

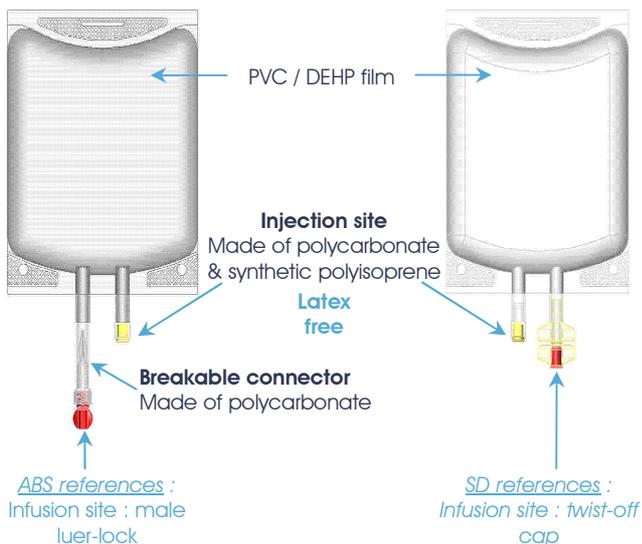


ACD Formula A

CHARACTERISTICS

ANTICOAGULANT SOLUTION FOR AUTOMATED APHERESIS, CONTAINED IN A FLEXIBLE PVC / DEHP BAG, STERILISED IN ITS INDIVIDUAL OVERWRAP.

1 Description



2 Solution

Composition :

- Trisodium Citrate 2H₂O.....22,0 g
- Citric Acid 1H₂O.....8,0 g
- Glucose 1H₂O.....24,5 g
- PPI Water : 1000 ml.

pH : 4,5-5,5 ; Osmolarity : 400-440 mOsm/kg.
Sodium content : 214-234 mol/l.

2 Sterilization method

- Steam sterilization in overwrap (121°C / 15 minutes).
- Sterile and non pyrogenic solution

3 Compliance

- Sterile **class IIb** device (compliant with EC labelling dossier).
- Directive 93/42/CEE.
- Good Manufacturing Practices (GMP's).
- Bonnes Pratiques de Fabrication (BPF).
- Norme ISO 594-2 :1998 (Luer-lock connexion, ABS references).

4 Storage conditions and shelf life

Do not store above +35°C in original overwrap.
Protect from light during storage. Do not freeze.
2 years shelf-life in original overwrap.

PACKAGING

| References | Volume | Units per box |
|-----------------|---------------|---------------|
| ABS0752EU | 500 ml | 18 |
| ABS1052EU | 1000 ml | 10 |
| SD10005Q | 50 ml | 70 |
| SD10050Q | 500 ml | 20 |
| SD10080Q | 800 ml | 12 |

Each bag is individually wrapped.

INSTRUCTIONS FOR USE

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Read carefully the notice for complete information.

1 Therapeutic indication

ACD-A solutions are intended for blood anticoagulation. MacoPharma anticoagulant solutions are strictly reserved for the automated apheresis procedures.

2 Precautions

- Device must be used by trained persons only.
- Check the integrity of the device and the overwrap before use.
- Do not put air intake.
- Single use solution ; do not re-sterile.
- Do not directly infuse the solution, blood for transfusion must not be stored in this device.

3 Dosage

Anticoagulant solution is added to whole blood during collection in a proportion defined by the person responsible for the procedure. The following rate is commonly advised by apheresis machines manufacturers: 1/9 for ACD-A solutions. This rate, however, can be changed according to the performance of the apheresis machines.

4 Instructions for use

- Peel open the overwrap using the corner flap.
- ABS references :
 - Unscrew the protective cap and connect the anticoagulant solution with the luer connector to the apheresis set.
 - Break the breakable connector by moving the connector back and forth 90° until an audible « snap » sound is heard in both directions.
- SD references :
 - Break and detach the twist-off situated at the end of the anticoagulant solution, and connect the bag using a spike.
 - Anticoagulant solutions connection to the apheresis system is carried out according to the separator's instructions
 - Hang the anticoagulant solution bag and follow the valid apheresis protocol of your institution.

5 Contra-indications

Contra-indications are those of blood collection.
For cellular apheresis, check haemostasis.
Use only for automated plasmapheresis or cytapheresis procedures.
Do not perform apheresis in case of : serious haemopathy with haemostatic trouble, cerebral vascular accidents, pericardial or endocardial cardiopathy, post surgical period after intervention on central nervous system and spinal cord.
Do not carry out apheresis among pregnant women, nor during lactation (except plasmatic exchange if absolutely (indicated) necessary).

6 Undesirable effect

Paresthesia : stinging sensations on lips and extremities ; Nausea ; Dysgeusia : weird taste sensation ; Cold sensation.

7 Overdose

Tentary possibility ; vomiting ; hypotension ; tachycardia.
In case of overdose, control clinic and electrographic signs.
If necessary inject calcium until (correction of the troubles) symptoms disappear.

8 Discard warnings

Discard according to local regulations' on the potentially dangerous biological products.
Cardboard box is recyclable.

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