

Basic Medical Synmax Exam Gloves

CAHP#: PC-VG1

Basic/Intco SKU: BMPF

Product Description for:

Basic Medical Synmax Exam Gloves

CAHP#: PC-VG1 Basic/Intco SKU: BMPF



Features

- 3.54 mil thickness at finger (2.76 mil at palm)
- Latex free, powder free, protein free
- Synthetic blend includes nitrile for superior performance and feel
- Smooth finish for greater tactile feedback
- Meets/Exceeds ASTM D6978 Permeation Testing for Chemotherapy Gloves
- Sizes: XS, S, M, L, and XL
- Color: Blue
- FDA 510(k)

Synmax Vinyl Hybrid Medical Exam Gloves

Blue | Medical Grade | Powder Free | FDA 510(k) | Latex Free

Synmax Examination Gloves

Revolutionary new formula of vinyl-based hybrid material, containing nitrile, uses properties with elastic and strong “bones” of gloves. They offer enhanced tactile sensitivity and a practical barrier of protection for a wide range of applications. They are also a good alternative for those suffering from Type I allergies.



Features

- Brand new product
- DOP,DEHP-free
- No latex proteins, low allergy potential
- Comfortable conforming latex-like fit
- Effective barrier and extra strength
- Enhanced tactile sensitivity
- Economical protection
- Resistance to acid, alkali and oil
- 100 gloves per box

Quality Standards

- Complies with EN 455 and EN 374
- Complies with ASTM D5250 (USA Related Product)
- Meets ASTM 6978 Chemotherapy Permeation Testing Standards
- Tensile Strength: 18MPa
- Palm Thickness: 0.08 mm minimum
- Finger thickness: 0.09 mm minimum (3.54 mil)
- Weight: 5.0 gm (size medium)
- Length: 230 mm minimum



Technical Information

| | |
|---|---|
| Type | Powder-free, unsterile |
| Material | Compound of Vinyl-based Hybrid |
| Colour | Blue, White, Purple, Pink |
| Model | Ambidextrous, with rolled rim |
| Storage | Protect from heat, humidity, strong light and ozone |
| Size/overall length as per EN 455-2 | XS, S, M, L and XL 240 mm (≥230mm for USA) |
| Impermeability as per EN 455-1 | AQL 1.5 |
| Durability, in original package if stored as per din 7716, ISO 2230 | Min. 5 years |



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| | |
|-------------------------------------|---|
| Device Classification Name | Vinyl Patient Examination Glove |
| 510(K) Number | K153028 |
| Device Name | Synmax Synthetic Patient Examination Vinyl Gloves, Powder Free, Blue |
| Applicant | ZIBO HUIYING MEDICAL PRODUCTS, CO. LTD. NO. 3 DA WU ROAD Linzi, CN 255400 |
| Applicant Contact | Fufang Wang |
| Correspondent | BASIC MEDICAL INDUSTRIES, INC. 12390 East End Ave Chino, CA 91710 |
| Correspondent Contact | Sophie Hao |
| Regulation Number | 880.6250 |
| Classification Product Code | LYZ |
| Date Received | 10/16/2015 |
| Decision Date | 02/05/2016 |
| Decision | Substantially Equivalent (SESE) |
| Regulation Medical Specialty | General Hospital |
| 510k Review Panel | General Hospital |
| Summary | Summary |
| Type | Traditional |
| Reviewed By Third Party | No |
| Combination Product | No |

Basic Medical Synmax Exam Gloves



Testing. Development. Problem Solving.

January 5, 2021

▪TEST REPORT▪


PN 156551

PHARMACEUTICAL SERVICES

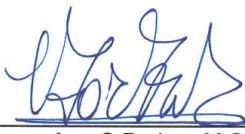
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Approved By:


Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

Rev 101218



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Intco Medical Industries Inc.

Page 2 of 5
PN 156551

SUBJECT: Permeation testing per ASTM D6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Synmax Vinyl Exam Glove.

TEST CHEMICALS:

Table 1. List of the Testing Drugs and their Sources

| TESTING CHEMOTHERAPY DRUGS | DRUG SOURCE |
|---|--|
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | Sigma Aldrich; Batch# 0000095754; Expiration 10/2021 |
| Cisplatin, 1.0 mg/ml (1,000 ppm) | Accord; Lot# P2001296; Expiration 01/2022 |
| Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm) | Accord; Lot# 19112225; Expiration 10/2021 |
| Dacarbazine, 10.0 mg/ml (10,000 ppm) | Teva; Lot# 31325414B; Expiration 09/2021 |
| Doxorubicin HCl, 2.0 mg/ml (2,000 ppm) | WestWard; Lot# BJ0051; Expiration 06/2021 |
| Etoposide, 20.0 mg/ml (20,000 ppm) | Teva; Lot# 31325485B; Expiration 07/2021 |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | Accord; Lot# P2001167; Expiration 01/2022 |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | Teva; Lot# 19K24KA; Expiration 11/2021 |
| ThioTepa, 10.0 mg/ml (10,000 ppm) | USP; Lot # R11380; Expiration 09/2021 |

