

# <sup>99m</sup>Tc colloidal tin

Hepatate®

## 1. Indications

<sup>99m</sup>Tc-colloidal tin is used reticuloendothelial imaging of liver and spleen.

## 2. Preparation

Approved product, but not commercially available in the Netherlands.

## 3. Quality control

See European Pharmacopeia *Technetium <sup>99m</sup>Tc Colloidal tin injection*

### Limits

pH: 4-7

Tin: ≤ 1 mg/ml

Test solution. Dilute 3,0 ml of the injection to be examined to 50,0 ml with a 103 g/l hydrochloric acid.

Reference solution. Dissolve 0,115 g of stannous chloride R in 103 g/l hydrochloric acid and dilute to 1000 ml with the same acid.

To 1,0 ml of each solution add 0,05 ml thioglycolic acid, 0,1 ml of dithiol reagent, 0,4 ml of a 20 f/l solution of sodium laurilsulfate and 3,0 ml of a 21 g/l solution of hydrochloric acid. Mix. Measure the absorbance of each solution at 540 nm, using a 21 g/l hydrochloric acid as the compensation liquid. The absorbance of the test solution is not greater than that of the reference solution.

Plate	TLC Silica gel plate
Test solution	The preparation to be examined
Mobile phase	Sodium chloride solution 0,9% purged with nitrogen.
Application	5-10 µl
Identification of the spots	Rf = 0-0,1 <sup>99m</sup> Tc tin colloid Rf = 0,9-1 <sup>99m</sup> TcO <sub>4</sub> <sup>-</sup>
Development	Over a path of 10-15 cm in about 10 min
Drying	In air
Limits	≥ 95% <sup>99m</sup> Tc tin colloid

#### 4. Interactions

Drugs known to be associated with short-term or long-term hepatotoxicity, such as cancer therapeutic agents, notably the nitrosoureas (lomustin, carmustin) may affect the biodistribution pattern of radiolabelled colloids. Tetracyclin and anticonceptives have been mentioned as well.

Liver uptake may also decrease after therapy with general anaesthetic agents, e.g. halothane, due to decrease of hepatic blood flow.

Aluminium and antacids may lead to an increased lung uptake.

#### 5. Adverse reactions

Adverse reactions have occasionally been reported following the intravenous injection of colloids for liver and spleen imaging. The reactions generally involve vasomotor problems with malaise, bradycardia and lowered blood pressure. Angio-oedema, often facial, may occur, as may central chest or back pain with shortness of breath, occasionally complicated by true bronchospasm. Cutaneous reactions are relatively rare. The majority of reactions have been relatively mild.

#### 6. Biodistribution & pharmacokinetics

The site of phagocytosis depends on a number of factors including the size of the particles - large particles are trapped in the lungs, smaller particles are taken up in the liver and spleen.

Upon intravenous injection, <sup>99m</sup>Tc colloidal tin is rapidly cleared from the blood by the reticuloendothelial system with a nominal clearance half-life of approximately one and a half minutes.

Uptake of the radioactive colloid by the components of the reticuloendothelial system is dependent upon relative blood flow rates and the functional capacity of phagocytic cells. In an average patient, 80-90% of the injected colloid particles are phagocytosed by the Kupffer cells of the liver, 5-10% are taken up by the spleen and by the bone marrow. If hepatic function is impaired, particles will be phagocytosed in the lung and bone marrow more than in the liver. Increased uptake in the spleen indicates diffuse liver disease.

#### 7. Stability

The labelled product must be injected within 6 h of reconstitution. Store the product at not above 25°C before and after reconstitution. Do not freeze.

#### 8. Literature

- SmPC Hepatate, kit for the preparation of Technetium [<sup>99m</sup>Tc] Colloidal Tin Injection.