

FOR A HIGHER DEGREE OF CONFIDENCE



SELECTING THE RIGHT HAND PROTECTION WHEN WORKING WITH CHEMOTHERAPY DRUGS.

> Introduction

Manufacturing specialized products in a pharmaceutical manufacturing environment has a specific set of requirements when it comes to hand protection. Production and handling of these types of products typically happens in a clean or controlled environment and quite often in a sterile environment as well. When this particular application is further specialized into manufacturing or handling of a particular set of pharmaceuticals known as chemotherapeutic agents additional requirements come into play when selecting appropriate hand protection. Examples of these types of drug products are listed in the tables on pages 3 and 4 .

This paper will explore these requirements and what an individual who is working in these environments should be concerned with, while selecting appropriate hand protection as part of their overall personal protective equipment ensemble. It should be noted that this paper discusses the use of gloves as personal protective equipment in an industrial or non-medical application. For those individuals who are handling chemotherapeutic agents in a medical setting additional regulatory requirements must be met.

There are two primary reasons to wear personal protective gloves when working with these types of drugs. First and foremost to protect the individual from exposure to a potentially harmful substance and secondarily to protect the product from contamination. Chemotherapeutic agents are a class of chemical compounds designed and formulated as a drug product to inhibit the growth of or destroy rapidly growing cancer cells within the body. Therefore, by definition, they are either cytostatic or cytotoxic compounds and as such require the use of personal protective gloves that will act as an effective barrier between the hand and the chemical compound in question. Since these materials are by nature destructive to human cells it is desirable to avoid exposure to these materials.

Determining Whether A Glove Provides Adequate Protection

How then does an individual working in these environments and potentially exposed to these types of chemical compounds know whether or not the gloves they are wearing will provide adequate protection? Gloves designed to be used in these environments can be evaluated for their protective qualities when in contact with chemical substances. **This is done by conducting what's known as a chemical permeation test and is conducted under the guidance of two industry consensus standards.** These standards are known as ASTM D6978 Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs and ASTM F739 Standard Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions

Permeation

is the process by which a chemical dissolves and/or moves through a protective glove material on a molecular level. Permeation can occur without damaging the material or by damaging the material by degrading it. Permeation is measured in the amount of time (minutes) it takes for a chemical to pass through the barrier and be detected, which is referred to as Chemical Breakthrough Time; and the Flow Rate which is the rate (volume over time) at which a chemical passes through the glove material.

of Continuous Contact respectively. Whereas ASTM F739 is the general test method used to conduct chemical permeation testing, ASTM D6978 includes some additional requirements specific to chemotherapy drugs.

Standard Test Methods

The ASTM F739 standard test method is used to identify the actual chemical permeation resistance of glove materials under continuous contact with chemicals. The glove material to be tested is placed into a permeation test cell and sandwiched between the test chemical and a collection medium. The collection medium, usually a gas or liquid, is analyzed quantitatively for its concentration of the chemical that has permeated the barrier as a function of time after its initial contact with the glove material.

Each material specimen to be tested is sampled from the palm of at least three gloves. An additional sample may be tested with just collection media as a test control depending upon the actual analytical methods used. All test specimens are cut to fit the same diameter as the flange of the permeation test cell (see *Figure 1*).

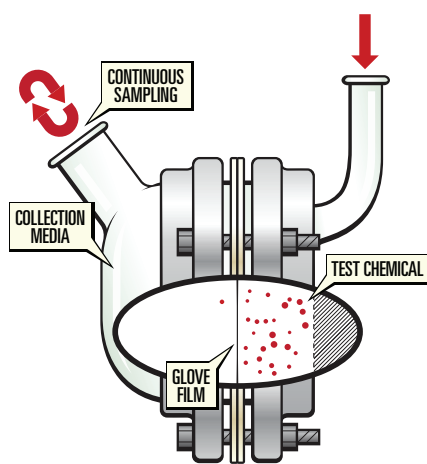


Figure 1: Chemical Permeation Test Cell

The test chemical is introduced into the challenge compartment of the permeation cell and time measuring device is started. The compartment containing the test chemical is completely filled during the period of the test. Under the requirements of ASTM F739 the breakthrough time of a chemical is deemed to occur when the sum of the permeation rates of each individual component reaches the rate of $0.1 \text{ Qg cm}^{-2}\text{min}^{-1}$. When a permeation rate of $0.1 \text{ Qg cm}^{-2}\text{min}^{-1}$ is detected, then the breakthrough time is reported in minutes for each test specimen. If the permeation rate does not reach $0.1 \text{ Qg cm}^{-2}\text{min}^{-1}$ then the duration of the test is reported.

However, for chemotherapy agents under the additional requirements of the standard ASTM D6978 a more conservative breakthrough time is reported by determining a breakthrough time when $0.01 \text{ Qg cm}^{-2}\text{min}^{-1}$ is reached. This is done in recognition of the cytotoxic properties of the chemical compounds in question.

