ACG Pharmapack Pvt Ltd
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ACG-pharmapack
INNOVATION

Technical data sheet

TB PVC/PE/PVdC

Characteristics	Designed with unique thermoforming properties, outstanding seal and peel seal characteristic for tailor- made product performance. PVC laminated with PE and coated with different grammages of PVdC to get excellent water vapour barrier as well oxygen barrier. PE layer helps in smooth thermoform cavity in blister.

Parameter	Description	Unit
Surface of base film	glossy/glossy	NA
Colours of base film	Transparent clear, opaque white, customized	NA
Thickness range of base film	180-600 µm (PVC)	µm
Additional layer 1	PE	µm
Additional layer 2	PVdC	g/m2
Thickness of composite film	(PVC Thickness+ PE Thick +(PVdC GSM /1.7)	µm
Total Grammage	((PVC Thickness *1.35) + (PE Thickness * 0.92)+ PVdC GSM)	g/m²
Yield	m²/kg (1000 / Total Grammage)	m²/ kg

Properties

Sr. No.	Properties	Test method reference	Specification
1	Thickness of base film	DIN 53370	180 –200 µm ± 10 % 250 – 350 µm ± 5%
2	Thickness of PE	DIN 53370	25/30/35/50 µm ± 10 %
3	GSM of PVDC (Dry)	DIN 53352	40 g/m² ± 5% 60 g/m² ± 5% 90 g/m² ± 5% 120 g/m² ± 5%
4	Tensile strength of base film	ASTM –D- 882	LD & TD 450 kg/m² (min)
5	Elongation of base film	ASTM –D- 882	LD & TD 30%
6	Dimensional stability (Oven, hot air)	DIN 53370 140°C / 10 min	Longitudinal (L) = - 7.0% maximum Transverse (T)= + 3.0% maximum
7	Scotch test	SOP-QA-06	Coating should not come out
8	Softening Point	DIN 53460	76 to 77 °C
9	Impact strength	DIN 53448	≥ 450 kj/in2
10	Water vapour transmission rate (guide value)	ASTM- F 1249	With 250 µ PVC film (gm/m²/day, @38°C & 90 % RH) 40 GSM ≤ 0.6 60 GSM ≤ 0.5 90 GSM ≤ 0.3 120 GSM ≤ 0.15
11	OTR at 23 Deg.C. & 85 % RH	Oxtran carrier gas method	With 250 µ PVC (cm³/m²/day) 40 GSM ≤ 1.15 60 GSM ≤ 1.0 90 GSM ≤ 0.7 120 GSM ≤ 0.6

Regulatory	Complies with the requirements of the European Pharmacoepia 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 Pharmacoepia 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