TÜVRheinland®

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

Scope: Design and Development, Manufacture and Distribution of Patient Examination Gloves

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜVRheinland®

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Quality Management System
EN ISO 13485:2016

Registration No.:

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Zhonghong Pulin Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Distribution of Patient Examination Gloves
/02	c/o Minghao Medical Products Co., Ltd. West Industrial Park, Luannan County, Tangshan City, 063500 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.:
Effective date: 2021-04-15
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Quality Management System
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Registration No.:

Organization: Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

The scope of certification also covers the following:

/03	c/o The First Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. Pachigang Industrial Park, Luannan County, Tangshan City, 063502 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves
/04	c/o The Fifth Tangshan Branch Company of Zhonghong Pulin Medical Products Co., Ltd. South Peituozi Village, Sigezhuang Town, Luannan County, Tangshan City, 063503 Hebei, P.R. China	Design and Development, Manufacture of Patient Examination Gloves

Report No.:
Effective date: 2021-04-15
Expiry date: 2024-04-14
Issue date: 2021-04-13

TÜV Rheinland LGA Products GmbH

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Business Stream Products
Certification Department

TÜVRheinland®
LGA
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TÜV Rheinland LGA Products GmbH • 51105 Köln

Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park, Luannan County, Tangshan City,
063500 Hebei, P.R. China

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date April 13, 2021

Application for:
Certificate No. : [redacted]
Requirement : EN ISO 13485:2016

Dear Madam or Sir,

Enclosed please find the new certificate I ZHONGHONG PULIN I replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,

Jing Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

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VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller

November 15, 2017

Zhonghong Pulin Medical Products Co., Ltd.
℅ Da Shi
Manager
Zhonghong Pulin Medical Products Co.,Ltd.
800 - 10 Four Seasons Place
Toronto, M9B 6H7 Ca

Re: ZHONGHONG PULIN

Trade/Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non Sterile, Tested for Use with Chemotherapy Drugs
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: Class I
Product Code: LZA, LZC
Dated: October 13, 2017
Received: October 13, 2017

Dear Da Shi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

ZHONGHONG PULIN

510(k) Number *(if known)*

Device Name
Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

Indications for Use *(Describe)*
A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 3.3 mg/ml	14.7
Cisplatin 1.0 mg/ml	>240
Cyclophosphamide (Cytoxan) 20 mg/ml	>240
Cytarabine 100 mg/ml	>240
Dacarbazine (DTIC) 10.0 mg/ml	>240
Doxorubicin Hydrochloride 2.0 mg/ml	>240
Etoposide (Toposar) 20.0 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Thiotepa 10.0 mg/ml	58.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note the following drugs have extremely low permeation times: Carmustine (BCNU) (3.3mg/ml) 14.7 minutes and Thiotepa (10 mg/ml) 58.8 minutes.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

Preparation Date: Nov. 8th, 2017

Submitter:

Company Name:	Zhonghong Pulin Medical Products Co., Ltd.
Address:	Pachigang Industrial Park, Luannan County Tangshan, Hebei, 063502
Country:	China
Phone No.:	+86 315-4165760
Fax No.:	+86 315- 4167664
E-mail Address:	RA@zhonghongpulin.com

Contact Person:

Contact Person :	Li, Jinge (Regulatory Affairs Manager)
Contact Email:	ljg@zhonghongpulin.cn

Name of the Device:

Device trade or proprietary name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs
Device common or usual name: Patient Examination Glove
Device Classification Name: LZA - Polymer Patient Examination Glove
Device Classification Name: LZC - Patient Examination Glove, Specialty
Regulation Number: 21 CFR 88.6250
FDA Device Class: Class 1
Product Code: LZA, LZC

Predicate Device:

Class I patient Examination glove and tested for use with Chemotherapy Drugs, Powder Free, LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.

Device Name: Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs
Copmany Name: Kossan International Sdn. Bhd.
510(K) Number:

Device Description:

The subject device in this 510(k) Notification is a Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile, Tested for Use with Chemotherapy Drugs

The subject device is a patient examination glove made from nitrile compound, blue in color, powder free and non-sterile (as per 21 CFR 880.6250, class I).

