CERTIFICATE OF ANALYSIS

DRAXIMAGE MAA kit, CND (10 vials/kit)

2.5 mg of Stannous Albumin Macro Aggregate / vial

# Certificate:	**2019DE06-1**		
Batch Number:	**9E506**	**Manufacturing Date:**	**2019MA21**
Lot Number (FP):	**9E506A**	**Expiry Date:**	**21 MA**
Product Number:	500150	**Specification Number and Version:**	500150_v14
Standard of Testing:	House, USP[1]	**Date of Release: (Date with QA Initials)**	LA 2019 DE12

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.	Conform
Resuspendability	10079	A white suspension which may separate on standing.	Conform
pH	10005	5.2 – 6.0	5.4
Loss on Drying	10021	≤ 5%	3%
Particle Density	10088	3 - 8 x 10^6 aggregated albumin particles in each vial	4 x 10E6 particles/vial
Particle Size	10080	Particle Size < 10 µm: ≤ 10%	4%
		Particle Size ≥ 10 µm - ≤ 70 µm: ≥ 90%	96%
		Particle Size > 100 µm: ≤ 0.2%	< 0.1%
		Particle Size > 150 µm: none	None
MAA Identification	10000	A blue color develops.	Conform
Uniformity of Dosage Units	10009	Stage I: The requirements are met if the acceptance value of the first 10 vials is less than or equal to L1.	8.3%
		Stage II: The requirements are met if the final acceptance value of the 30 vials is less than or equal to L1 and no individual content of the dosage unit is less than (1 – L2 x 0.01)M or more than (1 + L2 x 0.01)M.	N/A
$SnCl_2.2H_2O$ Assay	10039	≥ 0.06 mg/vial	0.10 mg/vial
Total Tin Assay	10040	≤ 0.12 mg of $SnCl_2 \cdot 2H_2O$/vial	0.07 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)	5.0 mg/vial
Sodium Chloride	10084	0.96 – 1.44 mg/vial	1.32 mg/vial
Safety Test / Toxicity (for Biologics) [1]	USP<88>	Meets USP	Conform

A Jubilant Pharma Company

OUR VALUES

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MT 2019 DE 06

CERTIFICATE OF ANALYSIS

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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)	Conform
Sterility[1,2]	10007	Sterile	Conform
Bacterial Endotoxins	10008	≤ 16.5 EU/vial	<1.2 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.	2%
		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: 93% Animal 2: 87% Animal 3: 91%
		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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MLT
2019 DE06

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Product Number:	500150	**Specification Number and Version:**	500150_v14
Standard of Testing:	House, USP[1]	**Date of Release: (Date with QA Initials)**	LA 2019 DE 12

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: 94% Animal 2: 98% Animal 3: 93%
		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 TOLCHABI, QC Sr. Supervisor — M. Tolchabi — 2019 DE 06

Verified by: Name and Title — Signature — Date

LAITMAS NYOUAZ, QA Associate — 2019 DE 12

Approved by: Name and Title — Signature — Date

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