



CERTIFICATE OF ANALYSIS

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

# Certificate:	2020DE22-1		
Batch Number:	0L261	Manufacturing Date:	2020OC19
Lot Number (FP):	0L261B	Expiry Date:	10/2022
Product Number:	30000001020	Specification Number and Version:	30000001020_v01
Standard of Testing:	House, USP ¹	Date of Release: (Date with QA Initials)	MTN 2020 DE 23

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	5.4
Loss on Drying	10021	≤ 5%	<1%
Particle Density	10088	3 - 8 x 10 ⁶ aggregated albumin particles in each vial	5 x 10E6 part./vial
Particle Size	10080	Particle Size < 10 µm: ≤ 10%	7%
		Particle Size ≥ 10 µm - ≤ 70 µm: ≥ 90%	93%
		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	0.10 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)	4.9 mg/vial
Sodium Chloride	10084	0.96 – 1.44 mg/vial	1.30 mg/vial
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	< 1.0 EU/vial

² Outside testing

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 Reconstituted product

<u>Test Description</u>	<u>Analytical Method</u>	<u>Specifications</u>	<u>Results</u>
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 12 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.	5%
		Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 12 hours post labeling.	4%
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.	1: 75% 2: 92% 3: 92%
		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.	1: 1% 2: 2% 3: 2%
		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.	1: 1% 2: 1% 3: 1%
		In not less than 2 of 3 animals, at 12 -24 hours post labeling, not less than 80% of the radioactivity is found in the lungs of the animal at 15 minutes post injection.	1: 87% 2: 94% 3: 88%
		In not less than 2 of 3 animals, at 12 - 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.	1: 2% 2: 2% 3: 1%
		In not less than 2 of 3 animals, at 12 – 24 hours post labeling, not more than 5% of the radioactivity is found in the kidneys of the animal at 15 minutes post injection.	1: 1% 2: 1% 3: 1%

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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

2020 DE 22

Date

Faiza Muneer
F. Muneer QA Associate

Approved by:
Name and Title

F. Muneer

Signature

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