

Specification - IS 17334 Level 1 Surgical gown

2

Test Parameter	International / Indian Standard	No. of samples required	TAT
Impact penetration (g) – Critical zone	IS 17375	3 gowns	2 days
Impact penetration (g) – Less Critical zone			
Impact penetration (g) – Tie attachment outer			
Impact penetration (g) – Tie attachment Inner			
Impact penetration (g) – sleeve seam portion			
Impact penetration (g) – Less Critical zone – Back panel			
Particle release [log10 (lint count)]	IS 15891-10	2 gowns	
Tensile strength (dry) (N)	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)	Gown sample of impact penetration will be used	10 days
Tensile strength (wet) (N)			
Bursting strength (dry) (kPa)			
Bursting strength (wet) (kPa)			
Cleanliness-microbial (CFU/g)	IS/ISO 11737-1		
Cytotoxicity	IS/ISO 10993-5 IS/ISO 10993-12	1 gown (unopened)	
Skin irritation	IS 17932 (Part 7)	5 gowns (unopened)	4 months
Skin Sensitization	IS 17932 (Part 6)		

Specification – IS 17334 Level 2 Surgical gown

2

Test Parameter	International / Indian Standard	No. of samples required	TAT
Impact penetration (g) – Critical zone – Front panel	IS 17375	3 gowns	2 days
Impact penetration (g) – Critical zone – Sleeve panel			
Impact penetration (g) – Critical zone – sleeve seam portion			
Impact penetration (g) – Tie attachment outer			
Impact penetration (g) – Tie attachment Inner			
Impact penetration (g) – Less Critical zone – Back panel			
Hydrostatic resistance (cmwc) – Critical zone – Front Panel	IS 391	5 gowns	
Hydrostatic resistance (cmwc) – Critical zone – Sleeve panel			
Hydrostatic resistance (cmwc) – Critical zone seam portion			
Hydrostatic resistance (cmwc) – Tie attachment outer			
Hydrostatic resistance (cmwc) – Tie attachment Inner			
Hydrostatic resistance (cmwc) – Back panel			
Hydrostatic resistance (cmwc) – Arm seam			
Hydrostatic resistance (cmwc) – Shoulder seam			
Particle release [log10 (lint count)]	IS 15891-10	2 gowns	
Tensile strength (dry) (N)	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)	Gown sample of impact penetration will be used	
Tensile strength (wet) (N)			
Bursting strength (dry) (kPa)			
Bursting strength (wet) (kPa)			
Cleanliness–microbial (CFU/g)	ISO 11737-1		7 days
Resistance to microbial penetration — Dry	IS 16548		3 days
Cytotoxicity	IS/ISO 10993-5 IS/ISO 10993-12	1 gown (unopened)	10 days
Skin irritation	IS 17932 (Part 7)	5 gowns (unopened)	4 months
Skin Sensitization	IS 17932 (Part 6)		

Specification – IS 17334 Level 3 Surgical gown

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Test Parameter	International / Indian Standard	TAT	No. of samples required	
			Reinforced	Non-reinforced
Impact penetration (g) – Critical zone – Front panel	IS 17375	2 days	3 gowns	3 gowns
Impact penetration (g) – Critical zone – Sleeve panel				
Impact penetration (g) – Critical zone – sleeve seam portion				
Impact penetration (g) – Tie attachment outer				
Impact penetration (g) – Tie attachment Inner				
Impact penetration (g) – Less Critical zone – Back panel				
Hydrostatic resistance (cmwc) – Critical zone – Front Panel	IS 391		5 gowns	5 gowns
Hydrostatic resistance (cmwc) – Critical zone – Sleeve panel				
Hydrostatic resistance (cmwc) – Critical zone seam portion				
Hydrostatic resistance (cmwc) – Tie attachment outer				
Hydrostatic resistance (cmwc) – Tie attachment Inner				
Hydrostatic resistance (cmwc) – Back panel				
Hydrostatic resistance (cmwc) – Arm seam				
Hydrostatic resistance (cmwc) – Shoulder seam				
Particle release [log10 (lint count)]	IS 15891-10		2 gowns	2 gowns
Tensile strength (dry) (N)	IS 1966 (Part 1)		2 gowns	Gown sample of impact penetration will be used
Tensile strength (wet) (N)				
Bursting strength (dry) (kPa)	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)		2 gowns	Gown sample of impact penetration will be used
Bursting strength (wet) (kPa)				
Cleanliness–microbial (CFU/g)	ISO 11737-1	7 days	3 gowns	3 gowns
Resistance to microbial penetration — Dry	IS 16548	3 days		
Resistance to microbial penetration —Wet	IS 16549	3 days		
Cytotoxicity	IS/ISO 10993-5 IS/ISO 10993-12	10 days	1 gown	1 gown
Skin irritation	IS 17932 (Part 7)	4 months	5 gowns	5 gowns
Skin Sensitization	IS 17932 (Part 6)	4 months		

Specification - IS 17334 Level 4 surgical gown

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Test Parameter	International / Indian Standard	TAT	No. of samples required	
			Reinforced	Non-reinforced
Viral Penetration Resistance Test	IS 16545	5 days	1 gown	1 gown
Synthetic Blood Penetration Resistance	IS 16546			
Particle release [log10 (lint count)]	IS 15891-10	2 days	2 gowns	2 gowns
Tensile strength (dry) (N)	IS 1966 (Part 1)			
Tensile strength (wet) (N)				
Bursting strength (dry) (kPa)	Nonwoven: IS 15891 (Part 3), Woven: IS 1969 (Part 1)			
Bursting strength (wet) (kPa)				
Moisture vapour transmission rate (Optional)	Annex F of IS 16390	4 days		
Cleanliness-microbial (CFU/g)	ISO 11737-1	7 days	1 gown	1 gown
Cytotoxicity	IS/ISO 10993-5 IS/ISO 10993-12	10 days	1 gown	1 gown
Skin irritation	IS 17932 (Part 7)	4 months	5 gowns	5 gowns
Skin Sensitization	IS 17932 (Part 6)	4 months		