

Report No : 123-20-04-01

Report Date : 09.03.2021

Application No : 123-20-04-01

1. COMPANY INFORMATION:

DENTAPHARMA İLAÇ MEDİKAL GIDA SANAYİ VE TİCARET LİMİTED ŞİRKETİ
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2. PPE INFORMATION:

Disposable non-sterile gown.

3. PPE TYPE IDENTIFICATION

EN ISO 13688:2013 Protective clothing - General requirements
EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
EN 13034:2005+A1:2009 Protective Clothing Against Liquid Chemicals (Type PB 6-B)
EN 1149-5: 2018 Protective clothing - Electrostatic properties

4. PPE PICTURES



5. PPE DIMENSIONS:

DGOWN DG11B model product has been found to be produced using S-M-L-XL-2XL-3XL size.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (123-20-03-01)**

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of coated fabric.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- Protective clothing doesn't contain any sharp or hard edges or rough surfaces.
- Wearer donned and removed without any difficulties and clothing fits perfectly.
- The clothing doesn't obstruct blood circulation in any part of the body.
- The clothing design at armholes and crotch are appropriately proportioned and positioned.
- Sufficient closure arrangements given in the clothing and all the closures systems functioning properly.
- The coverage of protection zones of protective material is maintained during movements as extreme as it is anticipated a user would make.
- Wearer doesn't observe any difficulties while standing, sitting, walking, stair climbing, raising both hands above the head and bending over and picking up a small objects.
- While movements the protective material covers body area sufficiently.
- No difficulties in putting on and removing other items of PPE such as gloves and boots.

8. ANALYSIS AND EVALUATIONS:

EN ISO 13688:2013

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
pH value	6,89	3,5 – 9,5	PASS
Azodyes	<5 (mg/kg)	Max. 30 mg/kg	PASS

EN 13034:2005+A1:2009

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Abrasion resistance	>10 cycles	1 (>10 cycle)	PASS
	>10 cycles		
	>10 cycles		
	>10 cycles		
Tear resistance	37,05	2 (>20N)	PASS
	36,97		
	39,84		
	40,24		
	41,47		
	90,58		
	96,47		
	94,87		
	93,87		
98,21			

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Tensile strength	88,06 89,34 85,24 86,39 83,47 41,98 40,98 41,74 42,98 44,87	1 (>30N)	PASS
Puncture resistance	7,35 7,36 6,88 7,23	1 (>5N)	PASS
Repellency to liquids	H2SO4: 98,1 NaOH: 98,6	3 (>90N) 3 (>90N)	PASS
Resistance to penetration by liquids	H2SO4: 0,9 NaOH: 0,7	3 (<1%) 3 (<1%)	PASS
Seam Strength	67,03 77,58 76,95 69,58 90,24 85,24	2 (>50N)	PASS

EN 14126:2003

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Penetration by blood borne pathogens (Bacteriophage)	0 (PFU/ml) See the table below	3 (3,5 kPa)	PASS

Sample	Material Compatibility Ratio	Thickness (mm)	Mass per unit area g/m ²	Starting Bacteriophage Challenge Titer PFU/ml	Ending Bacteriophage Challenge Titer PFU/ml	Penetration (PFU/ml)	Visible Liquid Penetration
Sample 1	1,0	0,20	60	2,7x10 ⁸	2,1x10 ⁸	< 1	No penetration
Sample 2				2,7x10 ⁸	2,7x10 ⁸	< 1	No penetration
Sample 3				2,7x10 ⁸	2,6x10 ⁸	< 1	No penetration

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TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Resistance to wet bacterial penetration	Total penetration 0,23 % See the table below	1 (t≤15 min)	PASS

Plates	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
Plate 1	3	2	3	3	4
Plate 2	6	5	6	4	6
Plate 3	5	4	6	5	5
Plate 4	5	6	4	4	4
Plate 5	5	2	5	5	6
Penetration (%)	0,24	0,19	0,24	0,21	0,25
Total Penetration (%)	0.23				

TEST	RESULT	PERFORMANCE LEVEL	EVALUATION
Dry microbial penetration	2,04 log cfu	1 (2<log cfu≤3)	PASS

9. DECISION

Analysis and examinations DGOWN DG11B model coded personal protective equipment; EN ISO 13688:2013, EN 13034:2005+A1:2009, EN 14126:2003, EN 1149-5: 2018 are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- User Instruction

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DATE : 09.03.2021