



Water Resistance: Hydrostatic Pressure Final Report

Test Article: Surgical Isolation Gown

Sponsor: Jingzhou Haixin Green Cross Medical Products Co.,Ltd

Study Number: Lot.HXG10-03

Study Received Date:Oct.30.2017

Test Procedure(s):Standard Test Protocol (STP) Number: 112 Rev 06

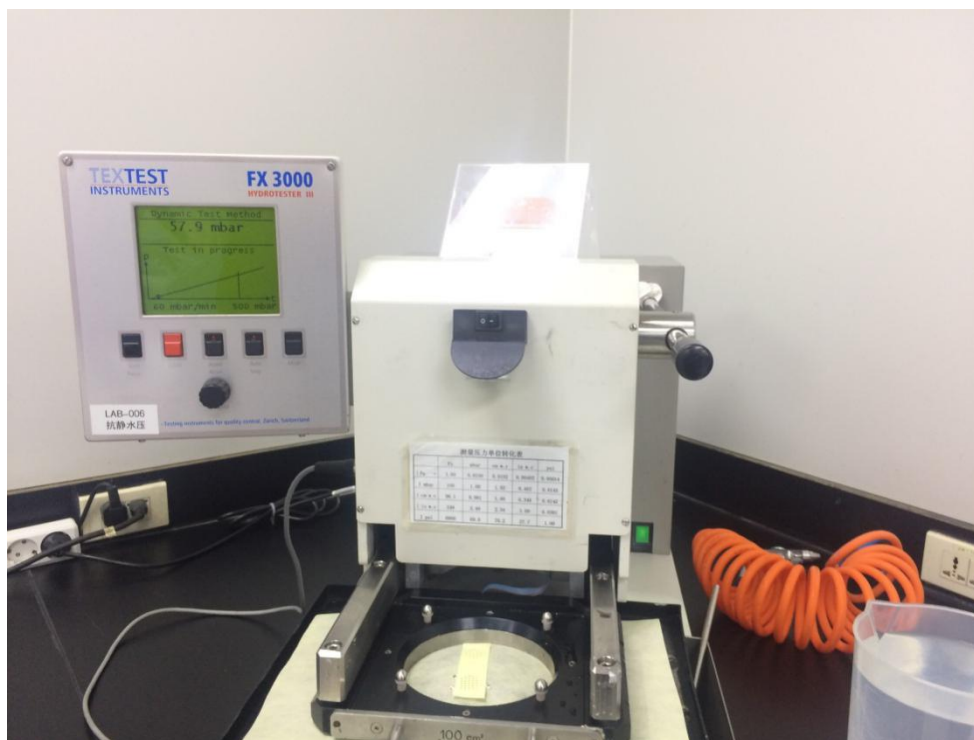
Summary: This test method was performed to evaluate the resistance of a material to the penetration of water under hydrostatic pressure using apparatus option 2; Hydrostatic Head Tester.The hydrostatic pressure test method complies with AATCC Test Method 127,ANSI/AAMIPB70,and ISO 811;sampling was at the discretion of the sponsor. All test method Acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210,211 and820

Test Article Preparation: Cut Front(Chest) of Gown, Back of Gown, Sleeve Seams, Side Seams and Belt Seams (attachment point) at Random.

Test Article Size: 210 x 297 mm(A4)

Test Article Side Tested:Outside

Laboratory Conditions:22.5 ° C and 50% relative humidity (RH)



Results:**Front :Lot HXG10-03**

Test Article Number	Failure Pressure (cm H ₂ O)	Test Article Number	Failure Pressure (cm H ₂ O)
1	65.2	17	65.6
2	72.6	18	86.1
3	83.5	19	76.0
4	82.4	20	72.1
5	70.2	21	75.0
6	71.5	22	72.6
7	78.1	23	79.5
8	71.8	24	68.9
9	81.4	25	80.2
10	69.5	26	76.0
11	67.6	27	71.3
12	77.6	28	71.8
13	70.5	29	76.9
14	69.6	30	73.2
15	80.6	31	74.8
16	70.4	32	67.2

Average Failure Pressure : 74.1cm H₂O**Back :Lot HXG10-03**

Test Article Number	Failure Pressure (cm H ₂ O)	Test Article Number	Failure Pressure (cm H ₂ O)
1	70.0	17	75.6
2	72.3	18	69.8
3	86.0	19	76.7
4	77.2	20	72.4
5	82.4	21	77.1
6	75.5	22	80.7
7	67.8	23	70.5
8	74.0	24	86.0
9	84.0	25	71.0
10	86.1	26	78.8
11	85.0	27	83.3
12	69.8	28	69.0
13	75.1	29	75.3
14	60.6	30	81.7
15	79.0	31	75.6
16	83.4	32	78.2

Average Failure Pressure : 76.6cm H₂O

Sleeve Seams :Lot HXG10-03

Test Article Number	Failure Pressure (cm H ₂ O)	Test Article Number	Failure Pressure (cm H ₂ O)
1	61.2	17	61.0
2	57.6	18	56.6
3	55.4	19	61.6
4	61.6	20	65.9
5	65.6	21	61.0
6	61.9	22	52.0
7	60.7	23	66.6
8	60.6	24	57.1
9	54.0	25	67.8
10	61.6	26	51.7
11	55.1	27	63.6
12	66.4	28	65.5
13	53.8	29	57.3
14	58.0	30	60.2
15	60.2	31	53.6
16	67.2	32	61.7

