

EXCEL[®] IV Container FAQ

How are B. Braun IV containers different from those that contain PVC?

B. Braun IV containers are biologically inert and are not made with PVC or the plasticizer DEHP. When certain medications, such as diazepam, nitroglycerin, cyclosporine or paclitaxel, come in contact with PVC, there is potential for sorption of the drug and therefore the release of DEHP into the fluid and/or absorption of the active ingredient with subsequent sub-therapeutic dosing. Using B. Braun IV containers minimizes patient exposure to the toxic DEHP plasticizer compared to using PVC containers containing DEHP.¹

Can we use a marking pen to write on EXCEL IV containers?

We do not conduct any biocompatibility testing on the inks used in the manufacturing of marking pens. Therefore, we do not recommend using any marking pen on the fluid contact area of EXCEL IV containers.

How long and at what temperature can EXCEL IV containers be placed in a warmer?

In addition to the already described shelf life testing at 25°C and 40°C, B. Braun also conducted chemical and microbiological testing of 0.9% sodium chloride for injection in the EXCEL IV container after 30 days of exposure at 2°-8°C. Based on this testing the IV solutions in the EXCEL IV container is stable and can be refrigerated prior to use for up to 30 days. Product that has been exposed to 2°-8°C and not used within 30 days must be discarded and not returned to storage.

The labeling for EXCEL IV products contains a statement that exposure of pharmaceutical products to heat should be minimized and that excessive heat should also be avoided. The labeling also recommends that the product be stored at room temperature (25°C); however, brief exposure at 40°C does not adversely affect uncompromised product in an intact overwrap bag. Product that has been exposed to 40°C and not used within four (4) weeks must be discarded and not returned to storage.

Can EXCEL IV containers be transported in a pneumatic tube system?

While the EXCEL IV container design offers tremendous clinical, safety, and environmental benefits, it is not as indestructible as PVC. Consequently, it must be handled differently with each type of pneumatic tube system.

6 inch Pneumatic Tube Systems: The EXCEL IV container can survive transport in well-maintained 6 inch tube systems. Foam padding should also be used when transporting IV bags.

- Reduce the potential for the container film getting pinched by placing the container in the carrier on its side and performing a visual check.
- Padding can cushion the impact and protect the container from sharp edges inside the carrier. In 6 inch carriers, special foam inserts can be used for this purpose.

What are the target and overfill volume specifications of the EXCEL IV container?

The United States Pharmacopeia (USP) requirements for the fill volume of a large volume parenteral product state that each intravenous solution container is filled with "a volume in slight excess of the labeled 'size' or 'that volume which is to be withdrawn'." Under hospital use conditions, most of the excess solution is expended in the process of flushing and filling the administration set at the initiation of the infusion. For containers of 50 mL or greater volume, the USP <1151> recommended excess volume is 2% (3% for viscous solutions), which is considered sufficient to permit withdrawal and administration of the labeled volume.

The overfill volume for the EXCEL IV container includes the addition of a sufficient amount of solution (approximately 2%) to allow for water vapor transmission losses out of the container over the shelf life of the product. The remaining overfill volume, which is accounted for by the variation in the amount of solution dispensed by the filling equipment, assures that the product contains at least the labeled volume plus the overfill volumes described below. Solutions in EXCEL IV containers are formulated such that the vapor transmission losses do not affect the claimed solution volumes and concentrations over the shelf life of the product. The overfill volumes for EXCEL IV containers are as follows:

| Container Size (mL) | Nominal Fill Volume (mL) | Lower Limit (mL) | Upper Limit (mL) |
|---------------------|--------------------------|------------------|------------------|
| 250 mL | 270 | -7 | +6 |
| 500 mL | 532 | -9 | +18 |
| 1000 mL | 1058 | -15 | +30 |

How long can the EXCEL IV container be stored without its plastic overwrap?

The EXCEL 250mL, 500mL and 1000mL size IV containers, without any additions, can be stored at 25°C for one (1) month without plastic overwrap (or until its expiration date, whichever is sooner). This storage time is based on B. Braun testing. We recommend that you follow your facility protocol regarding proper storage of drug product containers.