The principle operation of the medical device to provide single use barrier protection for the wearer and the device meets all the requirement specifications for Barrier Protection, tensile properties as defined in ASTM D6319-10, Standard specification for Nitrile Examination Gloves.

Intended use of the Device (Indication for use)

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.
These gloves were tested for use with chemotherapy drugs per ASTM D6978-05 (Reapproved 2013) Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs.

Drug and Concentration	Minimum Breakthrough Detection Time in Minutes
Carmustine (BCNU) 3.3 mg/ml	14.7
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Etoposide (Toposar) 20.0 mg/ml	>240
Fluorouracil 50.0 mg/ml	>240
Ifosfamide 50.0 mg/ml	>240
Methotrexate 25 mg/ml	>240
Mitomycin C 0.5 mg/ml	>240
Mitoxantrone 2.0 mg/ml	>240
Paclitaxel (Taxol) 6.0 mg/ml	>240
Thiotepa 10.0 mg/ml	58.8
Vincristine Sulfate 1.0 mg/ml	>240

Please note that the following drugs have extremely low permeation times: Carmustine (BCNU) 14.7 minutes and Thiotepa 58.8 minutes.

Summary of the Technological Characteristics of the Device:

The subject device is summarized with the following technological characteristics compared to ASTM or equivalent standard.

Characteristics	Standard	Device performance
Dimension	ASTM standard D 6319-10	Meets
Physical Properties	ASTM standard D 6319-10	Meets
Freedom from pinholes	21 CFR 800.20 ASTM D5151-11	Meets
Powder Residual	ASTM D6319-10 and D6124-06(Reapproved 2011)	Meets
Biocompatibility	Primary Skin Irritation ISO 10993-10:2010	Not a primary skin irritant under the conditions of the study
	Dermal sensitization in the guinea pig ISO 10993-10:2010	Not a contact sensitizer under the conditions of the study

Substantial Equivalence Based on Assessment of Non-Clinical Performance Data

Bench tests were conducted to verify that the proposed device met all specifications and the proposed device is Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

ASTM D6319-10 Standard Specification for Nitrile Examination Gloves for Medical application.
ASTM D5151-06 (2011), Standard Test Method for Detection of Holes in Medical Gloves.
ASTM D6124-06 (2011), Standard Test Method for Residual Powder on Medical Gloves.
ASTM D6978-05 Standard Practice for Assessment of Medical Gloves to Permeation by Chemotherapy Drugs

The subject device meets the same test standards conducted by the predicate device. Both device has the same sizes, color, physical and dimensional characteristics.

The minimum breakthrough detection time of Carmustine for the subject device is below 30 minutes, similar with predicate .

The minimum breakthrough detection time of Thiotepa for the subject device is at 58.8 minutes. The subject device is having longer permeation time than predicate .

Warning statement (Do Not Use with Carmustine and Thiotepa) for subject device is included in Labeling, similar with predicate device.

The subject device has similar thickness with predicate at palm, and similar length with predicate .

The subject device is having identical specification with predicate ZHONGHONG PULIN with thickness at minimum 0.05mm and length at minimum 230mm.

The difference in labeling with additional drugs tested do not affect the safety and effectiveness of the subject device.

The subject device and the predicate device ZHONGHONG PULIN share the same intended use, same Nitrile material, same compliance with ASTM standards. There is no difference between the subject device and the predicate device ZHONGHONG PULIN with respect to intended use, non-clinical performance data and technological characteristics.

Consequently, the gloves that are the subject of this submission are substantially equivalent to a legally marketed glove ZHONGHONG PULIN

Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for this submission.

Biocompatibility

Biocompatibility tests indicated that under the conditions of the studies, the gloves were non-sensitizing and non-irritating.