Average Failure Pressure : 60.1cm H₂O**Side Seams: Lot HXG10-03**

Test Article Number	Failure Pressure (cm H ₂ O)	Test Article Number	Failure Pressure (cm H ₂ O)
1	77.2	17	69.7
2	54.4	18	53.0
3	62.9	19	51.3
4	59.2	20	53.7
5	60.7	21	53.8
6	68.9	22	63.3
7	67.6	23	64.0
8	53.6	24	47.8
9	51.3	25	69.2
10	57.7	26	63.3
11	57.2	27	66.6
12	55.4	28	61.5
13	52.5	29	64.2
14	58.6	30	47.2
15	71.2	31	55.7
16	58.4	32	54.0

Average Failure Pressure : 59.5cm H₂O

Belt Seams: Lot HXG10-03

Test Article Number	Failure Pressure (cm H ₂ O)	Test Article Number	Failure Pressure (cm H ₂ O)
1	56.7	17	51.5
2	51.8	18	50.7
3	49.5	19	53.0
4	49.8	20	52.0
5	51.1	21	52.0
6	50.6	22	51.3
7	51.3	23	52.0
8	41.3	24	50.5
9	55.0	25	52.5
10	54.3	26	53.1
11	50.5	27	54.0
12	51.1	28	54.8
13	52.1	29	51.7
14	52.0	30	53.7
15	51.4	31	53.5
16	50.7	32	51.0

Average Failure Pressure : 51.8cm H₂O

Note: All above physical property data represent typical test result of the received samples.



PGI (CHINA) QUALITY DEPARTMENT

.....Water Resistance: Impact Penetration Final Report.....

Test Article: Surgical Isolation Gown

Sponsor: Jingzhou Haixin Green Cross Medical Products Co.,Ltd

Study Number: Lot.HXG10-03

Study Received Date: Oct.30.2017

Test Procedure(s):Standard Test Protocol (STP) Number:113 Rev 04

Summary: This test method was performed to evaluate the resistance of a material to the penetration of water by impact using the type I Tester apparatus. The impact penetration test method complies with AATCC Test Method 42 and is in accordance with ANSI/AAMI PB70.Sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing particle(GMP) regulations 21 CFR Parts 210,211 and 820.

Test Article Preparation:Cut Front(Chest) of Gown, Back of Gown, Sleeve Seams,Side Seams, and Belt Seams (attachment point) at Random.

Test Article Size:210 x 297mm (A4.)

Test Article Side Tested:Outside

Blotter Paper:Grade 989

Blotter Paper Size:150 x 225mm

Average Flow Rate: 20 sec



Results:**Front :: Lot HXG10-03**

Test Article Number	Amount of Penetration(g)	Test Article Number	Amount of Penetration(g)
1	0.04	17	0.03
2	0.04	18	0.04
3	0.05	19	0.03
4	0.05	20	0.03
5	0.04	21	0.05
6	0.04	22	0.03
7	0.03	23	0.03
8	0.04	24	0.03
9	0.04	25	0.03
10	0.04	26	0.03
11	0.03	27	0.04
12	0.04	28	0.04
13	0.04	29	0.04
14	0.05	30	0.03
15	0.04	31	0.04
16	0.04	32	0.03

Average Amount of Penetration: 0.04g**Back: Lot HXG10-03**

Test Article Number	Amount of Penetration(g)	Test Article Number	Amount of Penetration(g)
1	0.03	17	0.03
2	0.04	18	0.02
3	0.03	19	0.03
4	0.04	20	0.03
5	0.04	21	0.02
6	0.03	22	0.03
7	0.04	23	0.03
8	0.03	24	0.04
9	0.03	25	0.04
10	0.03	26	0.04
11	0.04	27	0.04
12	0.03	28	0.03
13	0.03	29	0.04
14	0.04	30	0.03
15	0.03	31	0.03
16	0.03	32	0.03

Average Amount of Penetration: 0.03g

Sleeve Seams:Lot HXG10-03

Test Article Number	Amount of Penetration(g)	Test Article Number	Amount of Penetration(g)
1	0.04	17	0.04
2	0.04	18	0.05
3	0.04	19	0.03
4	0.03	20	0.04
5	0.03	21	0.04
6	0.05	22	0.05
7	0.04	23	0.04
8	0.02	24	0.04
9	0.03	25	0.05
10	0.04	26	0.05
11	0.05	27	0.05
12	0.03	28	0.04
13	0.04	29	0.04
14	0.05	30	0.05
15	0.03	31	0.02
16	0.04	32	0.02

Average Amount of Penetration: 0.04 g

Side Seams: Lot HXG10-03

Test Article Number	Amount of Penetration(g)	Test Article Number	Amount of Penetration(g)
1	0.02	17	0.03
2	0.04	18	0.02
3	0.04	19	0.04
4	0.04	20	0.04
5	0.03	21	0.04
6	0.04	22	0.05
7	0.04	23	0.03
8	0.03	24	0.03
9	0.05	25	0.03
10	0.05	26	0.03
11	0.03	27	0.04
12	0.04	28	0.03
13	0.03	29	0.03
14	0.03	30	0.04
15	0.02	31	0.02
16	0.05	32	0.04

Average Amount of Penetration: 0.03g

Belt Seams: Lot HXG10-03

Test Article Number	Amount of Penetration(g)	Test Article Number	Amount of Penetration(g)
1	0.02	17	0.03
2	0.03	18	0.02
3	0.03	19	0.03
4	0.02	20	0.02
5	0.03	21	0.04
6	0.02	22	0.01
7	0.03	23	0.02
8	0.02	24	0.01
9	0.03	25	0.03
10	0.03	26	0.03
11	0.03	27	0.03
12	0.03	28	0.01
13	0.03	29	0.02
14	0.01	30	0.01
15	0.03	31	0.03
16	0.02	32	0.03

Average Amount of Penetration: 0.02g

Note: All above physical property data represent typical test result of the received samples.



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