

Technical data sheet

BR

Barex (medical device)

Characteristics

This calendar grade film is an impact modified acrylonitrile methyl acrylate copolymer. It is having excellent gas barrier and chemical resistance. This material can sterile with ETO, Gamma and E-beam sterilization. It has got excellent sealing ability. These materials can thermoform with wide range of temperature without having any modification in present thermoforming machinery.

Parameter	Description	Unit
Surface	Glossy/glossy	NA
Colours	Transparent clear, opaque white, customized	NA
Thickness	250 – 350 µm	µm
Grammage (Transparent)	g/m ² (Barex Thickness *1.15)	g/m ²
Yield (Transparent)	m ² /kg (1000 / Thickness * 1.15)	m ² / kg

Properties

Sr. No.	Particulars	Test method reference	Specifications
1	Thickness	DIN 53370	250 μm $\pm 10\%$ 350 μm $\pm 10\%$
2	GSM	DIN 53352	= (Barex thickness X 1.15*) g/m ² * Density of Barex in g/cc
3	Dimensional Stability	DIN 53377	LD – 22 \pm 3 TD – 13 \pm 3
4	Tensile strength	DIN 5345	LD \geq 55 N /mm ² TD \geq 50 N /mm ²
5	Elongation	DIN 5345 100 mm/min	LD \geq 60 % TD \geq 30 %
6	Toxicity	USP - 31	Non toxic
7	Softening point	Din 5346	72 Deg.C.
8	WVTR at 38 Deg.C. & 90 % RH (Guide value)	DIN 53122	\sim 2.0 gm/ m ² /day Depending on thickness
9	OTR at 23 Deg.C. & 85 % RH (Guide value)	Oxtran carrier gas method	0.35 cc/ m ² /day
10	Impact Strength	DIN 5344	\geq 550 Kj / m ²

Regulatory	Complies with the requirements of the 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