Legally Marketed Device to which Substantial Equivalence is Claimed

The legally marketed predicate device in scope is as follows:

ZHONGHONG PULIN Powder Free Nitrile Patient Examination Glove, White Colored, Non-Sterile, Powder Free Nitrile Patient Examination Glove, Blue Colored, Non-Sterile

(2012)国认监认字(507)号

CNAS 检 测 L0518

20120003341Z

Test Report

Name of product: Nitrile Powder Free Patient Examination Gloves, Blue Color

Manufacturer: Zhonghong Pulin Medical Products Co.,Ltd.

Sample Provider: Zhonghong Pulin Medical Products Co.,Ltd.

Test type: Entrusted Test

National Quality Supervisor & Inspection Center of Latex Products

Points for attention

1. The report is invalid without "special seal for test report" or official seal of the test unit.
2. The copied report is invalid if the "special seal for test report" or the official seal of the test unit isn't affixed again.
3. The report is invalid without signature of the tester， auditor and approver.
4. The report is invalid if altered.
5. If there are some objections against the test report, please raise them to the test unit within 15 days of receiving the report. otherwise they won't be accepted.
6. Entrusted test is only in charge of the delivered samples.
7. The test result can't be as the basis of products' marketing.

Address: No.818, East Xinhua Road,Hetang District, Zhuzhou,Hunan,China.

Postcode: 412003

Tel: 86-731-22495120 Fax: 86-731-22495101

E-mail: Latex101@sina . com Zb9211@21cn . com

National Quality Supervisor & Inspection Center of Latex Products

Test Report

Product name	Nitrile Powder Free Patient Examination Gloves, Blue Color	Size	S、M、L、XL (Powder-free)
Manufacturer and address	Zhonghong Pulin Medical Products Co.,Ltd. Pachigang Industrial Park, Luannan County,Tangshan City,063502 Hebei ,China		
Entruster and address	Zhonghong Pulin Medical Products Co.,Ltd. Pachigang Industrial Park, Luannan County,Tangshan City,063502 Hebei,China		
Sender	Wang Hailan	Arrival date of sample	May.08,2015
Sample state	Normal	Manufacture lot	ZH150402
Sampling radix	(35001-150000) pcs	Sample quantities	320 pcs
Total sample	320 pcs	Basis of test	ASTM D6319-10
Test period	May.11-15,2015	Temperature of environment	（21-25）℃
Test type	Entrusted Test	Test writer	Tang Mimi

Conclusion:

The properties tested are accorded with the requirements of ASTM D6319-10,the product is up to the standard.

Signature date: May 28, 2015

Remark: /

Approver: 刘三伟 Auditor: 李秋静 Tester: 唐静

Title: 副主任

National Quality Supervision & Testing Center

of Latex Products

Test Results

1.Dimension checked on 13pcs sub-samples(S-2):

All within tolerance.

Size	S												
Width(mm)	84	85	86	84	84	86	84	84	85	85	84	84	86
Length(mm)	239	241	236	247	241	237	240	237	238	239	240	241	239
Thickness Finger tip(mm)	0.10	0.10	0.11	0.11	0.10	0.10	0.10	0.09	0.10	0.10	0.10	0.10	0.09
Thickness Palm(mm)	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.06	0.07

Size	M												
Width(mm)	95	95	95	95	95	95	94	93	95	95	95	93	94
Length(mm)	246	241	240	240	238	242	241	235	238	240	238	240	242
Thickness Finger tip(mm)	0.11	0.10	0.11	0.10	0.09	0.10	0.10	0.11	0.11	0.11	0.10	0.10	0.10
Thickness Palm(mm)	0.07	0.07	0.07	0.06	0.07	0.07	0.07	0.07	0.07	0.06	0.06	0.07	0.07

Size	L												
Width(mm)	104	105	106	105	107	105	106	106	106	105	107	104	105
Length(mm)	238	243	245	241	245	246	252	245	240	242	238	239	245
Thickness Finger tip(mm)	0.10	0.10	0.10	0.12	0.10	0.09	0.09	0.10	0.10	0.11	0.10	0.09	0.10
Thickness Palm(mm)	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.06	0.07	0.07	0.07	0.08

