

February 28, 2020

■ TEST REPORT ■

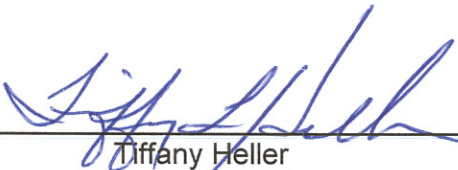
PN 150353C

PHARMACEUTICAL SERVICES


Prepared For:

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SUBJECT: Permeation testing per ASTM F739 on one glove type submitted by the above company.

RECEIVED: One (1) blue glove not identified by customer.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

TEST CHEMICAL	CHEMICAL SOURCE
Acrylamide, 40%	Sigma Aldrich; Lot# SLCD0441; CAS# 79-06-1
Benzalkonium Chloride, 50%	Spectrum; Lot# YP0272; CAS# 8001-54-5
Chlorhexidine Gluconate, 4%	Sigma; Lot# BCBR2911V; CAS# 18472-51-0
Cidex OPA	ASP; Lot# 931800114; Expiration 11-12-2021
Glutaraldehyde, 4%	Sigma Aldrich; Lot# MKBK5759V; CAS# 111-30-8
Hydrochloric Acid, 37%	J.T. Baker; Lot# 0000119228; CAS# 7647-01-0
Hydrogen Peroxide, 30%	Sigma Aldrich; Lot# MKBX1362V; CAS# 7722-84-1
Isopropyl Alcohol, 99%	Pharmco-Aaper; Lot# C1712007; CAS# 67-63-0
Methanol, 99.8%	Sigma Aldrich; Lot# SHBK0449; CAS# 67-56-1
Silver Nitrate, 0.5%	Sigma Aldrich; Lot# MKBS1748V; CAS# 7761-88-8
Sodium Hydroxide, 40%	EMD; Lot# B0484969 016; CAS# 1310-73-2
Sodium Hypochlorite, 10-13%	VWR; Lot# 192229; CAS# 7681-52-9

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Acrylamide, 40%	Distilled Water
Benzalkonium Chloride, 50%	Distilled Water
Chlorhexidine Gluconate, 4%	Distilled Water
Cidex OPA	Distilled Water
Glutaraldehyde, 4%	Distilled Water
Hydrochloric Acid, 37%	Distilled Water
Hydrogen Peroxide, 30%	Distilled Water
Isopropyl Alcohol, 99%	Helium
Methanol, 99.8%	Helium
Silver Nitrate, 0.5%	Distilled Water
Sodium Hydroxide, 40%	Distilled Water
Sodium Hypochlorite, 10-13%	Distilled Water

*ARDL is ISO 17025 accredited by A2LA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.

NOTE: Non-ISO 17025 accredited test methods are designated with the ^ symbol to differentiate from ISO 17025 accredited methods in the body of the test report.*

TESTING CONDITIONS:

Standard Test Method Used:	ASTM F 739
Deviation from Standard Test Method:	Used 2" ASTM Standard Permeation Cell
Analytical Method:	UV/VIS Spectrometry /GC Chromatography /pH Measurement
Testing Temperature:	23.0°C ± 1.0
Collection System:	Closed Loop (UV/VIS; pH)/ Open Loop (Arnel GC)
Specimen Area Exposed:	18.726 cm ²
Selected Data Points:	10 -25/test depending on the sample and/or technique
Number of Specimens Tested:	3/test
Location Sampled From:	Palm area

DETECTION METHOD OF CHEMICAL PERMEATION:**A) UV/VIS ABSORPTION SPECTROMETRY:**

Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop at 11 ml/minute of flow rate through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown in Table 3.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TEST CHEMICAL	WAVELENGTH (nm)
Acrylamide, 40%	197
Benzalkonium Chloride, 50%	192
Chlorhexidine Gluconate, 4%	192
Cidex OPA	206
Glutaraldehyde, 4%	233
Hydrogen Peroxide, 30%	191
Silver Nitrate, 0.5%	199
Sodium Hypochlorite, 10-13%	292

B) GAS CHROMATOGRAPHY (GC):

Instrument: Perkin Elmer Clarus 500 Gas Chromatograph with Autosampler*
 Column: Zebron ZB-5 7HM-G002-11 (30m x 0.32mm I.D. x 0.25mm)
 Detector: FID

GC was run at specific conditions to separate and measure the amount of permeated test chemical throughout the testing period.

