

^{99m}Tc albumin

^{99m}Tc HSA, Vasculosis[®], HSA (Human serum albumin)

1. Indications

^{99m}Tc human serum albumine (HSA) is not an approved product in The Netherlands. ^{99m}Tc HSA is indicated for blood pool imaging, angiocardiology and ventriculography.

2. Preparation

The lyophilized preparation is readily soluble in ^{99m}Tc pertechnetate injection in saline. Aseptically sterile ^{99m}Tc pertechnetate should be injected into the vial in a volume of 1-8 ml, with an activity up to 2,20 GBq. Freshly eluted ^{99m}Tc pertechnetate (less than 2 h) should be used obtained from generators previously eluted within the last 24 h. After introduction of the volume of ^{99m}Tc pertechnetate, without removing the needle, withdraw an equivalent volume of nitrogen in order to avoid excess pressure in the vial. Shake the vial carefully several times and allow to stand for 20 min.

3. Quality control

Several methods with thin-layer chromatography (TLC) are described to establish radiochemical purity.

European Pharmacopeia (monograph 0640)

Plate: TLC silica gel plate

Mobile phase: methyl ethyl ketone

Application: 5-10 µl

Development over a path of 10-15 cm in about 10 min

Drying: in air

Retardation factors:

^{99m}Tc Technetium human albumin = 0,0

^{99m}Tc pertechnetate ion (impurity A) = 0,9-1,0

Limit: impurity A: maximum 5% of total radioactivity due to ^{99m}Tc pertechnetate

Product information Vasculosis[®]

Plate: Whatman 1 strip of sufficient length and not less than 2,5 cm wide.

Mobile phase: methanol/water (80/20)

Application: 5-10 µl

Development over a path of 10-15 cm, time not stated

Drying: in air

Retardation factors:

^{99m}Tc Technetium human albumin = 0,0

^{99m}Tc pertechnetate ion (impurity A) = 0,6

Limit: impurity A: maximum 5% of total radioactivity due to ^{99m}Tc pertechnetate

4. Interactions

No information.

5. Adverse reactions

Flushing, shortness of breath, dizziness, tachycardia, facial edema and low blood pressure are probable reactions. Allergic reactions, vascular dilation and vascular syncope may also occur.

6. Biodistribution & pharmacokinetics

Human albumin occurs naturally as the major protein component of blood. When labeled with ^{99m}Tc and given intravenously, it is distributed throughout the body in much the same way as the patient's serum albumin, and serves as a suitable tracer with which to transiently image the vascular compartment. It stays for at least 4 h in the bloodstream. No significant concentration of ^{99m}Tc Technetium human serum albumin outside the vascular space is observed, except in kidney, bladder and liver. It does not concentrate in thyroid, salivary and gastric glands. The major loss from the albumin pool resulted from urinary excretion.

7. Stability

The product has a shelf-life of about 6 h after labeling and should be stored at 2-8°C in the refrigerator.

8. Literature

- SmPC Vasculosis 10 mg kit for radiopharmaceutical preparation, CIS bio international, member of IBA Molecular group of companies, 12/2012.