



CERTIFICATE OF ANALYSIS

DRAXIMAGE MAA kit, CND (10 vials/kit)
2.5 mg of Stannous Albumin Macro Aggregate / vial

| | | | |
|-----------------------------|-------------------------|---|------------------|
| # Certificate: | 2022FE28-1 | | |
| Batch Number: | 1K139 | Manufacturing Date: | 2022JA17 |
| Lot Number (FP): | 1K139 | Expiry Date: | 2024 - JA |
| Product Number: | 500150 | Specification Number and Version: | 500150_v15 |
| Standard of Testing: | House, USP ¹ | Date of Release: (Date with QA Initials) | MMN 2022 FE 23 ① |

| Tests on the Lyophilized product | | | |
|--|-------------------|--|--------------------------|
| Test Description | Analytical Method | Specifications | Results |
| Description | 10019 | A white freeze-dried plug or powder, clean and free of foreign matter. The flip-off cap is blue. | Conforms |
| Resuspendability | 10079 | A white suspension which may separate on standing. | Conforms |
| pH | 10005 | 5.2 – 6.0 | 5.5 |
| Loss on Drying | 10021 | ≤ 5% | 2% |
| Particle Density | 10088 | 3 - 8 x 10 ⁶ aggregated albumin particles in each vial | 5 x 10E06 particles/vial |
| Particle Size | 10080 | Particle Size < 10 µm: ≤ 10% | 8% |
| | | Particle Size ≥ 10 µm - ≤ 70 µm: ≥ 90% | 92% |
| | | Particle Size > 100 µm: ≤ 0.2% | <0.1% |
| | | Particle Size > 150 µm: none | None |
| MAA Identification | 10000 | A blue color develops. | Conforms |
| SnCl ₂ ·2H ₂ O Assay | 10039 | ≥ 0.06 mg/vial | 0.11 mg/vial |
| Total Tin Assay | 10040 | ≤ 0.12 mg of SnCl ₂ ·2H ₂ O/vial | 0.09 mg/vial |
| Stannous Albumin Macro Aggregated Complex | 10082 | 2.2 – 3.0 mg/vial | 2.5 mg/vial |
| Human Serum Albumin | 10068 | 3.5 – 6.5 mg/vial (or alternative method 10089) | 5.4 mg/vial |
| Sodium Chloride | 10084 | 0.96 – 1.44 mg/vial | 1.34 mg/vial |

① PA 142623 MMN 2022 FE 28

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A Jubilant Pharma Company

OUR VALUES



Radiopharmaceuticals Division
Jubilant DraxImage Inc., dba Jubilant Radiopharma
16 751 TransCanada Highway
Kirkland, Québec, Canada H9H 4J4
Tel.: +1 888 633 5343
Fax: +1 866 431 4288
<http://www.jubilantradiopharma.com>



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| Tests on the Lyophilized product | | | |
|----------------------------------|-------------------|---|---|
| Test Description | Analytical Method | Specifications | Results |
| Residual Solvents ¹ | USP<467> | Meets USP requirements (No Test Required) | Conforms |
| Sterility ^{1,2} | 10007 | Sterile | Conforms |
| Bacterial Endotoxins | 10008 | ≤ 16.5 EU/vial | 8.2 EU/vial ⊗ |

| Tests on the Reconstituted product | | | |
|------------------------------------|-------------------|---|---|
| Test Description | Analytical Method | Specifications | Results |
| Radiochemical Purity | 10043 | Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at 15 – 30 minutes post labeling. | 100% |
| | | Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at least 8 hours post labeling. | 100% |
| Centrifugation Procedure | 10087 | Not more than 10% of the total radioactivity is found in the supernatant liquid, at 15 – 30 minutes post labeling. | 3% |
| | | Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 8 hours post labeling. | 2% |
| Biological Distribution | 10044 | In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection. | Animal 1: 89% Animal 2: 98% Animal 3: 98% |
| | | In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection. | Animal 1: 1% Animal 2: 1% Animal 3: 1% |
| | | In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection. | Animal 1: 1% Animal 2: 1% Animal 3: 1% |

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| Lot Number (FP): | 1K139 | Specification Number and Version: | 500150_v15 |
| Product Number: | 500150 | Date of Release: (Date with QA Initials) | MTN 20 22 FE 23 (1) |
| Standard of Testing: | House, USP ¹ | | |

Tests on the Reconstituted product

| Test Description | Analytical Method | Specifications | Results |
|-------------------------|-------------------|--|---|
| Biological Distribution | 10044 | In not less than 2 of 3 animals, at 8 -24 hours post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection. | Animal 1: 99% Animal 2: 93% Animal 3: 98% |
| | | In not less than 2 of 3 animals, at 8 - 24 hours post labeling, not more than a total of 5% of the radioactivity is found in the liver of the animal at 15 minutes post injection. | Animal 1: 1% Animal 2: 1% Animal 3: 1% |
| | | In not less than 2 of 3 animals, at 8 – 24 hours post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection. | Animal 1: 1% Animal 2: 1% Animal 3: 1% |

² Outside testing

This batch of product has been tested by Jubilant DraxImage Quality Control Laboratory under Canadian Establishment License Number **101869-A** and complies with the specification requirements.

MUSTAPHA TOLLABI
QC Sr. Supervisor

Verified by:
Name and Title

M. Tollabi

Signature

2022 FE 28

Date

FAIZA MINOONI QA Associate

Approved by:
Name and Title

F. Minooni

Signature

2022 FE 28

Date

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