

September 9, 2021

TEST REPORT

PN 160249 – Rev 1

PHARMACEUTICAL SERVICES

Prepared For:

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SUBJECT: Permeation testing per ASTM F739-20 on sample submitted by the above company.

RECEIVED: One (1) glove type identified by customer as; Nitrile Gloves (Blue), Powder Free. Manufactured By: Better Care Plastic Technology Co., Ltd. / Syntex Healthcare Products Co., Ltd.

TEST CHEMICALS:

Table 1. List of the Tested Chemicals and their Sources, Lot, and CAS#'s or Expiration Dates

TEST CHEMICAL	CHEMICAL SOURCE
Acetic Acid, 99.7%	Sigma Aldrich; Lot# MKCN3763; CAS# 64-19-7
Acrylamide, 40%	Sigma Aldrich; Lot# BCCC3516; CAS# 79-06-1
Ammonium Hydroxide, 28-30%	Sigma Aldrich; Lot# MKCH8892; CAS# 1336-21-6
CaviCide	Metrex; Lot# 20-2301; Expiration 10/01/2022
Chlorhexidine Digluconate, 4%	Spectrum Chemical; Lot# 11H0322; CAS# 18472-51-0
Cidex OPA	ASP; Lot# 931800114; Expiration 11/12/2021
Ethidium Bromide (Saturated)	Sigma Aldrich; Lot# MKCJ7007; CAS# 1239-45-8
Single Enzyme Solution	Medline; Lot# 0022766; Expiration 01/13/2023
Formaldehyde, 37%	Sigma Aldrich; Lot# MKCL5930; CAS# 50-00-0
Formalin Buffered	Sigma Aldrich; Lot# MKCH7023; CAS# 50-00-0
Glutaraldehyde, 50%	Sigma; Lot# MKBK5759V; CAS# 111-30-8
Hydrochloric Acid, 37%	Sigma Aldrich; Lot# MKCK5165; CAS# 7647-01-0
Hydrogen Peroxide, 3%	Sigma Aldrich; Lot# MKCH7315; CAS# 7722-84-1
Isopropanol, 70%	Columbus Chemical Industries (CCI); Lot# 2020050415; CAS# 67-63-0
MetriCide 14 Day	Metrex Research; Lot# 21-1014; Exp. 03/01/2022 14-Day Glutaraldehyde Solution Metrex Research; Lot# 20-3351; Exp. 03/01/2022 Activator 14
n-Hexane, 96%	Sigma Aldrich; Lot# MKCH5843; CAS# 110-54-3
Oxycide Concentrated & Ready to Use	Ecolab; Lot# 12211606; Expiration 09/2021
Povidone Iodine	Amazon Brand – Solimo; Lot# 0489732; Expiration 11/2022
Quaternary Cleaner	3M; Lot# 6836-78-10350; Expiration N/A
Sodium Hydroxide, 50%	Sigma Aldrich; Lot# MKCP2541; Lot# 1310-73-2
Sodium Hypochlorite, 10-13%	EMD Millipore; Lot# 2020021965; CAS# 7681-52-9
Sulfuric Acid, 50%	Sigma Aldrich; Lot# MKCL8138; CAS# 7664-93-9

TESTING CONDITIONS:

Standard Test Method Used: ASTM F739-20
Analytical Method: UV/VIS Spectrometry /GC Chromatography/pH Measurement
Testing Temperature: 27.0°C ± 1.0
Collection System: Closed Loop (UV/VIS & pH); Open Loop (GC Chromatography)
Specimen Area Exposed: 18.726 cm²
Selected Data Points: 10-49/test depending on the sample and/or technique
Number of Specimens Tested: 3/test
Location Sampled From: Palm area

*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.*

COLLECTION MEDIA:

Table 2. Collection Media for Test Chemicals

TEST CHEMICAL	COLLECTION MEDIUM
Acetic Acid, 99.7%	Distilled Water
Acrylamide, 40%	Distilled Water
Ammonium Hydroxide, 28-30%	Distilled Water
CaviCide	Distilled Water
Chlorhexidine Digluconate, 4%	Distilled Water
Cidex OPA	Distilled Water
Ethidium Bromide (Saturated)	Distilled Water
Single Enzyme Solution	Distilled Water
Formaldehyde, 37%	Distilled Water
Formalin Buffered (Tested for Formaldehyde)	Distilled Water
Formalin Buffered (Tested for Methanol)	Helium
Glutaraldehyde, 50%	Distilled Water
Hydrochloric Acid, 37%	Distilled Water
Hydrogen Peroxide, 3%	Distilled Water
Isopropanol, 70%	Helium
MetriCide 14 Day	Distilled Water
n-Hexane, 96%	Helium
Oxycide Concentrated & Ready to Use (RTU)	Distilled Water
Povidone Iodine	Distilled Water
Quaternary Cleaner	Distilled Water
Sodium Hydroxide, 50%	Distilled Water
Sodium Hypochlorite, 10-13%	Distilled Water
Sulfuric Acid, 50%	Distilled Water

