# *Anticoagulant Sodium Citrate 4%*

Anticoagulant Sodium Citrate 4% w/v Solution, USP in 250 mL
PP bag container


Please see Structured Product Labeling (SPL) on page 3 for Anticoagulant Sodium Citrate 4% w/v Solution, USP.

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# Anticoagulant Sodium Citrate 4% w/v Solution, USP is a sterile solution containing 4 g/100 mL of Sodium Citrate Dihydrate in water for injection. pH is adjusted with Citric Acid Monohydrate.

- **Anticoagulant Sodium Citrate 4%** is intended for extracorporeal use as anticoagulant for **whole blood in automated apheresis procedures**. Not for direct intravenous infusion
- **Anticoagulant Sodium Citrate 4%** is supplied in **flexible polypropylene (PP) plastic** bags containing **250 mL of solution**
- The container is **free of PVC**, plasticizers, adhesives, and latex
- The solution is **aqueous-based**, **clear,** and **colorless**

The quantitative composition and function of each component of the solution are shown in table.

| Component | Function | Quantity per 100 mL 250/500 mL | Quality Standard |
|---|---|---|---|
| Sodium Citrate Dihydrate | Active substance | 4 g | USP |
| Citric Acid Monohydrate* | pH Adjustment | q.s. pH 6.4 to 7.5 | USP |
| Water for Injection | Solvent | q.s. 100 mL | USP/Ph. Eur |

*The amount of Citric Acid Monohydrate is appropriate per the FDA Inactive Ingredient Database.

**Individual overwrap of polypropylene** that protects and maintains the sterility of the container and limits evaporative moisture loss from the primary solution container. It is transparent to allow visual inspection and has a **peelable opening system.**

# Anticoagulant Sodium Citrate 4%, benefits and features


Do not use unless solution is clear and no leaks detected.

### Designed for safe and easy handling

Integrated eyelet support for easy and safe handling of the container during the utilization.

### Product information

- Inclusion of the National Drug Code
- Inclusion of lot and expiration date
- Sequential number

### High sealing resistance

High resistance pressure cuffs respond satisfactorily to 400 mmHg pressure for 72 hours.

### Outlet port

PP tube closed with a PP twist-off for the connection to the apheresis device.

## ANTICOAGULANT SODIUM CITRATE - trisodium citrate dihydrate solution
**LABORATORIOS GRIFOLS SA**

### ANTICOAGULANT SODIUM CITRATE 4% w/v SOLUTION USP

Rx only
250 mL
Intended for use only with automated apheresis devices.
Each 100 mL contains:
Sodium Citrate (Dihydrate), USP 4 g (pH adjusted with Citric Acid, Monohydrate, USP)

### CAUTION

Not for direct intravenous infusion. The pouch is a moisture barrier. Do not use unless solution is clear and no leaks detected. Single use container. Discard unused portion.

### STERILE, nonpyrogenic fluid path.

### RECOMMENDED STORAGE:

Store at 20 °C to 25 °C (68 °F to 77 °F); excursions permitted between 15 °C to 30 °C (59 °F to 86 °F) [See USP Controlled Room Temperature]. Brief exposure up to 40 °C (104 °F) does not adversely affect the product. Protect from freezing.

### Laboratorios Grifols, S. A.

SPAIN
Review: 10/2019

# Guidelines for Anticoagulant Sodium Citrate 4%

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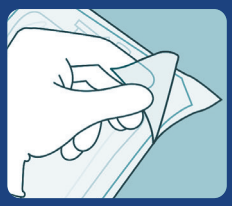
## Overwrap removal

The overwrap serves as a moisture barrier. It is intended to limit evaporative moisture loss from the primary solution container.



**1.** The overwrap is designed to be opened by pulling apart the 2 sheets of the overwrap.

**2.** The recommended method to remove the overwrap is to peel off sheet by the corner while holding the other sheet at one end. Carefully remove the solution container.

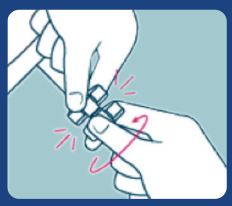
**The overwrap should not be removed until product is to be used.**

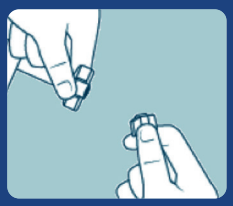
## Container inspection

Visually inspect the container for particulate matter and discoloration.
Check for minute leaks by squeezing inner container firmly. **If leaks are found, discard solution as sterility may be impaired.**
If the ports are damaged, detached, or not present, discard container as solution path sterility may be impaired.

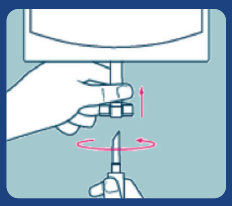
**Do not administer unless the solution is clear and seal is intact.**

## Attach administration set

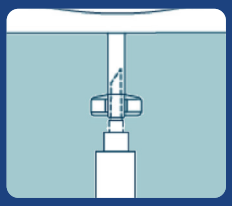




**1.** Open the breakable access port of the bag.



**2.** Hold the container properly and aseptically connect the bag to the anticoagulant line of the apheresis device set. Completely insert the spike of the apheresis device tubing set through the port as far as it will go.
To ensure proper connection and prevent leakage, push the set using a circular motion up to the shoulder of the spike. Do not move the spike back and forth once inserted.



**3.** Verify that the bag has been securely attached to the anticoagulant line of the system's tubing set to avoid flow interruption, leaks, and connection errors.

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