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Fludeoxyglucose F 18 Injection

Change to read:

DEFINITION

Fludeoxyglucose F 18 Injection is a sterile, aqueous solution of Δ fludeoxyglucose F 18. The chemical name of fludeoxyglucose F 18 is 2-deoxy-2-[^{18}F]fluoro-D-glucose (also known as 2-deoxy-2-fluoro-[^{18}F]D-glucopyranose). Δ (USP 1-May-2024) It contains NLT 90% and NMT 110% of the labeled amount of Δ fludeoxyglucose F 18 ($\text{C}_6\text{H}_{11}^{18}\text{FO}_5$) Δ (USP 1-May-2024) expressed in MBq (or mCi)/mL at the time indicated in the labeling. It may contain buffering agents, preservatives, stabilizing agents, or sodium chloride. It does not contain any added carrier.

IDENTIFICATION

• A. RADIONUCLIDIC IDENTITY

(See [Radioactivity \(821\)](#), [5. Identification of Radionuclides](#), [5.1 Half-Life Determination](#))

Acceptance criteria: The half-life is 105–115 min.

• B. RADIOCHEMICAL IDENTITY

Spray reagent: 10 mg/mL of [p-anisidine](#) in a mixture of [methanol](#) and [butanol](#) (10:90)

Procedure: After completing the *Analysis* in the test for *Radiochemical Purity*, spray the TLC strip with *Spray reagent* and heat strip on a hot plate until the spot for [USP Fludeoxyglucose RS](#) is visible.

Acceptance criteria: The R_f value of fludeoxyglucose F 18 in the *Sample solution* is 90%–110% of the R_f value of [USP Fludeoxyglucose RS](#) in the *Standard solution* as determined in the test for *Radiochemical Purity*.

ASSAY

Change to read:

• RADIOACTIVE CONCENTRATION (STRENGTH)

(See [Radioactivity \(821\)](#), [6. Assay of Radionuclides](#).)

Analysis: Using a dose calibrator or other suitable instrument for radiation measurements, measure the quantity of radioactivity in a known volume of the Injection. Determine the radioactivity, in MBq (or mCi)/mL.

Acceptance criteria: Δ 90%–110% Δ (USP 1-May-2024) at the time indicated on the label

PURITY

• RADIONUCLIDIC PURITY

(See [Radioactivity \(821\)](#), [5. Identification of Radionuclides](#), [5.2 Gamma-Ray Spectrometry](#).)

[NOTE—This may be a periodic quality indicator test. The Injection may be distributed and dispensed prior to completion of this test.]

Analysis: Determine the purity of fludeoxyglucose F 18 in the portion of Injection taken for the *Radionuclidic Impurities* test:

$$\text{Result} = [1 - (C_i/C_T)] \times 100$$

C_i = sum of the concentrations of all longer-lived radionuclides, decay corrected to the expiration time from the *Radionuclidic Impurities* test (Bq/mL or $\mu\text{Ci/mL}$)

C_T = sum of the concentrations of all long-lived radionuclides and fludeoxyglucose F 18, all decay corrected to the expiration time from the *Radionuclidic Impurities* test (Bq/mL or $\mu\text{Ci/mL}$)

Acceptance criteria: At the time of expiration, NLT 99.5% of radionuclides in the Injection corresponds to ^{18}F .

Change to read:

• RADIOCHEMICAL PURITY

Δ Δ (USP 1-May-2024)

Standard solution: Δ 5 Δ (USP 1-May-2024) mg/mL of [USP Fludeoxyglucose RS](#) in Δ [water](#) Δ (USP 1-May-2024)

Sample solution: A volume of Injection, appropriately diluted Δ with [water](#) Δ (USP 1-May-2024) to a concentration of Δ 18.5–111 Δ (USP 1-May-2024) MBq/mL (Δ 0.5–3 Δ (USP 1-May-2024) mCi/mL) or to a concentration suitable for the detector to be used

