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Ammonia N 13 Injection

DEFINITION

Change to read:

▲Ammonia N 13 Injection is a sterile aqueous solution of [^{13}N] Ammonia ($^{13}\text{NH}_3$). It contains NLT 90% and NMT 110% of the labeled amount of [^{13}N] Ammonia ($^{13}\text{NH}_3$) expressed in MBq(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. ▲2S (USP41)

IDENTIFICATION

Change to read:

• A. RADIONUCLIDIC IDENTITY

▲(See [Radioactivity \(821\), 5. Identification of Radionuclides, 5.1 Half-Life Determination](#).) The half-life of ^{13}N is 9.5–10.5 min. ▲2S (USP41)

Change to read:

• B. RADIOCHEMICAL IDENTITY

▲**Procedure:** After completing the *Analysis* in the *Radiochemical Purity* test, spray or stain the TLC strip with [iodoplatinate TS](#). Allow the TLC strip to develop for 10 min. Place the developed TLC strip in an iodine chamber. The spot due to ammonium ion on the strip for the *Standard solution* appears as an orange-brown spot against a light maroon background.

Acceptance criteria: The R_f value of $^{13}\text{NH}_3$ in the *Sample solution* is 90%–110% of the R_f value of the ammonium ion as determined in the *Standard solution* in the test for *Radiochemical Purity*. ▲2S (USP41)

ASSAY

Change to read:

• RADIOACTIVE CONCENTRATION (STRENGTH)

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

Analysis: Determine the radioactivity, in MBq (or mCi)/mL, of the Injection, using a suitable calibrated system.

Acceptance criteria: ▲90%–110% at the time indicated on the label ▲2S (USP41)

PURITY

Change to read:

• 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 ammonia N 13 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 (μCi/mL)

C_T = sum of the concentrations of all long-lived radionuclides and ammonia N 13, all decay corrected to the expiration time from the *Radionuclidic Impurities* test (Bq/mL) or (μCi/mL)

Acceptance criteria: At the time of expiration, NLT 99.5% of radionuclides in the Injection correspond to ^{13}N . ▲2S (USP41)

Change to read:

• RADIOCHEMICAL PURITY

▲ **Standard solution:** 100 mg/mL of [USP Ammonium Chloride RS](#) in [water](#)

Sample solution: A volume of Injection, appropriately diluted if necessary, to a concentration of 5–30 MBq (0.135–0.81 mCi)/mL or to a concentration suitable for the detector to be used

Chromatographic system

Mode: TLC

Detection: Radio-TLC scanner

Adsorbent: Cellulose diethylaminoethyl strips; 1.5-cm × 8-cm

Application volume: 0.5 µL

Developing solvent: [Methanol](#) and [water](#) (75:25)

Analysis

Samples: *Standard solution* and *Sample solution*

Apply the *Standard solution* and *Sample solution* independently as two adjacent spots on the TLC strip. Allow the spots to dry. Place the TLC strip in the developing chamber with *Developing solvent*. When the solvent front reaches about 1 cm from the top of the strip, remove the strip from the chamber and allow it to dry. Determine the radioactivity distribution by scanning the chromatogram with a suitable radiation detector. After completing the test for *Radiochemical Purity*, use the TLC radiochromatogram for the *Radiochemical Impurities* test. After completing the test for *Radiochemical Purity*, use the TLC strip for the *Radiochemical Identity* test.

Calculate the percentage of the labeled amount of $^{13}\text{NH}_3$ in the portion of Injection taken from the chromatogram of the *Sample solution*:

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

r_U = response of $^{13}\text{NH}_3$ from the *Sample solution*

r_T = sum of the responses of all peaks including $^{13}\text{NH}_3$ from the *Sample solution*

Acceptance criteria: NLT 95% of the total radioactivity is due to ammonia N 13. ▲2S (USP41)

IMPURITIES

Add the following:

▲ • 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: A suitable volume of Injection, decayed for a suitable length of time to eliminate interference due to ^{13}N emissions

Analysis: Using a suitable gamma-ray spectrometer, count an appropriate aliquot of the sample solution 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 ammonia N 13, 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. ▲2S (USP41)

Add the following:

▲ • RADIOCHEMICAL IMPURITIES

Analysis: Calculate the percentage of radiochemical impurities in the portion of Injection taken from the TLC radiochromatogram of the *Sample solution*, as obtained in the *Radiochemical Purity* test.

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

r_i = sum of the responses all peaks excluding the response of $^{13}\text{NH}_3$ from the *Sample solution*

r_T = sum of the responses of all peaks including $^{13}\text{NH}_3$ from the *Sample solution*

Acceptance criteria: NMT 5% ▲2S (USP41)