

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)- anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution

Fenwal, Inc.

CPD/ADSOL™ BLOOD-PACK™ Unit Quadruple OPTIPAC™ Opti-System

Instructions for Blood Collection Using CPD OPTIPAC™ Unit with an Integrally Attached Container of ADSOL™ Red Cell Preservation Solution

Rx Only

Opti-System

Use aseptic technique

Caution: Do not use unless the solutions are clear.

1. Identify BLOOD-PACK™ OPTIPAC™ unit using appropriate donor identification system.
2. Adjust donor scale to desired collection weight/volume.
3. Suspend primary container from donor scale as far as possible below donor arm and clamp donor tubing with hemostat.
4. Apply pressure to donor's arm and disinfect site of venipuncture.
5. If blood pressure cuff is used, inflate to approximately 60 mm Hg, or use tourniquet as applicable.
6. Remove needle cover per instructions below:
 - a) Hold the needle hub upwards. With the other hand, grasp the base of the needle cover (Figure 1), twist approximately 1/4 turn to break tamper evident seal (Figure 2).
 - b) Remove needle cover (Figure 3), be careful not to drag cover across the needle point (Figure 4).
7. Perform venipuncture, appropriately secure donor needle and/or tubing and release hemostat.
8. **Mix blood and anticoagulant at several intervals during collection and immediately after collection.**
9. Collect labeled volume of blood. Anticoagulant volume is sufficient for labeled volume \pm 10%.
10. Apply hemostat to donor tubing.
11. If it is necessary, obtain whole anticoagulated blood samples for typing or crossmatching by returning donor tubing blood to the primary bag, mixing and allowing tubing to refill. Repeat once. Seal donor tubing at the desired intervals in order to obtain the desired total blood samples.
12. Centrifuge primary and secondary bags in order to prepare CPD Red Blood Cells.
13. Refer to the OPTIPRESS™ Blood Components Automated Extractor User Manual, in order to prepare the components.
14. After separation, seal transfer tubing in three places near the primary bag and cut middle seal taking care to avoid fluid splatter.
NOTE: In OPTIPAC Quadruple BLOOD-PACK unit, the empty transfer unit may be used for preparation of other components.
15. Fill empty tubing of OPTIPAC AS-1 for red blood cells by stripping the tubing and mixing the AS-1 container, twice, in order to ensure that the tubing is correctly filled. Seal on "X" marks on tubing in order to obtain red blood cells samples.
16. Mix Adsol Solution and red cells thoroughly.

17. Store suspended Red Blood Cells between 1 and 6 °C.

For further processing, use standard techniques for component processing.

Sterile, non-pyrogenic fluid path. Sterilized by steam. Single use only. Dispose of container appropriately.

Store at Controlled Room Temperature

USP Definition of "Controlled Room Temperature"

United States Pharmacopeia, General Notices.

United States Pharmacopeial Convention, Inc.

12601 Twinbrook Parkway, Rockville, MD



FIGURE 1



FIGURE 2

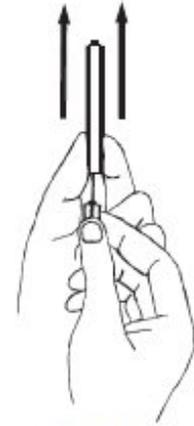
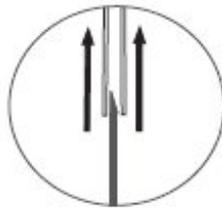


FIGURE 3



NO



YES

FIGURE 4



FIGURE 5



Manufactured by:

Fenwal International, Inc.