Chromatographic system

Mode: TLC

Adsorbent: ▲0.2 or 0.25▲ (USP 1-May-2024) -mm layer of [chromatographic silica gel](#) strip

Application volume: 0.5 µL

Developing solvent system: ▲[Acetonitrile](#) and [water](#) (95:5)▲ (USP 1-May-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram in the *Developing solvent system* until the solvent has moved about 90% of the length of the strip. Remove the strip and allow to dry in the air or under a stream of a compressed gas such as nitrogen or air. Determine the radioactivity distribution by scanning the chromatogram with a suitable collimated radiation detector. After completing the test for *Radiochemical Purity*, use the TLC strip for the *Radiochemical Identity* test.

Calculate the percentage of fludeoxyglucose F 18 ▲(C₆H₁₁¹⁸FO₅)▲ (USP 1-May-2024) in the portion of Injection taken:

$$\text{Result} = (r_u/r_T) \times 100$$

r_u = area of the peak due to fludeoxyglucose F 18 in the radio-TLC chromatogram

r_T = sum of areas of all the peaks including the peak due to fludeoxyglucose F 18 in the radio-TLC chromatogram

Acceptance criteria: NLT 90% of the total radioactivity is due to fludeoxyglucose F 18

IMPURITIES

Change to read:

• RADIONUCLIDIC IMPURITIES

[NOTE—This may be a periodic quality indicator test. The Injection may be distributed or dispensed prior to completion of the test.]

▲**Sample solution:**▲ (USP 1-May-2024) A suitable volume of Injection, decayed for a suitable length of time to eliminate interference due to ¹⁸F emissions

Analysis: Using a suitable gamma-ray spectrometer count an appropriate aliquot of the ▲*Sample solution*▲ (USP 1-May-2024) for a period of time sufficient to collect a gamma spectrum. The resultant gamma spectrum should be analyzed for the presence of identifiable photopeaks, which are characteristic of radionuclidic impurities.

Determine the concentration of radionuclidic impurities in Bq (or µCi)/mL, decay corrected to the expiration time of the Injection:

$$\text{Result} = (C_i/C_T) \times 100$$

C_i = sum of the concentrations of all longer-lived radionuclides, decay corrected to the expiration time (Bq/mL or µCi/mL)

C_T = sum of the concentrations of all long-lived radionuclides and fludeoxyglucose F 18, all decay corrected to the expiration time (Bq/mL or µCi/mL)

Acceptance criteria: Total radionuclidic impurities are NMT 0.5% of the radioactivity of the Injection (see the Assay), decay corrected to the time of expiration.

• RADIOCHEMICAL IMPURITIES

Analysis: From the radio-TLC chromatogram obtained in the *Radiochemical Purity* test, calculate the radiochemical impurities in the portion of Injection taken:

$$\text{Result} = (r_i/r_T) \times 100$$

r_i = sum of areas of all the peaks other than fludeoxyglucose F 18 in the radio-TLC chromatogram

r_T = sum of areas of all the peaks including the peak due to fludeoxyglucose F 18 in the radio-TLC chromatogram

Acceptance criteria: NMT 10%

• LIMIT OF FLUDEOXYGLUCOSE RELATED COMPOUND A

[NOTE—Perform this test if fludeoxyglucose related compound A (also known as aminopolyether) is used in the synthesis of fludeoxyglucose F 18.]

Adsorbent: Aluminum oxide strips

Standard solution: 50 µg/mL of [USP Fludeoxyglucose Related Compound A RS](#) in [saline TS](#)

Sample solution: Use the Injection.

Application volume: 4 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Spot the *Standard solution* and *Sample solution* on the strip. Allow to dry and place the strip in a chamber containing fresh [iodine](#) crystals. Develop the plate until a spot is visible on the strip for the *Standard solution*.

Acceptance criteria: The size and intensity of the spot from the *Sample solution* is NMT that from the *Standard solution*.

Change to read: