

Indian Standard IS 16011:2012 – Aluminium and Aluminium alloy foil for Pharmaceutical packaging - Specification

Aluminium and aluminium alloy foil is essential in the pharmaceutical industry due to its excellent barrier properties that prevent **moisture, micro-organisms, oxygen, and light** from affecting sensitive products.

The standard includes specifications for **bare, coated, and laminated foils**, with thicknesses ranging from 20 to 40 micrometers (μm), making them suitable for various pharmaceutical packaging applications such as bare **blister packs and strip packs**.

Given the sensitive nature of pharmaceutical products stringent quality is expected for aluminium foils used in packaging. One of the primary expectations is superior **barrier protection** against moisture, oxygen, and light. Foil quality is often also assessed based on its **pinhole count**. A lower pinhole count signifies better quality, as fewer pinholes mean enhanced barrier properties

The foils should have adequate mechanical strength to withstand the packaging process without tearing or splitting thus parameters like **bursting strength and peel strength** are critical. Additionally, the **surface finish** of the foil is expected to be smooth and free from defects such as splits, slivers, wrinkles, and oil stains ensuring effective printing and coating, essential for product identification and enhancing the foil's barrier properties. Coated blister pack foils have one side coated with heat seal lacquer, enhancing the seal integrity with the packaging material.

The standard provides detailed specifications for quality of aluminium foils. It outlines guidelines for chemical composition, mechanical properties, and permissible defects. It also specifies pinhole count and coating requirements.

Additionally, the standard defines thickness tolerances and mechanical strength requirements, such as bursting and peel strength. The provisions for manufacturing defects, coating uniformity, and acceptable quality levels (AQL) for defects help manufacturers maintain consistent quality, meeting the high standards demanded by the pharmaceutical industry.

By adhering to the IS 16011:2012 standard, manufacturers can produce aluminium foils that fulfil the stringent requirements of pharmaceutical packaging, ensuring product safety, efficacy, and a longer shelf life for medications.