

ANTICOAGULANT CITRATE DEXTROSE A ACD-A- anticoagulant citrate dextrose a acid injection, solution

Arteriocyte Medical Systems, Inc.

**Anticoagulant Citrate Dextrose Solution,
Solution A, USP**

**ACD-A 50 mL
Catalog # AMSACD-A**

Anticoagulant intended for use only with devices that prepare Platelet Rich Plasma (PRP) products for extracorporeal use. See Operator's Manuals for additional information and complete usage instructions.

Sterile. Non-pyrogenic. Do not use unless the solution is clear and the container is intact and undamaged.

Rx only. Single use container.

Caution

Not for preparation of blood products for transfusion or for direct intravenous infusion.

Recommended storage

Room temperature (68° to 77°F, 20° to 25°C)

Avoid excessive heat. Protect from freezing.

Each 10mL contains

Citric Acid Monohydrate USP	0.08 g
Sodium Citrate Dihydrate USP	0.220 g
Dextrose Monohydrate USP	0.245 g
In Water for Injection USP	

Manufactured for Arteriocyte Medical Systems, Inc.

45 South Street, Hopkinton, MA., 01748

by Ivex Pharmaceuticals, Larne, BT40 2SH, UK.

**ARTERIOCYTE
CELLULAR THERAPIES
MEDICAL SYSTEMS**

Lot

Expiry Date

PRINCIPAL DISPLAY PANEL - 50 Pouch Case Label

Anticoagulant Citrate Dextrose Solution,
Solution A USP ACD-A

50 mL

50 x 50 mL

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ANTICOAGULANT CITRATE DEXTROSE A ACD-A

anticoagulant citrate dextrose a acd-a injection, solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:43203-852
Route of Administration	EXTRACORPOREAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	0.08 g in 10 mL
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR) (SODIUM CATION	SODIUM CITRATE,	0.220 g

- UNII:LXR4M0NH37)	UNSPECIFIED FORM	in 10 mL
DEXTROSE MONOHYDRATE (UNII: LX22YL083G) (ANHYDROUS DEXTROSE - UNII:5SL0G7R0OK)	DEXTROSE MONOHYDRATE	0.245 g in 10 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	9.76 g in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43203-852-47	50 in 1 CASE		
1		1 in 1 POUCH		
1		50 mL in 1 BAG; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	BA110057	05/11/2011	

Labeler - Arteriocyte Medical Systems, Inc. (809012870)

Registrant - Terumo BCT, Inc. (801679200)

Establishment

Name	Address	ID/FEI	Business Operations
Terumo BCT, Ltd.		233649834	MANUFACTURE(43203-852) , ANALYSIS(43203-852) , STERILIZE(43203-852) , LABEL(43203-852)

Revised: 12/2018

Arteriocyte Medical Systems, Inc.