

Specification – IS 17334 Level 1 - surgical drape

Test Parameter		International / Indian Standard	Sample Required	Turn Around Time
Impact penetration (g) – Critical zone		IS 17375	10 gowns/ drapes	2 days
Impact penetration (g) – Less Critical zone		IS 17375		
Impact penetration (g) – seam portion		IS 17375		
Particle release [log10 (lint count)]		IS 15891-10		
Tensile strength (dry) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Tensile strength (wet) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Bursting strength (dry) (kPa)		IS 1966 (Part 1)		
Bursting strength (wet) (kPa)		IS 1966 (Part 1)		
Cleanliness–microbial (CFU/g)		IS/ISO 11737-1	4 gowns/ drapes (unopened pack)	7 days
Cytotoxicity	Direct	IS/ISO 10993-5 IS/ISO 10993-12		10 days
	In Direct			10 days
	Test on extract			10 days
Skin irritation		IS 17932 (Part 7)		3 Months
Skin Sensitization		IS 17932 (Part 6)		4 Months

Specification – IS 17334 Level 2 - surgical drape

Test Parameter		International / Indian Standard	Sample Required	Turn Around Time
Impact penetration (g) – Critical zone		IS 17375	10 gowns/ drapes	2 days
Impact penetration (g) – Less Critical zone		IS 17375		
Impact penetration (g) – seam zone		IS 17375		
Hydrostatic resistance (cmwc) – Critical zone		IS 391		
Hydrostatic resistance (cmwc) – Less Critical zone		IS 391		
Hydrostatic resistance (cmwc) – Seam zone		IS 391		
Particle release [log10 (lint count)]		IS 15891-10		
Tensile strength (dry) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Tensile strength (wet) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Bursting strength (dry) (kPa)		IS 1966 (Part 1)		
Bursting strength (wet) (kPa)		IS 1966 (Part 1)		
Cleanliness–microbial (CFU/g)		IS/ISO 11737-1	4 gowns/ drapes (unopened pack)	7 days
Resistance to microbial penetration — Dry		IS 16548		3 days
Cytotoxicity	Direct	IS/ISO 10993-5 IS/ISO 10993-12		10 days
	In Direct			10 days
	Test on extract			10 days
Skin irritation		IS 17932 (Part 7)		3 Months
Skin Sensitization		IS 17932 (Part 6)	4 Months	

Specification – IS 17334 Level 3 - surgical drape

Test Parameter		International / Indian Standard	Sample Required	Turn Around Time
Impact penetration (g) – Critical zone		IS 17375	10 gowns/ drapes	2 days
Impact penetration (g) – Less Critical zone		IS 17375		
Impact penetration (g) – seam zone		IS 17375		
Hydrostatic resistance (cmwc) – Critical zone		IS 391		
Hydrostatic resistance (cmwc) – Less Critical zone		IS 391		
Hydrostatic resistance (cmwc) – seam zone		IS 391		
Particle release [log10 (lint count)]		IS 15891-10		
Tensile strength (dry) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Tensile strength (wet) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Bursting strength (dry) (kPa)		IS 1966 (Part 1)		
Bursting strength (wet) (kPa)		IS 1966 (Part 1)		
Cleanliness-microbial (CFU/g)		IS/ISO 11737-1	4 gowns/ drapes (unopened pack)	7 days
Resistance to microbial penetration — Dry		IS 16548		3 days
Resistance to microbial penetration — Wet		IS 16549		3 days
Cytotoxicity	Direct	IS/ISO 10993-5 IS/ISO 10993-12		10 days
	In Direct			10 days
	Test on extract			10 days
Skin irritation		IS 17932 (Part 7)		3 Months
Skin Sensitization		IS 17932 (Part 6)	4 Months	

Specification - IS 17334 Level 4 surgical drape

Test Parameter		International / Indian Standard	Sample Required	Turn Around Time
Synthetic Blood Penetration Resistance		IS 16546	10 drapes	2 days
Particle release [log10 (lint count)]		IS 15891-10		
Tensile strength (dry) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Tensile strength (wet) (N)		Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		
Bursting strength (dry) (kPa)		IS 1966 (Part 1)		
Bursting strength (wet) (kPa)		IS 1966 (Part 1)		
Cleanliness-microbial (CFU/g)		IS/ISO 11737-1		
Cytotoxicity	Direct	IS/ISO 10993-5 IS/ISO 10993-12	10 days	
	In Direct		10 days	
	Test on extract		10 days	
Skin irritation		IS 17932 (Part 7)	3 Months	
Skin Sensitization		IS 17932 (Part 6)	4 Months	