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 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
CaviCide	205
Chlorhexidine Digluconate, 4%	192
Cidex OPA	206
Ethidium Bromide (Saturated)	285
Single Enzyme Solution	192
Formaldehyde, 37%	191
Formalin Buffered (Tested for Formaldehyde)	191
Glutaraldehyde, 50%	233
Hydrogen Peroxide, 3%	191
MetriCide 14 Day	206
Oxycide Concentrated & Ready to Use (RTU)	199
Povidone Iodine	194
Quaternary Cleaner	194
Sodium Hypochlorite, 10-13%	292

DETECTION METHOD OF CHEMICAL PERMEATION (cont.)**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: Nitrile Gloves (Blue), Powder Free. Manufactured By: Better Care Plastic Technology Co., Ltd. / Syntex Healthcare Products Co., Ltd.

TEST CHEMICAL	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Acetic Acid, 99.7%	0.069	0.065	0.064	0.066
Acrylamide, 40%	0.070	0.062	0.063	0.065
Ammonium Hydroxide, 28-30%	0.071	0.064	0.063	0.066
CaviCide	0.074	0.070	0.063	0.069
Chlorhexidine Digluconate, 4%	0.061	0.070	0.063	0.065
Cidex OPA	0.064	0.069	0.063	0.065
Ethidium Bromide (Saturated)	0.061	0.063	0.062	0.062
Single Enzyme Solution	0.061	0.064	0.066	0.064
Formaldehyde, 37%	0.060	0.062	0.062	0.061
Formalin Buffered (Formaldehyde)	0.059	0.063	0.065	0.062
Formalin Buffered (Methanol)	0.072	0.069	0.062	0.067
Glutaraldehyde, 50%	0.069	0.070	0.061	0.067
Hydrochloric Acid, 37%	0.061	0.062	0.070	0.065
Hydrogen Peroxide, 3%	0.062	0.061	0.068	0.064
Isopropanol, 70%	0.061	0.062	0.061	0.061
MetriCide 14 Day	0.061	0.063	0.063	0.062
n-Hexane, 96%	0.062	0.067	0.063	0.064
Oxycide Concentrated	0.061	0.065	0.060	0.062
Oxycide Ready to Use (RTU)	0.063	0.064	0.069	0.065
Povidone Iodine	0.062	0.062	0.071	0.065
Quaternary Cleaner	0.065	0.063	0.060	0.063
Sodium Hydroxide, 50%	0.065	0.063	0.061	0.063
Sodium Hypochlorite, 10-13%	0.063	0.072	0.069	0.068
Sulfuric Acid, 50%	0.064	0.073	0.071	0.069
Weight/Unit Area (g/m²)	57.9			

RESULTS:

Table 6. Breakthrough Time and Steady State Permeation Results on: Nitrile Gloves (Blue), Powder Free. Manufactured By: Better Care Plastic Technology Co., Ltd. / Syntex Healthcare Products Co., Ltd.