COLLECTION MEDIA:

Table 2. Collection Media for Test Drug

| 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 (Cytosan), 20.0 mg/ml (20,000 ppm) | Distilled Water |
| Dacarbazine, 10.0 mg/ml (10,000 ppm) | Distilled Water |
| Doxorubicin HCl, 2.0 mg/ml (2,000 ppm) | Distilled Water |
| Etoposide, 20.0 mg/ml (20,000 ppm) | Distilled Water |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | 9.20 pH Sodium Hydroxide Solution |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | 30% Methanol Aqueous Solution |
| ThioTepa, 10.0 mg/ml (10,000 ppm) | Distilled Water |

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January 5, 2021

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Page 3 of 5
PN 156551

TESTING CONDITIONS:

| | |
|-----------------------------|-----------------------|
| Standard Test Method Used: | ASTM D6978 |
| Analytical Method: | UV/VIS Spectrometry |
| Testing Temperature: | 35.0°C ± 2.0 |
| Collection System: | Closed Loop |
| Specimen Area Exposed: | 5.067 cm ² |
| Selected Data Points: | 25/test |
| Number of Specimens Tested: | 3/test |
| Location Sampled From: | Cuff |

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 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 DRUG | 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 (20,000 ppm) | 200 |
| Dacarbazine, 10.0 mg/ml (10,000 ppm) | 320 |
| Doxorubicin HCl, 2.0 mg/ml (2,000 ppm) | 232 |
| Etoposide, 20.0 mg/ml (20,000 ppm) | 205 |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | 269 |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | 232 |
| ThioTepa, 10.0 mg/ml (10,000 ppm) | 199 |

SAMPLE CHARACTERISTICS:

Table 4. Thickness characteristics for the tested: One (1) glove type identified as: Synmax Vinyl Exam Glove.

| Testing Drug | Thickness (mm) | | | Average (mm) |
|--------------------------------------|----------------|----------|----------|--------------|
| | Sample 1 | Sample 2 | Sample 3 | |
| Carmustine (BCNU) | 0.056 | 0.050 | 0.050 | 0.052 |
| Cisplatin | 0.055 | 0.057 | 0.054 | 0.056 |
| Cyclophosphamide (Cytoxan) | 0.056 | 0.057 | 0.054 | 0.056 |
| Dacarbazine | 0.051 | 0.051 | 0.053 | 0.052 |
| Doxorubicin | 0.051 | 0.052 | 0.054 | 0.052 |
| Etoposide | 0.049 | 0.054 | 0.051 | 0.051 |
| Fluorouracil | 0.053 | 0.051 | 0.055 | 0.053 |
| Paclitaxel | 0.052 | 0.050 | 0.054 | 0.052 |
| ThioTepa | 0.057 | 0.053 | 0.057 | 0.056 |
| Weight/Unit Area (g/m ²) | 62.2 | | | |

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January 5, 2021

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Page 4 of 5
PN 156551

RESULTS:

Table 5. Permeation Test Results on testing of: One (1) glove type identified as: Synmax Vinyl Exam Glove.

| TEST CHEMOTHERAPY DRUGS | AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes) | AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) ($\mu\text{g}/\text{cm}^2/\text{minute}$) | OTHER OBSERVATIONS |
|--|---|---|---------------------------------------|
| Carmustine (BCNU), 3.3 mg/ml (3,300 ppm) | 12.6 (12.6,13.3,12.7) | 0.2 (0.2,0.2,0.1) | Slight swelling and no degradation |
| Cisplatin, 1.0 mg/ml (1,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Dacarbazine, 10.0 mg/ml (10,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Doxorubicin HCl, 2.0 mg/ml (2,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Etoposide, 20.0 mg/ml (20,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Fluorouracil, 50.0 mg/ml (50,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| Paclitaxel, 6.0 mg/ml (6,000 ppm) | >240 min. | N/A | Slight swelling and no degradation |
| ThioTepa, 10.0 mg/ml (10,000 ppm) | 15.4 (15.4,16.3,17.6) | 0.6 (0.7,0.6,0.6) | Slight swelling and no degradation |

January 5, 2021

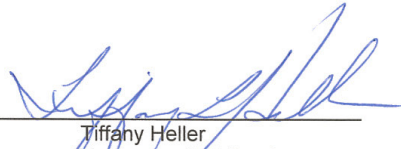
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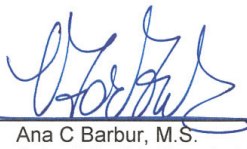
Page 5 of 5
PN 156551

SAMPLES RECEIVED:

One (1) glove type (2 boxes) identified as; Synmax Vinyl Exam Gloves 100 pieces Size M, 100 Pieces Size Lg



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