

Technical Data Sheet

APET Film

Characteristics	High clarity thermo formable material for general blisters as well as liquid dose package Thermoforming in medical Applications (medical devices).
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Product Specifications

Properties

Sr. No.	Particulars	Test Method reference	Specifications
1	Total Thickness	DIN 53370	200 - 250 μm $\pm 10\%$
2	Total GSM	DIN 53352	266 - 332.5 $\pm 10\%$
3	Yield		3.75-3.00 m^2/kg $\pm 10\%$
4	Tensile Strength	ASTM-D 882	LD- $\geq 600-650 \text{ kg/cm}^2$ TD- $\geq 600-650 \text{ kg/cm}^2$
5	Elongation	ASTM-D 882	LD- $\geq 500\%$ TD- $\geq 500\%$
6	Toxicity	USP-31	Non toxic
7	Impact strength	ISO 8256	LD- $\geq 400 \text{ kJ/m}^2$ TD- $\geq 350 \text{ kJ/m}^2$

Reel width maximum 980 mm \pm 1.5 mm

Regulatory	Complies with the requirement of European Pharmacopoeia and with Directive 2002/72/EC and amendments in their current version
	Complies with the relevant US Code of Federal regulations CFR 21 and with the US Pharmacopoeia where applicable
	Complies with Directive 94/62/EC and with US CONEG regulations
	Formulation filed with FDA, DMF 15884 Type III
	Production and quality controls according to cGMP rules

Storage Conditions and Shelf Life:

It is recommended to store the reels in original packaging between 18° C-25°C and 40%-60% RH. The component shelf life is 18 months after date of manufacture on label. Manufactured under industry accepted standards for cGMP. Film composed of ingredients in compliance with existing regulations of FDA, USP and is registered for ACG Pharmapack's Drug Master File #15884. Data supplied in good faith for information only. End user assumes all liability in using this product for the purpose intended.