ISOLOGIC
Innovative Radiopharmaceuticals

SULPHIDE COLLOID KIT
for the preparation of ^{99m}Tc Sulphide Colloid Injection
PRODUCT MONOGRAPH

DESCRIPTION
The kit consists of 30 mL vials, which contain the sterile, non-pyrogenic, non-radioactive ingredients necessary to produce Technetium ^{99m}Tc Sulphide Colloid for intravenous use.
The following ingredients are present in each vial

1. Sulphide Colloid Solution 'A' (The total volume of kit component is adjusted to meet the needs of the individual customer)

	per mL
Sodium Thiosulfate Pentahydrate	3 mg
Potassium Perrhenate	0.5 mg
Gelatin	4 mg
Sterile Water for Injection	qs 1 mL

2. Sulphide Colloid Solution 'B' (The total volume of kit component is adjusted to meet the needs of the individual customer)

	per mL
Sodium Phosphate Dibasic Heptahydrate	93 mg
Sodium Phosphate Monobasic Monohydrate	8 mg
Sterile Water for Injection	qs 1 mL

3. 1N HCl

When prepared according to the directions, the labeling is greater than 95% and remains stable throughout the useful life of preparation. No bacteriostatic agent is present.

ACTION
When colloidal particles of 0.1 µ or 1 µ size are injected intravenously, their distribution in the body such that 80% or 90% is captured by the phagocytic (Kupffer) cells of the liver 5 to 10% is captured by the phagocytic cells of the spleen and the remainder by the reticuloendothelium of the bone marrow. Nearly all of the colloid particles are too small to lodge in the capillary bed of the lungs. The gall bladder, GI tract, urinary bladder are likewise not visualized and therefore no organ interference occurs on the scan.

INDICATIONS
Technetium ^{99m}Tc Sulphide Colloid Injection may be used to perform: i) liver and spleen imaging; ii) bone marrow imaging; and iii) lymphoscintigraphy.

CONTRAINDICATIONS
None known.

WARNINGS
The contents of the kit are NOT radioactive before preparation and are NOT to be administered directly to the patient. After the addition of Sodium Pertechnetate ^{99m}Tc, adequate shielding of the final preparation must be maintained.

Adequate studies have not yet been performed on animals to determine whether this drug affects fertility, or has teratogenic potential or other adverse effects on the fetus. This radiopharmaceutical should not be administered to pregnant or nursing women unless it is considered that the benefits to be gained outweigh the potential hazards.

Where an assessment of the risk-to-benefit ratio suggests the use of this product in lactating mothers, nursing should be stopped.
Ideally, the use of radiopharmaceuticals in women of childbearing age, especially in examination of an elective nature, should be limited to the first few days (approximately 10) following the onset of menses.

The risk-to-benefit ratio should be assessed before the use of this radiopharmaceutical in children.

^{99m}Tc Sulphide Colloid should be used only under supervision of a health professional experienced in the use of radioactive drugs and whose experience has been approved by the appropriate agency authorized to license the use of radionuclides.

PRECAUTIONS
The components of the kit are sterile and non-pyrogenic. It is essential that the user follows the directions carefully and adheres to strict aseptic procedures during preparation.

Pertechnetate solutions containing more than 10 µg/mL of aluminum ion should not be used for the formation of ^{99m}Tc Sulphide Colloid Injection.

The stability of colloid preparations may be decreased in the presence of polyvalent cations and aging, resulting in the aggregation of the individual colloidal particles.

As in the use of any other radioactive material, care should be taken to ensure minimal radiation exposure to the patient and occupational workers.

Diagnostic — For intravenous, intradermal and subcutaneous use

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ADVERSE REACTIONS

Hypersensitivity reactions, including anaphylaxis, have been reported in patients receiving sulphide colloid preparations. Also, on rare occasions, pyrogenic reactions have been reported. These reactions are believed to be due to gelatin used to stabilize the product.

PHARMACOLOGY

Liver scanning using ^{99m}Tc Sulphide Colloid is a simple technique to image functioning hepatic parenchyma and to determine the size, shape and intra-abdominal location. After injection, the colloidal particles are phagocytized by the cells of the RES. Blood and plasma clearance occurs rapidly, i.e. - 1 hour post injection plasma concentration was reported to be 0.005% in humans. Once the colloidal particles are engulfed by the RES cells they remain fixed for the duration of the scanning procedure because the colloidal particles remain in the liver indefinitely and therefore the biological half-life of ^{99m}Tc Sulphide Colloid is equal to its physical hall-life (6.02 hours). In 3 patients, the 24 hour urinary excretion ranged from 0.2% to 3% of the administered dose and fecal excretion from 0.1% to 1% in 48 hours.

