ACD SOLUTION MODIFIED - acd solution modified solution
AnazaoHealth Corporation

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

ACD SOLUTION MODIFIED

Per your order, we have compounded ACD Solution Modified as a solution of 10 mL in a 100 mL vial. The characteristics of this compounded preparation are as follows

DESCRIPTION

Each 100 mL vial contains 80 mg citric acid, 224 mg sodium citrate anhydrous, and 120 mg dextrose anhydrous in a sterile, non-pyrogenic solution of 10 mL. The pH of the solution has been adjusted to be between 4.5 to 5.5

CLINICAL PHARMACOLOGY

In vitro, citrate ions combine with ionic calcium in the blood and the resulting

lack of ionic calcium prevents coagulation. Blood that has been treated with citrate anticoagulants is nontoxic to the body when injected in small amounts intravenously. After injection, citrate ions are rapidly removed from the blood by the liver, polymerized into glucose, and then metabolized in the usual manner

INDICATIONS AND USAGE

ACD solution modified is to be used in the labeling of red blood cells for intravenous administration with Cr-51 Sodium Chromate.

CONTRAINDICATIONS

There are no known contraindications.

DOSAGE AND ADMINISTRATION

Red Blood Cell Labeling Procedure

1. Labeling may be performed without washing or centrifugation steps directly in the reaction vial.
2. A 30 to 50 mL sample of whole blood is withdrawn from the patient and added aseptically to a vial of ACD Solution Modified.
3. 50 to 150 microcuries of Sodium Chromate 51 is then injected into the reaction vial using a shielded syringe. The amount of radioactivity added to the vial will
   depend on the intended use of the labeled red blood cells.
4. The suspension is incubated for 30 to 60 minutes at room temperature with frequent, gentle agitation.
5. After incubation, 100 mg Ascorbic Acid Injection is injected into the vial. The ascorbic acid reduces any remaining unbound dianionic chromium 51 to the anionic state which does not penetrate red blood cells; thus in vivo labeling of red blood cells is prevented.

Storage and Handling

Store the product at room temperature

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Figure 1

ACD SOLUTION MODIFIED

acd solution modified solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51808-201
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL) (ANHYDROUS CITRIC ACID - UNII:XF417D3PSL)	ANHYDROUS CITRIC ACID	8 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS TRISODIUM CITRATE (UNII: RS7A450LGA)	22.4 mg in 1 mL
ANHYDROUS DEXTROSE (UNII: 5SL0G7R0OK)	12 mg in 1 mL

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51808-201-01	10 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		05/23/2012	

Labeler - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE

Revised: 5/2012 AnazaoHealth Corporation