

Technical Data Sheet Ultramax B Film (Non Toxic Food/Pharma Grade Material)

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Sr.No.	Properties	Test Method	Unit	Specification
1	Color & Appearance	In-house		As per standard sample
2	Thickness of Rigid PVC film	DIN 53370	microns	250 ± 10%
3	Thickness of Rigid PE film	DIN 53370	microns	25 ± 10%
4	Total Thickness	DIN 53370	microns	385 ±10%
5	GSM of Rigid PVC film	DIN 2286	gm/m2	340 ± 10%
6	GSM of Rigid PVDC film	DIN 2286	gm/m2	180 ± 6
7	GSM of Rigid PE film	DIN 2286	gm/m2	23 ± 10%
8	Total GSM	DIN 2286	gm/m2	543 ± 10%
9	Dimensional Changes - Longitudinal	ASTM D1204	%	-5.0
	Dimensional Changes - Transversal			+2.0
10	Dart Impact Strength (from height of 1.52 mtrs)	ASTM D1709	gm	350 min.
11	Tensile Strength - Longitudinal	ASTM D882	kg/Sq.cm	450 min.
	Tensile Strength - Transverse			450 min.
12	Elongation - Longitudinal	ASTM D882	%	5 min.
	Elongation - Transverse			5 min.
13	WVTR @ 38°C & 90% RH	ASTM F1249	$gm/m^2/24$ hr.	0.06 Max.
14	OTR @ 23°C & 0% RH	ASTM D 3985	$cc/m^2/24$ hr.	0.2 Max.
15	Forming Temperature	In-house	°C	110 - 170
16	Toxicity Test	USP Current Edition	-	Non-toxic
17	Residue VCM	ASTM D 3749	ppm	1 max
18	Identification - PVC	FTIR	-	As per Standard IR spectrum
19	Identification - PVDC	In-house	-	Color of PVdC lay shall turn brown
20	Heat Seal Strength	In-house	Kg/cm	0.30 min.
21	Global migration	2005/79/EC	ppm	< 60
22	Inner Diameter of Core	In-house	mm	76 +/- 1
23	Width	In-house	mm	Std. +/- 1



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Regulatory Compliances:

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- Commission Directive 2005/79/EC (including amendment 2004/19/EC): Plastic material and articles in contact with Food Regulations.
- Commission Directive 94/63/EC (including amendment 2004/12/EC): Packaging and packaging waste (providing limits in the heavy metal content)
- Council Directive 78/142/EEC Specifying limit of vinyl chloride monomer content.
- European Pharmacopoeia 3.1.11 (Current Edition) Containers for Dry Dosage Forms for Oral Administration
- European Pharmacopoeia 3.2.2 (Current Edition) Plastic Containers and Closures for Pharmaceutical Use
- USP 661 (Current Edition) Containers for Non-Sterile Solid & Liquid Dosage Forms.
- The additives used in these films comply with the quantitative and qualitative requirements of EC and 21 CFR Part 177.