shri S. Prasad Shri Narain Balakrishana (*Alternate* I) Shri K. Karmakar (*Alternate* II)
CEMILAC, Bangalore	Dr P. Ragothan Rao Shri Kishore Shetty (*Alternate*)
DGAQA, New Delhi/Bangalore	Shri V. K. Sachdeva Shri V. O. Janardhanan (*Alternate*)
DGS&D, Kolkata/New Delhi	Shri B. Dasgupta Shri M. A. Khan (*Alternate*)
DMRL, Hyderabad	Dr Amol A. Gokhale Dr Vijay Singh (*Alternate*)
DRDL, Hyderabad	Dr S. Sundarrajan Dr G. Raja Singh (*Alternate*)
Escorts Knowledge Management Centre, Faridabad	Shri Alok Nayar
Hindalco Industries Ltd, Renukoot	Shri Pramod N. Koparde Shri Atul Gupta (*Alternate*)
Hindustan Aeronautics Ltd, Bangalore	Dr R. R. Bhatt
Indian Space Research Organization, Bangalore	Shri T. S. Nanjunda Swamy Shri Rajendra Hulyal (*Alternate*)
Institute of Indian Foundrymen, New Delhi	Shri K. S. Satyanarayana Shri A. K. Anand (*Alternate* I) Dr H. Sundara Murthy (*Alternate* II)
J. N. Aluminum, R&D Design Centre, Nagpur	Shri J. Mukhopadhyay Dr K. V. Ramana Rao (*Alternate* I) Shri R. N. Chauhan (*Alternate* II)
Jindal Aluminum Ltd, Bangalore/New Delhi	Shri K. R. Raghunath Shri S. C. Agarwal (*Alternate*)

Organization	*Representative(s)*
Ministry of Defence, CQA (Met), Ambernath Ichapur	Shri V. H. Kakani Shri K. Yadav (*Alternate*)
Ministry of Micro, Small and Medium Enterprises (Department of Micro, Small and Medium Enterprises), New Delhi	Shri J. K. Arya Shri V. K. Gupta (*Alternate*)
National Aluminium Co Ltd, Bhubneshwar	Shri S. Nanda Shri S. Sankaran (*Alternate*)
National Metallurgical Laboratory, Jamshedpur	Dr K. L. Sahoo Dr K. Venkateshwarlu (*Alternate*)
National Test House, Ghaziabad	Shri R. N. Ram Shri Vinay Saxena (*Alternate*)
Ordance Factory, Ambajhari	Representative
RDSO (M&C Directorate), Lucknow	Shri Radhey Shyam Shri V. D. Meharkure (*Alternate*)
Regional Research Laboratory, Bhopal	Dr A. K. Gupta
Salco Extrusions (P) Ltd, Mumbai	Shri Gopal M. Pai Shrimati Pooja Kamat (*Alternate*)
Shri Ram Institute of Industrial Research, Delhi	Dr P. K. Kaicker Shrimati Laxmi Rawat (*Alternate* I) Shri B. Govindan (*Alternate* II)
BIS Directorate General	Shri P. Ghosh, Scientist 'F' and Head (MTD) [Representing Director General (*Ex-officio*)]

Member Secretary
Shri Deepak Jain
Scientist 'E' (MTD), BIS

Bureau of Indian Standards

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Amend No.	Date of Issue	Text Affected

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