Size	XL												
Width(mm)	116	114	117	116	114	115	115	114	116	117	116	114	115
Length(mm)	255	254	255	251	256	249	249	253	247	246	245	252	255
Thickness Finger tip(mm)	0.12	0.11	0.12	0.10	0.11	0.08	0.09	0.12	0.11	0.11	0.10	0.10	0.10
Thickness Palm(mm)	0.06	0.07	0.07	0.06	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07	0.07

Spec. Width: S:(80 ±10)mm M:(95±10)mm L:(110±10)mm XL:(120±10)mm

Length:S≥220mm M,L,XL≥230mm

Thickness: Palm:≥0.05mm Finger tip:≥0.05mm

AQL:4.0 Ac/Re:1/2Found defects:0pc

Result:Within AQL.

2.Water leakage checked on 200pcs sub-samples(Ⅰ) (ASTM D 5151-06 1000ML WATER LEAK TEST):

Result as following:

No.	Location of Water leakage (Distance from cuff),(mm)
No leakage	

AQL:2.5 Ac/Re:10/11

Found defects:0pc

Result:Within AQL

3.Physical requirements checked on 13pcs sub-samples(S-2),(tension test before aging & after accelerated aging).

Results as following:

-Before aging

No.	Ultimate elongation(%)	Tensile strength(MPa)
01	570	30
02	580	30
03	560	30
04	570	32
05	580	33
06	570	30
07	570	31
08	560	32
09	570	34
10	550	30
11	570	32
12	560	33
13	560	31

-After aging

No.	Ultimate elongation(%)	Tensile strength(MPa)
01	580	21
02	560	26
03	570	23
04	560	22
05	530	19
06	570	21
07	550	17
08	540	17
09	580	22
10	560	19
11	570	20
12	570	21
13	560	21

Spec. Before aging: ≥14MPaMin.(Tensile strength) ≥500%Min.(elongated rate)

After aging: ≥14MPaMin.(Tensile strength) ≥400%Min.(elongated rate)

AQL:4.0 Ac/Re:1/2

Found defects:0pc

Within AQL

4.Powder Residue checked on 5pcs sub-samples(N=5).Result as following:

Spec. Powder residual: ≤2.0mg/pc

AQL:N/A

Mean:1.1mg/pc

Result: accorded with the requirements of ASTM D 6319-10

Checker: 潘超俊

Tester: 钱静

March 9, 2017

· TEST REPORT ·

ZHONGHONG PULIN

CHEMICAL ANALYTICAL SERVICES

Da Shi
Zhonghong Pulin Medical Products Co., Ltd.
West Industrial Park,
Luannan County,
Tangshan, Hebei, 063500
China

Prepared By: _____
Tiffany L. Heller
Assistant Manager, Pharmaceutical Services

Approved By: _____
Ana C. Barbur, M.S.
Manager, Chemical, Microbiological, & Pharmaceutical Services

ACCREDITED
A Testing Lab
*Certificate Numbers 255.01 & 255.02

An A2LA ISO 17025 Accredited Testing Laboratory — Certificate Numbers 255.01 & 255.02
ISO 9001:2008 Registered

ISO 9001:2008
Registered

March 9, 2017

Da Shi
Zhonghong Pulin Medical Products Co., Ltd.

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

RECEIVED: Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212.

TESTING CHEMOTHERAPY DRUGS:

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

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Lot# 016M4028V; Expires 09/2017
Cisplatin, 1.0 mg/ml (1,000 ppm)	Fresenius Kabi; Lot# 6114286; 01/2018
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Sigma Aldrich; Lot# BCBM8984V; Expiration 04/2017
Cytarabine, 100 mg/ml (100,000 ppm)	Sigma Aldrich; Lot# LRAA8717; Expiration 01/2018
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31318323B; Expiration 10/8/2017
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Sigma Aldrich; Lot# SLBM7382V; Expiration 08/2017
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31321666B; Expiration 09/2019
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# PT04300; Expiration 10/2018
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Sigma Aldrich; Lot# 106K1063V; Expiation 12/2017
Methotrexate, 25 mg/ml, (25,000 ppm)	Teva; Lot# 16A28MA, Expiration 01/2018
Mitomycin C, 0.5 mg/ml (500 ppm)	Sigma; Lot# MKBR2210V; Expiration 03/2017
Mitoxantrone, 2.0mg/ml (2,000ppm)	Sigma Aldrich; Lot# MKBR2210V; Expiration 11/2017
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	Hospira; Lot# C126865AA; Expiration 12/2017
Thiotepa, 10.0 mg/ml (10,000 ppm)	Sigma Aldrich; Lot# SLBQ8871V; Expiration 02/2018
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Sigma Aldrich; Lot# SLBQ9329V; Expiration 01/2018