Road 357, Km. 0.8

Maricao, PR 00606

Made in USA

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07/2010

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– Manufacturer

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PACKAGE/LABEL DISPLAY PANEL

Code: A4R7473

3 Units

Fenwal™

CPD/ADSOL™ BLOOD-PACK™ Unit Quadruple OPTIPAC™ Opti-System

Rx only

Each unit consists of a PL 146 bag containing 63 mL of Citrate, Phosphate and Dextrose Anticoagulant Solution (CPD) with 450 mL of capacity; a PL 146 transfer pack containing 100 mL of Adenine, Dextrose and Mannitol Solution (ADSOL), 450 mL of capacity; and two PL 1240 transfer packs, 400 mL of capacity.

Each 63 mL of CPD solution contains: 1.66 g, Sodium citrate (dihydrate), USP, 1.61 g Dextrose (monohydrate), USP, 188 mg Citric acid (anhydrous), USP, 140 mg Monobasic sodium phosphate (monohydrate), USP. Water for Injection USP to 63 mL.

Each 100 mL of ADSOL solution contain: Sodium chloride, USP, 900 mg, Dextrose monohydrate, USP, 2.20 g, Adenine, USP, 27.0 mg, Mannitol, USP, 750 mg. Water for Injection USP to 100 mL.

See instructions for use. Sterile, non-pyrogenic fluid path. Steam sterilized. Single use only. Do not vent. Do not use if there is any visible sign of deterioration. Dispose of container appropriately.

Store at Controlled Room Temperature (refer to direction insert).

Unused units in open foil pouch may be kept up to 60 days by folding and securing open end of foil pouch to prevent possible loss of moisture.

Direct handling of product surfaces prior to extended storage in the foil pouch may result in mold growth.

Units removed from the foil pouch must be used within 4 days (96 hours). Units out of the foil pouch for longer than 4 days must be discarded.



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Fenwal International, Inc.

Road 357, Km. 0.8

Maricao, PR 00606

Made In USA

Imported and distributed in Philippines by:

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No.31 Visayas Ave.,

Vasra, Quezon City 1100

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Reg No.: DEPKES RI AKL 20209902359

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07-28-05-041 REV: A

Lot:

Exp. Date:



CPD/ADSOL™ BLOOD-PACK™ Unit

Quadruple OPTIPAC™

Opti-System

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Made In USA

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ADSOL RED CELL PRESERVATION SOLUTION SYSTEM IN PLASTIC CONTAINER (PL 146 PLASTIC)

anticoagulant citrate phosphate dextrose (cpd) solution and adsol preservation solution kit

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0942-6499
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0942-6499-04	1 in 1 KIT		

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BAG	63 mL
Part 2	1 BAG	100 mL

Part 1 of 2

CPD

citrate phosphate dextrose solution

Product Information

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Trisodium Citrate Dihydrate (UNII: B22547B95K) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	1.66 g in 63 mL
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	1.61 g in 63 mL
Anhydrous Citric Acid (UNII: XF417D3PSL) (Anhydrous Citric Acid - UNII:XF417D3PSL)	Anhydrous Citric Acid	188 mg in 63 mL
Sodium Phosphate, Monobasic, Monohydrate (UNII: 593YOG76RN) (PHOSPHATE ION - UNII:NK08V8K8HR)	Sodium Phosphate, Monobasic, Monohydrate	140 mg in 63 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		63 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	09/28/2010	

Part 2 of 2

ADSOL RED CELL PRESERVATION SOLUTION SYSTEM

adsol red cell preservation solution solution

Product Information

Route of Administration INTRAVENOUS

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Dextrose Monohydrate (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	Dextrose Monohydrate	2.2 g in 100 mL
Sodium Chloride (UNII: 451W47IQ8 X) (SODIUM CATION - UNII:LYR4M0NH37)	Sodium Chloride	900 mg in 100 mL
Mannitol (UNII: 3OWL53L36A) (Mannitol - UNII:3OWL53L36A)	Mannitol	750 mg in 100 mL
Adenine (UNII: JAC85A2161) (Adenine - UNII:JAC85A2161)	Adenine	27 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	09/28/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	BN8 11104	09/28/2010	

Labeler - Fenwal, Inc. (794519020)