

SULFUR COLLOID - sulfur colloid injection, powder, lyophilized, for 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](#).

Sulfur Colloid Kit
(for the preparation of Tc99m-Sulfur Colloid injection)

DESCRIPTION

Dear Medical Professional,

AnazaoHealth Sulfur Colloid Kit consists of three separate nonradioactive components:

1. A 10 milliliter **reaction** vial containing: Sodium Thiosulfate, 4.8 mg, Gelatin (Porcine), 3.6 mg and Sodium Edetate, 2.3 mg. The contents of the vial are lyophilized and are under vacuum
2. Vial A, a 5 ml. vial containing: 0.25 N. Hydrochloric Acid. The total volume in this vial is 1.2 mL.
3. Vial B, a 5 ml. vial containing: Sodium Hydroxide, 12 mg, Sodium Phosphate dibasic, 15.7 mg, Sodium Phosphate, monobasic, 48.4 mg, Sterile Water for Injection. The total volume in this vial is 1.2 mL

INDICATIONS AND USAGE

Tc99m Sulfur Colloid is used in lymphoscintigraphy studies in breast cancer patients, for liver, spleen and bone marrow imaging and gastric transit studies and gastroesophageal reflux.

INSTRUCTIONS

Preparation of Technetium Tc 99m-Sulfur Colloid:

1. Collect components: 10 ml. Reaction Vial, Solution A, Solution B, Lead Pig, Boiling Water Bath.
2. Draw up 1 ml. Solution A. (HCl solution) in syringe.
3. Draw up 2.5 ml. Tc-99m Pertechnetate containing desired activity, dilute with sterile normal saline if necessary.
4. Add the 2.5 ml Tc-99m Pertechnetate to the shielded reaction vial.
5. Immediately add the 1 ml. Solution A.
6. **Vent vial to release excess vacuum. Remove vent before boiling.**
7. Shake gently to mix.
8. **Place shielded vial in boiling water bath for 5 minutes for liver imaging and 3 minutes for lymphoscintigraphy imaging use.**
9. Remove from boiling water and let cool for a few minutes.
10. Draw up 1 ml. Solution B. (Phosphate Buffer) while reaction vial is cooling
11. After cooling Reaction vial, add the 1 ml Solution B and shake gently to mix. Caution: be sure vial is cool to avoid excess pressure
12. Quality control: ITLC-SG in normal saline. Greater than 95% should stay at the origin
13. Tc 99m Sulfur Colloid expires 6 hours after mixing

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Sulfur Colloid Reaction Vial Tc99m Labeling

Sodium Thiosulfate 6mg, Edetate Disodium 2.3mg

Gelatin (Porcine) 4.5mg

Lot#:

Pharmacy Compounded

Exp:

Sterile, non-pyrogenic for injection



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SULFUR COLLOID

sulfur colloid injection, powder, lyophilized, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51808-220
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
GELATIN (UNII: 2G86QN327L) (GELATIN - UNII:2G86QN327L)	GELATIN	4.5 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM THIOSULFATE (UNII: HX1032V43M)	6 mg
EDETATE DISODIUM (UNII: 7FLD91C86K)	2.3 mg

Product Characteristics

Color		Score	score with uneven pieces
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51808-220-01	1 in 1 KIT		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		07/01/2012	

Labeler - AnazaoHealth Corporation (011038762)

Registrant - AnazaoHealth Corporation (011038762)

Establishment

Name	Address	ID/FEI	Business Operations
AnazaoHealth Corporation		011038762	MANUFACTURE(51808-220)

Revised: 7/2012

AnazaoHealth Corporation