What are the residual volume specifications for the EXCEL IV container?

After administration, it is common for a small amount of solution to remain in any IV bag. The residual amount is negligible and should not significantly affect the therapeutic dose of IV additives.

What are the additive volume specifications of the EXCEL IV container?

Additive volume for the different size containers are as follows:

Container Size Recommended Maximum Additive Volume

| Container Size | Recommended Maximum Additive Volume |
|----------------|-------------------------------------|
| 250 mL | 40 mL |
| 500 mL | 50 mL |
| 1000 mL | 200 mL |

How long can the EXCEL IV container be stored without its plastic overwrap?

The EXCEL 250mL, 500mL and 1000mL-size IV containers, without any additions, can be stored at 25°C for one month without plastic overwrap (or until its expiration date, whichever is sooner). This storage time is based on B. Braun testing. We recommend that you follow your facility protocol regarding proper storage of drug product containers.

What are the dimples on the back side of the EXCEL IV container?

The trays used for the sterilization process cause the dimpled texture on the back of the container. This does not affect the integrity of the container.

Why is there moisture between the primary container and the overwrap?

The overwrap of the EXCEL IV container may contain moisture due to condensation from the sterilization process. Over the period of a few months the area between the overwrap and the container will dry. A moist container is not an unusual phenomenon and is certainly not an indication of a leaking container. However, a significant amount of fluid (an inch or more) could indicate a leaking container. The container should be squeezed to check for minute leaks after removing from the overwrap.

Can EXCEL IV containers be recycled?

EXCEL IV containers are made of a rubberized blend of propylene and ethylene and are recyclable with the number "7" as the resin identification number. Please follow your facility's protocol for the recycling of fluid containers.

Can the Excel IV container be pressure infused?

B. Braun has conducted compatibility testing and recommends the following pressure cuffs for use with the Excel IV container^{3,4}:

| 250mL EXCEL |
|---|
| Ethox Medical Infu-Surge 4005H |
| BD-Carefusion Vital Signs IN800048 |
| BD-Carefusion Vital Signs IN800012 |
| Spacelabs Healthcare/ StatCorp Medical Unifusor Plus 1103X-05 |
| Premier Pro Pressure Infuser 8800 |
| 500mL EXCEL |
| Ethox Medical Infu-Surge 4005H |
| BD-Carefusion Vital Signs IN800048 |
| BD-Carefusion Vital Signs IN800012 |
| Spacelabs Healthcare/ StatCorp Medical Unifusor Plus 1103X-05 |
| Premier Pro Pressure Infuser 8800 |
| 1000mL EXCEL Products |
| Ethox Medical Infu-Surg 4010H |
| BD-Carefusion Vital Signs IN900012 |
| Spacelabs Healthcare/ StatCorp Medical Unifusor Plus 1104X-05 |
| Premier Pro Pressure Infuser 8800 |

The EXCEL IV container is designed to withstand pressure infusion up to 300 mmHG for 24 hours.

How long and at what temperature can the Excel IV container be placed in a refrigerator?

B. Braun conducted chemical and biological stability testing of the IV solutions in the Excel IV container throughout the labeled shelf life of the product. This testing was conducted at 25°C and 40°C. In addition, B. Braun conducted functional integrity testing of the Excel IV container after exposure to 2-8°C for thirty (30) days. The stability and functional testing demonstrate that 2-8°C exposure for thirty (30) days has no impact on the solution or container.⁵

The labeling for Excel IV products contains a statement to protect from freezing. The labeling also recommends that the product be stored at room temperature (25°C). Product that has been exposed to 2-8°C and not used within thirty (30) days must be discarded and not returned to storage.

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1 Bristol-Myers Squibb Company, Oncology Division. Taxol (Paclitaxel) Injection Administration, Equipment, 11/99 Equipment

2 Chemical and Physical Compatibility of Selected Drugs in EXCEL® Container System

3 RPT-PH-1007854

4. RPT-PH-1007855

5. RPT-PH-1008016