B BRAUN
SHARING EXPERTISE

FAQ

0.9% Sodium Chloride Injection USP, 1,000 mL in E3® IV Container

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 E3 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 E3 IV containers.

What are the additive volume specifications of the E3 IV Containers?

Container Size	Maximum Recommended Additive Volume
1000 mL	150 mL

How long and at what temperature can the E3 IV container be placed in a warmer?

B. Braun conducted chemical and biological stability testing of 0.9% Sodium Chloride in the E3 IV container throughout the labeled shelf life of the product. This testing was conducted at 25°C through expiry and at 40°C for 3 months and six months.[2] Based on the chemical and biological stability testing, E3 can be stored at 40°C for up to 6 months.

The labeling for E3 IV products contains a statement that exposure of pharmaceutical products to heat should be minimized and that excessive heat should also be avoided.[3] B. Braun's product manufactured in the E3 IV container should be stored at room temperature (25°C); however, brief exposure at 40°C does not adversely affect uncompromised product.

How long and at what temperature can the E3® IV container be placed in a refrigerator?

B. Braun conducted chemical and biological stability testing of 0.9% Sodium Chloride in the E3 IV container throughout the labeled shelf life of the product. This testing was conducted at 25°C through expiry and at 40°C for 3 months and six months. In addition, B. Braun conducted chemical and biological testing of the IV solution after exposure to 2°-8°C for ninety (90) days. The stability testing demonstrate that 2°-8°C exposure for ninety (90) days has no impact on the solution.

The labeling for E3 IV products contains a statement to protect from freezing. The labeling also recommends that the product be stored at room temperature (25°C).[2] Product that has been exposed to 2°-8°C and not used within ninety (90) days must be discarded.[3]

Can E3 IV containers be transported in a pneumatic tube system?

Tube system companies manufacture the carriers in two (2) sizes: 4 inch and 6 inch. E3 solution containers can be freely transported in both the 4-inch and 6-inch carriers. Care should be exercised to ensure that the carrier latches are securely closed and that the container is not pinched between carrier shells.

What are the target and overfill volume specifications of the E3 IV container?

The United States Pharmacopeia (USP) requirements for the fill volume of a large volume parenteral product state that each intravenous solution container must be 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%, which is considered sufficient to permit withdrawal and administration of labeled volume.

The overfill volume for the E3 IV container includes the 2% overfill recommended by the USP <1151> to compensate for the residual volume left in the container after drainage, and 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 listed below. Solutions in the E3 IV container are formulated to ensure 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 E3 IV containers are as follows:

Container Size	Nominal Fill Volume	Lower Limit	Upper Limit
1000 mL	1027 mL	1022	1032

What are the residual volume specifications for the E3 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.

Can the E3 IV container be pressured infused?

B. Braun has conducted compatibility testing and recommends the following pressure cuffs for use with the E3 IV container:[4]

1000 mL E3
Ethox Medical Infu-Surg 4010H
BD-Carefusion Vital Signs IN900012
Spacelabs Healthcare/StatCorp Medical Unifusor Plus 1104X-05
Premier Pro Pressure Infusor 8800

The E3 IV container is designed to withstand pressure infusion up to 300 mmHG for 24 hours.

Can the E3 IV containers be recycled?

E3 IV containers are made of a homogenous blend of polypropylene specifically developed for parenteral drugs and are recyclable with the number "7" as the resin identification number. Please follow your facility's protocol for the recycling of fluid containers.

Why doesn't the E3 IV container require an overwrap?

Unlike the EXCEL® IV container that does require an overwrap, E3 was designed and approved by the FDA without the need for an overwrap. The material composition of the E3 IV container is a different blend than the EXCEL IV container allowing for reduced water vapor transmission. This, along with the presence of tamper evident caps on both the medication port and additive port eliminates the need for an overwrap. For use of the E3 IV container, refer to the directions for use in the FDA approved product package insert.[3]

The expiration date printed on the unit container is valid as long as the product is used in accordance with the product labeling.

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[1]Bristol-Myers Squibb Company, Oncology Division. Taxol (Paclitaxel) Injection Administration, Equipment, 11/99 Equipment
[2]RPT-PH-1009451
[3]E8000 FDA approved Package Insert and IFU
[4]RPT-EXCEED-1000568