Reference: For plasma conc. and fecal and urinary excretion: Harper P.C., Lathrop K.A. and Gottschalk A.: Radioactive Pharmaceuticals AEC Symposium Series 6: p335 (April) 1966

PHYSICAL CHARACTERISTICS

Technetium ^{99m}Tc decays by Isometric transition with a physical half-life of 6.02 hours. The principal photon that is useful for detection and imaging studies is a gamma photon with a mean percentage disintegration of 89% and a mean energy of 140.5 keV. The exposure rate constant for ^{99m}Tc is 0.78 R/millicurie hr. at 1 cm. The hall-value layer is 0.2 mm of Pb. To facilitate control of the radiation exposure from millicurie amounts of this radionuclide, the use of 2.5 mm thickness of Pb will attenuate the radiation emitted by a factor of 1000.

Table 1. Radiation attenuation by lead shielding

Shield Thickness (Pb) cm	Coefficient of Attenuation
0.2	0.5
0.8	10^{-1}
1.6	10^{-2}
2.5	10^{-3}
3.3	10^{-4}
4.5	10^{-5}

Table 2. Physical Decay Chart: ^{99m}Tc half-life 6.02 hours

Hours	Fraction Remaining	Hours	Fraction Remaining
0*	1.000	5.0	0.562
0.5	0.994	5.5	0.531
1.0	0.841	6.0	0.501
1.5	0.841	6.5	0.473
2.0	0.794	7.0	0.446
2.5	0.750	7.5	0.421
3.0	0.708	8.0	0.398
3.5	0.668	8.5	0.375
4.0	0.631	9.0	0.355
4.5	0.595		* Calibration Time

To correct for physical decay of this radionuclide, the fractions that remain at selected intervals after the time of calibration are shown in Table 2.

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Radiation Dosimetry

The estimated absorbed radiation doses to average adult and pediatric patients from intravenous administration of ^{99m}Tc Sulphide Colloid based on the maximum adult dose of 300 MBq are shown in Table 3.

Table 3. Estimated ADULT and PEDIATRIC absorbed radiation dose (mGy)
^{99m}Tc Sulphide Colloid - Intravenous administration

	Adult	15 year	10 year	5 year	1 year
Weight (kg)	70	55	35	20	10
Usual Dose (MBq)	300	165	105	60	30
Organ					
Liver	22	16	15	11	10
Spleen	23	18	17	15	14
Bone Marrow	3.3	2.5	2.4	2.3	2.2
Testes	0.18	0.13	0.14	0.13	0.14
Ovaries	0.66	0.48	0.51	0.47	0.42
Whole Body	1.4	3.0	2.9	2.5	2.2
Effective Dose Equivalent (mSv/MBq)					

Modified from Radiation Dose to Patients from Radiopharmaceuticals, *Annals of the ICRP,* ICRP Publication 53: 180, 1994

Table 4. Estimated ADULT absorbed radiation dose at injection site
^{99m}Tc Sulphide Colloid Intradermal or Subcutaneous Administration

Injection Site	Dose (mGy/MBq)
Rectus Sheath	27
Finger Web Space	84
Toe Web Space	75
Perianal	43

Modified from Bronskill MJ, Radiation Dose estimates for Interstitial Radiocolloid Lymphoscintigraphy, Seminars in Nuclear Medicine 13: 20-25, 1983

DOSE AND ADMINISTRATION

The patient dose should be measured by a suitable radioactivity calibration system immediately prior to administration. Withdrawals for administration must be made aseptically.

ADULT

The recommended adult dosage range of ^{99m}Tc Sulphide Colloid is 40 to 300 MBq (1 to 8 mCi) by intravenous injection for liver/spleen and marrow imaging. For lymph node imaging 20 to 40 MBq (0.5 to 1.0 mCi) of filtered ^{99m}Tc Sulphide Colloid (using a 0.2 µm filter) is administered by either intradermal or subcutaneous injection.

PEDIATRIC

For liver/spleen imaging and bone marrow imaging a dose of 3 MBq/kg body weight should be used. A minimum dose of 7.4 MBq should be used for the procedure.

STORAGE AND EXPIRATION

The finished preparation should be stored with appropriate radiation shielding at room temperature and discarded 12 hours after the time of calibration. The kit should be stored at room temperature. After the first entry into solutions A, B and HCl, refrigerate the vials for use within 7 days.

KIT CONTAINS

Package Insert and Directions for Preparation
The sterile, pyrogen-free multi-dose solutions of

1. Sulphide Colloid Solution 'A'
2. 1N HCl
3. Sulphide Colloid Solution 'B'