TEST CHEMICAL	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STANDARDIZED BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$)	AVERAGE CUMULATIVE PERMEATION (Specimen 1/2/3) ($\mu\text{g}/\text{cm}^2$)	OTHER OBSERVATIONS
Acetic Acid, 99.7%	4.7 (4.0,4.0,6.0)	8.0 (6.0,10.0,8.0)	1.2E ⁺⁰³ (1.3E ⁺⁰³ ,1.0E ⁺⁰³ ,1.4E ⁺⁰³)	2.4E ⁺⁰³ (2.8E ⁺⁰³ ,1.8E ⁺⁰³ ,2.5E ⁺⁰³)	Moderate swelling and no degradation
Acrylamide, 40%	66.7 (70,50,80)	85.3 (90.4,72.2,93.2)	3.2 (3.2,3.1,3.4)	0.5 (0.5,0.5,0.4)	Slight swelling and no degradation
Ammonium Hydroxide, 28-30%	26.7 (20,30,30)	50.3 (40.4,52.5,57.9)	3.9E ⁺⁰¹ (2.3E ⁺⁰¹ ,2.6E ⁺⁰¹ ,6.7E ⁺⁰¹)	7.7E ⁺⁰¹ (9.4E ⁺⁰¹ ,8.3E ⁺⁰¹ ,5.5E ⁺⁰¹)	Moderate swelling and no degradation
CaviCide	33.3 (30,40,30)	33.4 (30.1,40.0,30.0)	2.9E ⁺⁰² (1.8E ⁺⁰² ,1.8E ⁺⁰² ,4.5E ⁺⁰²)	0.4 (0.4,0.4,0.3)	Slight swelling and no degradation
Chlorhexidine Digluconate, 4%	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Cidex OPA	50.0 (50,50,50)	50.5 (50.2,50.7,50.6)	2.8E ⁺⁰¹ (5.0E ⁺⁰¹ ,1.5E ⁺⁰¹ ,1.8E ⁺⁰¹)	6.3 (7.9,5.1,5.8)	Slight swelling and no degradation
Ethidium Bromide (Saturated)	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Single Enzyme Solution	176.7 (180,170,180)	217.4 (230.6,200.7,220.8)	1.5E ⁺⁰¹ (1.8E ⁺⁰¹ ,1.4E ⁺⁰¹ ,1.2E ⁺⁰¹)	7.4 (7.4,7.1,7.7)	Slight swelling and no degradation
Formaldehyde, 37%	46.7 (40,50,50)	97.3 (94.9,97.4,99.6)	2.9 (3.8,3.4,2.9)	0.01 (0.01,0.01,0.01)	Slight swelling and no degradation
Formalin Buffered (Formaldehyde)	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Formalin Buffered (Methanol)	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Glutaraldehyde, 50%	210.0 (240,190,200)	336.7 (400.1,280.1,330.1)	1.7E ⁺⁰² (1.8E ⁺⁰² ,1.7E ⁺⁰² ,1.6E ⁺⁰²)	3.5 (3.5,3.5,3.4)	Slight swelling and no degradation
Hydrochloric Acid, 37%	37.3 (44,34,34)	47.4 (54.0,44.2,44.0)	8.1E ⁺⁰² (9.7E ⁺⁰² ,9.4E ⁺⁰² ,5.2E ⁺⁰²)	2.0E ⁺⁰² (1.8E ⁺⁰² ,1.9E ⁺⁰² ,2.3E ⁺⁰²)	Moderate swelling and no degradation
Hydrogen Peroxide, 3%	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Isopropanol, 70%	8.0 (8,8,8)	15.6 (14.5,16.2,16.1)	11.4 (12.6,11.4,10.3)	11.6 (10.4,8.8,15.6)	Slight swelling and no degradation
MetriCide 14 Day	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
n-Hexane, 96%	0 (0,0,0)	6.5 (3.2,8.0,8.2)	4.8E ⁺⁰¹ (5.8E ⁺⁰¹ ,5.4E ⁺⁰¹ ,3.2E ⁺⁰¹)	N/A*	Moderate swelling and no degradation
Oxycide Concentrated	10.0 (10,10,10)	10.1 (10.1,10.1,10.1)	7.5E ⁺⁰¹ (7.2E ⁺⁰¹ ,7.6E ⁺⁰¹ ,7.6E ⁺⁰¹)	N/A*	Slight swelling and no degradation
Oxycide Ready To Use	190.0 (190,190,190)	277.2 (260.5,290.5,280.5)	2.2E ⁺⁰¹ (2.2E ⁺⁰¹ ,2.2E ⁺⁰¹ ,2.2E ⁺⁰¹)	2.4 (1.8,3.4,2.0)	Slight swelling and no degradation
Povidone Iodine	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Quaternary Cleaner	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Sodium Hydroxide, 50%	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Sodium Hypochlorite, 10-13%	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation
Sulfuric Acid, 50%	>480 min.	>480 min.	N/A	N/A	Slight swelling and no degradation

*Due to the strong permeation of the challenging media through the sample, steady state is not available; readings were outside of instruments reading range. **NOTES:** Cumulative permeation taken at Standardized Breakthrough.

SAMPLES RECEIVED:

Nitrile Gloves (Blue), Powder Free.

Manufactured By: Better Care Plastic Technology Co., Ltd. / Syntex Healthcare Products Co., Ltd.



Appendix

Decision Rules

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

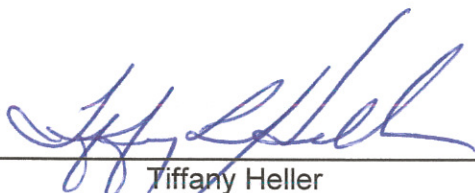
Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands", where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

REPORT REVISIONS:

<u>DATE</u>	<u>REVISION #</u>	<u>DETAILS</u>
09/02/2021	N/A	Original Final Report
09/09/2021	Rev 1	Company Name and Address Change; Sample Identification Changed

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