Product Contamination Concerns

While personal protection is the first concern when selecting a glove, protecting the product from external sources of contamination is equally important. Manufacturing of chemotherapy drugs is conducted under good manufacturing practices (GMP) in a sterile cleanroom environment and as such, product contamination must be avoided. A variety of sources of potential contamination must be taken into consideration, including biological, particulate and undesirable chemical residues. A contaminated product from any of these sources can lead to unacceptable production lots resulting in a costly and time consuming scenario to rectify.

Penetration (break-through)

is the movement of a chemical and/or micro-organism through the material, pinholes or other imperfections of a glove.

Degradation

is the loss of or change in the glove material's chemical resistance or physical properties due to exposure to chemicals and or use. These changes can occur as swelling, disintegration, becoming brittle, discoloration, flaking, hardening, or softening and is measured by taking before and after results of different metrics such as tensile strength, force at break, modulus, visual observation, and other metrics.

Recommended Solutions

How is an appropriate glove chosen for use with chemotherapy agents in an industrial setting?

As this paper illustrates several factors need to be taken into consideration.

- Protection against:
 - specific drugs being used
 - other hazards or chemicals in the work place
- Protection of the products from external contamination
- Comfort
- Fit
- Ergonomics
- Costs

Additionally, a common practice of wearing 2 pairs of single use gloves (double donning) can also enhance the end user's protection against chemotherapy agents provided the gloves are chemotherapy drug approved and proven to be elastic and comfortable. In consideration of all these factors Ansell has several product offerings that fulfill these challenging and very specific needs of this environment.

For sterile and cleanroom environments the following products are recommended along with their breakthrough time:

ANSELL GLOVES	TouchNTuff® 83-500	TouchNTuff® 93-700	TouchNTuff® 73-701	TouchNTuff® 73-500
POLYMER	Sterile Polyisoprene	Sterile Nitrile	Sterile Neoprene	Sterile Neoprene
Chemotherapy Drug Tested	Minimum Breakthrough Time (Minutes) using ASTM F739 and EN374 Test Methods			
Carmustine	15	2	29	30
Cisplatin	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Cyclophosphamide	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Cytarabine	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Docetaxel	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Doxorubicin Hydrochloride	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Etoposide (Toposar)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Fluorouracil	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Ganciclovir	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Ifosfamide	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Irinotecan	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Methotrexate	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Mitomycin	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Oxaliplatin	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Paclitaxel (Taxol)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Thiotepa	15	No breakthrough up to 240 minutes	105	60
Vinorelbine	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes

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For non-sterile environments Ansell also has three products to offer that are ideally suited to general laboratory work or medical applications with chemotherapy drugs. Note TouchNTuff® 92-605 listed in the table below is not approved for medical use.

ANSELL GLOVES	Microflex® Supremo® EC	TouchNTuff® 92-605	Microflex® NeoPro®	Microflex® NeoPro® EC
ITEM NUMBER	SEC-375	92-605	NPG-888	NEC-288
POLYMER	Non-Sterile Nitrile	Non-Sterile Nitrile	Non-Sterile Neoprene	Non-Sterile Neoprene
GRADE	Medical	Industrial	Medical	Medical
Chemotherapy Drug Tested	Minimum Breakthrough Time (Minutes) using ASTM F739 and EN374 Test Methods			
Amethopterine Hydrate	15	2	29	30
Bleomycin Sulfate	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Carboplatin (Paraplatin)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Carmustine	15	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Cisplatin	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Cyclophosphamide	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Cytarabine	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Dacarbazine	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Daunorubicin HCl (Cerubidine)	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Doxorubicin Hydrochloride	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Etoposide (Toposar)	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Fluorouracil	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Idarubicin HCl	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Ifosfamide	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Melphalan (Alkeran)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Methotrexate	15	No breakthrough up to 240 minutes	105	60
Mitomycin	No data	No data	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Mitoxantrone	No breakthrough up to 240 minutes	No data	No breakthrough up to 240 minutes	No data
Paclitaxel (Taxol)	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Thiotepa	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes	No breakthrough up to 240 minutes
Vincristine Sulfate	No breakthrough up to 240 minutes	No data	No data	No breakthrough up to 240 minutes

PERMEATION BREAKTHROUGH TIMES ACCORDING TO EN374 (minutes)

0	1	2	3	4	5	6
< 10	10 - 30	30 - 60	60 - 120	120 - 240	240 - 480	> 480
Not Recommended	Splash Protection		Medium Protection		High Protection	

About Ansell

Ansell is a world leader in providing superior health and safety protection solutions that enhance human well-being.

With operations in North America, Latin America/Caribbean, EMEA and Asia, Ansell employs nearly 14,000 people worldwide and holds leading positions in the personal protective equipment and medical gloves market, as well as in the sexual health and well-being category worldwide. Ansell operates in four main business segments: Medical, Industrial, Single Use and Sexual Wellness.

For information on how Ansell is helping life science customers and to request a free product sample visit www.ansell.com/lifesciences