



noClot-50™
Anticoagulant Citrate Dextrose Solution,
Solution A, U.S.P., ACD-A, PN 6053, 50 mL

DESCRIPTION

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD-A), is a sterile, non-pyrogenic solution of citric acid, sodium citrate, and dextrose, in water for injection. Each 10 mL of solution contains:

Citric Acid, anhydrous, USP	0.073 grams
Sodium Citrate, dihydrate, USP	0.220 grams
Dextrose, monohydrate, USP	0.245 grams
Water for Injection, USP	q.s.

pH: 4.5 – 5.5

CLINICAL PHARMACOLOGY

ACD-A acts as an anticoagulant by the action of the citrate ion chelating free ionized calcium, thus making calcium unavailable to the coagulation system.

INDICATIONS AND USAGE

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P. (ACD-A), is intended for use as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP). Refer to the manufacturer's Operator's Manual of the Autologous PRP System for the Directions for Use.

CONTRAINDICATIONS

NOT FOR DIRECT INTRAVENOUS INFUSION.

WARNINGS

None.

PRECAUTIONS

General

Aseptic technique must be maintained at all times. ACD-A solution is a clear solution. If the product shows any cloudiness or turbidity, the product should be discarded. The ACD-A solution may exhibit a slight "yellow" color, which is acceptable and in no way impairs the safe use of the product. The closure system provides a biological barrier and should be intact — discard product if system is compromised.

Information for Patients

None.

Laboratory Tests

There are no laboratory tests for the drug product at this time.

Drug Interactions

ACD-A is added to whole blood without any other drug products, and therefore, there are no drug interaction concerns.

Carcinogenesis, mutagenesis, impairment of fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential of ACD-A.

Pregnancy

Long-term studies in animals have not been performed to evaluate the effects of ACD-A on pregnant women.

Pediatric Use

The safety and effectiveness of ACD-A in children have not been established.

ADVERSE REACTIONS

Not applicable. This product is used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP).

OVERDOSAGE

Not applicable. This product is used as an anticoagulant in the extracorporeal blood processing with Autologous PRP Systems in production of platelet rich plasma (PRP).

DOSAGE AND ADMINISTRATION

Refer to the manufacturer's Operator's Manual of the Autologous PRP System for the Directions for Use.

HOW SUPPLIED

Anticoagulant Citrate Dextrose Solution, Solution A, U.S.P., (ACD-A),

NDC	REF	SIZE	CASE
23731-6051-5	6053	50 mL Vial	12 Vials/Case

It is recommended that the product be stored at ambient room temperature, 24°C (75°F); however, the product can be stored between 15°C (59°F) and 30°C (86°F). Protect from freezing and exposure to excessive heat should be minimized.

Rx Only

Manufactured for:



Citra Anticoagulants, Inc.
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 1-800-299-3411



Manufactured by:
 Cytosol Laboratories, Inc.
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