Brand :	FOCUS I	NDUSTRIES	Contact for Cus	tom Color and Thickness Orders	
Name:	4mi Nitrile Exa	am Glove (Blue)	3 FOCUS PORTIENT EXAMINATION COVES COVES		
Description:	4mil, PF,	TXT, Nitrile	100 1		
Color:	В	BLUE	AMDIDEXTROUS AMDIDEXTROUS HON-STERIE	CE TO A STATE OF THE PARTY OF T	
Packaging	Focus I	Industries	HOH-VALO INGTA	POWDER FREE NITNIE	
Carton Material:	3-layer yellow cardboard		GLOVES GLOVES		
Carton Size(mm) :	365×2	250×260	3 FOCUS GLOVES		
Box Material:	450g duple	ex paperboard			
Box Size(mm) :	450g duplex paperboard 248×121×70		100		
boxes/carton	248×121×70 10				
pcs/box	100				
pcs/carton	1	.000			
Item	Sneci	fications	ΔSTM	D6319/D36978	
Length (mm)	Specifications       240~260       XS     N/A       S     86±4       M     95±4       L     107±4       XL     114±4			220, M/L/XL≥230	
	xs	N/A	XS	70±10	
		-	S	80±10	
Palm Width(mm)	М	95±4	М	95±10	
	L	107±4	L	110±10	
	XL	114±4	XL	120±10	
	XXL	N/A	XXL	N/A	
	XXXL	N/A	XXXL	N/A	
Single Thickness (mm) Single Thickness (mil)	Finger	0.12±0.025 mm 4.7±1mil	Finger	≥0.05	
	Palm	0.10±0.02mm 4±0.8mil	Palm	<b>≽0.05</b>	
	Cuff	0.06±0.02 mm 2.5±0.8mil	Cuff	N/A	
	XS	N/A	XS	N/A	
	S	4.0±0.4	S	N/A	
	М	4.5±0.4	М	N/A	
Weight (g)	L	5.0±0.4	L	N/A	
	XL	5.5±0.4	XL	N/A	
	XXL	N/A	XXL	N/A	
	XXXL	N/A	XXXL	N/A	
Tensile Strength (MPa)	<b>Before Aging</b>	≥14	Before Aging	≥14	
Tensile Strength (MPa)	After Aging	≥14	After Aging	≥14	
Elasticity/Elongation(%)	<b>Before Aging</b>	≥500	Before Aging	≥500	
	After Aging	≥400	After Aging	≥400	
Powder Content (mg/pcs)	_ ≤	≤2.0		≤2.0	
Content(µg/dm²)		N/A		N/A	
Notes & Inspection Level			Formulation list:		
1. Functional test(leak tes	t)AQL1.5, sam	ple per ISO2859		ZnO	
2. Visual defects, AQL is "A				Blue Pigment	
3. Dimensional inspection		-		<u> </u>	
•	•				
<ul><li>4. Physical Property Testing sample 13 pcs per size, AQL</li><li>5. Packing per customer's request</li></ul>		TiO2			





March 28, 2010

# TEST REPORT -

PN 87901

# CHEMICAL ANALYTICAL SERVICES

Prepared For:

Mr. Albert Li Shen Wei (USA) Inocrporated 2845 Whipple Road Union City, CA 94587

Prepared By: \

ACCREDITED

Tiffany L. Heller

Chemical Technician, Chemical Services

Approved By:

Ana C. Barbur, M.S. Manager, Chemical Services

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# Testing. Development. Problem Solving.

March 28, 2010

Mr. Albert Li Shen Wei (USA) Incorporated

Page 1 of 3 - PN 87901

**SUBJECT:** Permeation testing per ASTM D 6978-05 on sample submitted by the above company.

RECEIVED: Glove sample identified as Pearlescent Nitrile Exam Gloves (Blue), Code: SH/091021151.

