CERTIFICATE OF ANALYSIS

DRAXIMAGE MAA kit, CND (10 vials/kit)

2.5 mg of Stannous Albumin Macro Aggregate / vial

# Certificate:	**2021DE21-1**		
Batch Number:	**1L260**	**Manufacturing Date:**	**2021NO08**
Lot Number (FP):	**1L260A**	**Expiry Date:**	**2023 - NO**
Product Number:	500150	**Specification Number and Version:**	500150_v15
Standard of Testing:	House, USP[1]	**Date of Release: (Date with QA Initials)**	HL 2021DE21

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%	<1%
Particle Density	10088	3 - 8 x 10^6 aggregated albumin particles in each vial	6 x 10E06 particles/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
$SnCl_2.2H_2O$ Assay	10039	≥ 0.06 mg/vial	0.10 mg/vial
Total Tin Assay	10040	≤ 0.12 mg of $SnCl_2 \cdot 2H_2O$/vial	0.08 mg/vial
Stannous Albumin Macro Aggregated Complex	10082	2.2 – 3.0 mg/vial	2.6 mg/vial
Human Serum Albumin	10068	3.5 – 6.5 mg/vial (or alternative method 10089)	4.8 mg/vial
Sodium Chloride	10084	0.96 – 1.44 mg/vial	1.36 mg/vial

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MT 2021 DE 21

A Jubilant Pharma Company

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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	6.6 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.	4%
		Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 8 hours post labeling.	3%
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: 87% Animal 2: 92% 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: 2% Animal 2: 2% Animal 3: 2%

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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: 95% Animal 2: 95% 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 — M. Tollabi — 2021 DE21

Verified by: Name and Title | Signature | Date

HALIMA LAHMIDI
QA, Associate — 2021 DE21

Approved by: Name and Title | Signature | Date

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