COLLECTION MEDIA:

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

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	Distilled Water
Cytarabine, 100 mg/ml (100,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Ifosfamide, 50.0 mg/ml (50,000 ppm)	Distilled Water
Methotrexate, 25 mg/ml, (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Mitoxantrone, 2.0mg/ml (2,000ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D 6978-05
Deviation From Standard Test Method:	Used 1" Permeation Cell
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff area

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)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000ppm)	200
Cytarabine, 100 mg/ml (100,000 ppm)	272
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	320
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	232
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Ifosfamide, 50.0 mg/ml (50,000 ppm)	200
Methotrexate, 25 mg/ml, (25,000 ppm)	303
Mitomycin C, 0.5 mg/ml (500 ppm)	217
Mitoxantrone, 2.0mg/ml (2,000ppm)	242
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	231
Thiotepa, 10.0 mg/ml (10,000 ppm)	199
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	220

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested specimens Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212

Testing Chemotherapy Drugs	Thickness (mm)			Average (mm)	Weight/Unit Area (g/m2)
	Sample 1	Sample 2	Sample 3		
Carmustine (BCNU)	0.046	0.049	0.047	0.047	52.3
Cisplatin	0.045	0.050	0.046	0.047	
Cyclophosphamide (Cytoxan)	0.047	0.043	0.048	0.046	
Cytarabine	0.047	0.044	0.048	0.046	
Dacarbazine (DTIC)	0.048	0.049	0.045	0.047	
Doxorubicin Hydrochloride	0.050	0.052	0.046	0.049	
Etoposide (Toposar)	0.048	0.052	0.046	0.049	
Fluorouracil	0.048	0.047	0.045	0.047	
Ifosfamide	0.044	0.049	0.048	0.047	
Methotrexate	0.045	0.047	0.054	0.049	
Mitomycin C	0.047	0.050	0.044	0.047	
Mitoxantrone	0.046	0.047	0.053	0.049	
Paclitaxel (Taxol)	0.048	0.042	0.044	0.045	
Thiotepa	0.047	0.049	0.043	0.047	
Vincristine Sulfate	0.045	0.044	0.048	0.046	

RESULTS:

Table 5. Permeation Test Results on: Glove sample identified as Nitrile Powder Free Glove, Blue, Lot# ZP161212.

TEST CHEMOTHERAPY DRUG AND CONCENTRATION	MINIMUM BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU) 3.3 mg/ml (3,300 ppm)	14.7 (15.1,14.7,16.8)	0.6 (0.5,0.5,0.7)	Moderate 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
Cyclophosphamide (Cytoxan) 20 mg/ml (20,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Cytarabine, 100 mg/ml (100,000 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
Doxorubicin Hydrochloride 2.0 mg/ml (2,000 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	Slight swelling and no degradation
Fluorouracil 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Ifosfamide, 50.0 mg/ml (50,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Methotrexate 25 mg/ml (25,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitomycin C 0.5 mg/ml (500 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation
Mitoxantrone, 2.0mg/ml (2,000ppm)	No breakthrough up to 240 min.	N/A	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
Thiotepa 10.0 mg/ml (10,000 ppm)	58.8 (110.0,58.8,67.0	0.5 (0.3,0.5,0.6)	Slight swelling and no degradation
Vincristine Sulfate 1.0 mg/ml (1,000 ppm)	No breakthrough up to 240 min.	N/A	Slight swelling and no degradation

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