### TESTING CHEMOTHERAPY DRUGS

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	CHEMICAL SOURCE		
Fluorouracil	APP; Lot# 204836; Expiration 01/2011		
Etoposide (Toposar)	Teva; Lot# 31303976B; Expiration 9/2011		
Cyclophosphamide (Cytoxan)	Sigma, Lot#079K1569; Expiration 01/2012		
Carmustine (BCNU)	Ben Venue; Lot# 9C4211A; Expiration 3/2012		
Thiotepa	USP; Lot# I; Expiration 12/2011		
Paclitaxel (Taxol)	Parenta; Lot# 92198504; Exp. 01/2012		
Doxorubicin Hydrochloride	Teva; Lot#31308631B; Expiration 08/2011		
Dacarbazine (DTIC)	Hospira; Lot# 31301352B; Expiration 03/2011		
Cisplatin Teva; Lot# 09H28MA; Expiration 02/			

# **COLLECTION MEDIA**

The collection media which were selected are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST CHEMICAL AND CONCENTRATION	COLLECTION MEDIUM
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water

Mr. Albert Li

Shen Wei (USA) Incorporated

Page 2 of 3 - PN 87901

#### TESTING CONDITIONS

Standard Test Method Used:

Deviation From Standard Test Method:

Analytical Method:

Testing Temperature: Collection System:

Specimen Area Exposed:

Selected Data Points:

Number of Specimens Tested:

Location Sampled From:

Comments/Other Conditions:

ASTM D 6978-05

Used 1" Permeation Cell

**UV/VIS Spectrometry** 

 $35.0^{\circ}\text{C} \pm 2.0$ 

Closed Loop

5.067 cm2

25/test

3/test Cuff area

Magnetic stir bar was used in the sampling chamber

### DETECTION METHOD OF CHEMICAL PERMEATION; 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 below.

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

TESTING CHEMOTHERAPY DRUGS	WAVELENGTH (nm)		
Fluorouracil	269		
Etoposide (Toposar)	205		
Cyclophosphamide (Cytoxan)	200		
Carmustine (BCNU)	229		
Thiotepa	199		
Paclitaxel (Taxol)	231		
Doxorubicin Hydrochloride	232		
Dacarbazine (DTIC)	320		
Cisplatin	199		

## SAMPLE CHARACTERISTICS

Table 4. Thickness characteristics for the tested specimens on: Glove sample identified as Pearlescent Nitrile Exam Gloves (Blue), Code: SH/091021151.

Testing	Thickness (mm)			Average	Weight/Unit Area	
Chemotherapy Drugs	#1	#2	#3	(mm)	(g/m2)	
Fluorouracil	0.104	0.106	0.094	0.101	86.5	
Etoposide (Toposar)	0.093	0.102	0.103	0.099	86.5	
Cyclophosphamide (Cytoxan)	0.100	0.095	0.094	0.096	86.5	
Carmustine (BCNU)	0.101	0.102	0.098	0.100	86.5	
Thiotepa	0.096	0.102	0.101	0.100	86.5	
Paclitaxel (Taxol)	0.104	0.106	0.103	0.104	86.5	
Doxorubicin Hydrochloride	0.094	0.098	0.100	0.097	86.5	
Dacarbazine (DTIC)	0.102	0.104	0.094	0.100	86.5	
Cisplatin	0.096	0.095	0.106	0.099	86.5	

Mr. Albert Li Shen Wei (USA) Incorporated

Page 3 of 3 - PN 87901

## RESULTS

<u>Table 5. Permeation Test Results on: Glove sample identified as Pearlescent Nitrile Exam Gloves (Blue), Code: SH/091021151.</u>

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Fluorouracil, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	2.10 (1.90,2.83,1.56)	0.839 (0.843,1.01,0.665)	Moderate swelling and no degradation
Thiotepa, 10.0 mg/ml (10,000 ppm)	27.17 (39.97,11.19,30.35)	1.29 (2.09,0.94,0.85)	Slight swelling and no degradation
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	No breakthrough up to 240 min.	N/A	Moderate swelling and no degradation
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

Tiffany L. Heller

Chemical Technician, Chemical and Pharmaceutical Services

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Ana C. Barbur, M.S,

Manager, Chemical and Pharmaceutical Services