* For gas sampling, an ARNEL multi-permeation chamber analyzer was used.

C) POTENTIOMETRY (pH MEASUREMENT):

Instruments: Oakton pH/mV/°C Meter; Cole-Parmer pH/mV/°C Meter

Electrodes: Oakton "2 in 1" pH Glass Electrode

The pH of the collection medium was measured for the acidic and basic test chemicals. Dual point standardization was performed for pH 7 and pH 4 or pH 10. Automatic Temperature Compensator (ATC) automatically compensated temperature change of the system during the test.

SAMPLE CHARACTERISTICS:

Table 4. Palm thickness characteristics for the tested: Blue glove not identified.

Testing Chemicals	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Acrylamide, 40%	0.082	0.078	0.080	0.080
Benzalkonium Chloride, 50%	0.077	0.078	0.080	0.079
Chlorhexidine Gluconate, 4%	0.081	0.079	0.079	0.080
Cidex OPA	0.081	0.077	0.079	0.079
Glutaraldehyde, 4%	0.072	0.080	0.078	0.077
Hydrochloric Acid, 37%	0.077	0.077	0.075	0.077
Hydrogen Peroxide, 30%	0.078	0.079	0.082	0.080
Isopropyl Alcohol, 99%	0.080	0.079	0.079	0.079
Methanol, 99.8%	0.080	0.077	0.081	0.079
Silver Nitrate, 0.5%	0.081	0.079	0.078	0.079
Sodium Hydroxide, 40%	0.080	0.080	0.079	0.080
Sodium Hypochlorite, 10-13%	0.080	0.075	0.082	0.079
Weight/Unit Area (g/m ²)	74.9			

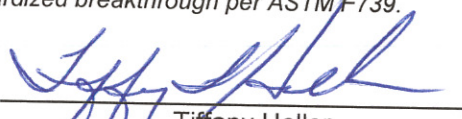
RESULTS:

Table 5. Permeation Test Results on: Blue glove not identified.

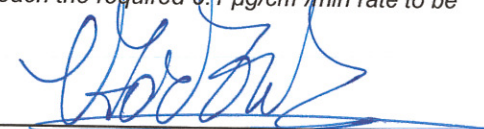
CHEMICAL TESTED	AVERAGE BREAKTHROUGH DETECTION TIME (Sample 1,2,3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH TIME (Sample 1,2,3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Sample 1,2,3) (µg/cm ² /minute)	OTHER OBSERVATIONS
Acrylamide, 40%	280 (260,280,300)	>480*	0.03 (0.03,0.03,0.03)	Slight swelling and no degradation
Benzalkonium Chloride, 50%	>480	>480	N/A	Slight swelling and no degradation
Chlorhexidine Gluconate, 4%	>480	>480	N/A	Slight swelling and no degradation
Cidex OPA	86.7 (100,80,80)	115.6 (122.5,101.8,122.5)	1.6 (1.6,1.7,1.5)	Slight swelling and no degradation
Glutaraldehyde, 4%	>480	>480	N/A	Slight swelling and no degradation
Hydrochloric Acid, 37%	40 (40,40,40)	61.7 (70.0,49.1,66.0)	3.9E+02 (3.0E+02, 2.2E+02, 6.5E+02)	Severe swelling and degradation
Hydrogen Peroxide, 30%	60 (60,60,60)	65.1 (64.2,64.9,66.2)	0.3 (0.4,0.3,0.2)	Slight swelling and no degradation
Isopropyl Alcohol, 99%	46.6 (41,49,49)	57.9 (61.5,54.3,58.0)	3.7 (2.7,4.3,4.2)	Moderate swelling and degradation
Methanol, 99.8%	0 (0,0,0)	0.7 (0.3,0.3,1.5)	29.4 (30.2,31.1,26.9)	Moderate swelling and degradation
Silver Nitrate, 0.5%	>480	>480	N/A	Slight swelling and no degradation
Sodium Hydroxide, 40%	>480	>480	N/A	Slight swelling and no degradation
Sodium Hypochlorite, 10-13%	>480	>480	N/A	No significant changes

* Though the chemical was detected at low levels in the collection media, the rate did not reach the required 0.1 µg/cm²/min rate to be deemed standardized breakthrough per ASTM F739.

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