

## **CERTIFICATE OF ANALYSIS**

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

# Certificate:	2021SE13-1		
Batch Number:	1D386	Manufacturing Date:	2021MA11
Lot Number (FP):	1D386A	Expiry Date:	05/2023
Product Number:	3000001020	Specification Number and Version:	3000001020_v01
Standard of Testing:	House, USP <sup>1</sup>	Date of Release: (Date with QA Initials)	HL 2021 SEIL

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	
рН	10005	5.2 - 6.0	5.5	
Loss on Drying	10021	≤ 5%	1%	
Particle Density	10088	3 - 8 x 10 <sup>6</sup> aggregated albumin particles in each vial	4 x 10E6 part./vial	
86		Particle Size < 10 µm: ≤ 10%	9%	
		Particle Size ≥ 10 μm - ≤ 70 μm: ≥ 90%	91%	
Particle Size	10080	Particle Size > 100 µm: ≤ 0.2%	< 0.1%	
		Particle Size > 150 μm: none	None	
MAA Identification	10000	A blue color develops.	Conforms	
SnCl <sub>2</sub> .2H <sub>2</sub> O Assay	10039	≥ 0.06 mg/vial	0.09 mg/vial	
Total Tin Assay	10040	≤ 0.12 mg	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)	5.1 mg/vial	
Sodium Chloride	10084	0.96 – 1.44 mg/vial	1.31 mg/vial	
Residual Solvents <sup>1</sup>	USP<467>	Meets USP requirements (No test required)	Conforms	
Sterility <sup>1,2</sup>	10007	Sterile	Conforms	
Bacterial Endotoxins	10008	≤ 16.5 EU/vial	<1.1 EU/vial	

<sup>&</sup>lt;sup>2</sup>Outside testing

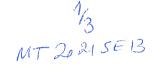
#### A Jubilant Pharma Company



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Tests on the Reconstituted product				
Test Description	Analytical Method	<u>Specifications</u>	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.		
		Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at least 12 hours post labeling.	99%	
Centrifugation Procedure	10087	Not more than 10% of the total radioactivity is found in the supernatant liquid, at 15 – 30 minutes post labeling.	1%	
		Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 12 hours post labeling.	1%	
Biological Distribution	15	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 : 91% 2 : 96% 3 : 93%	
		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: 1% 3: 1%	
	10044	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%	
	10044	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.	1:94% 2:95% 3:94%	
		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: 1% 2: 1% 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 TOLLIABI

OC Sr. Supervisor

Verified by:

Name and Title

M. Tollali

Signature

2021 SE 13

Date

HALÎMA LAHMÎDÎ QA, Associate

Approved by: Name and Title - Pp.

Signature

2021 SE14

Date

3/3 MT 2021 SE 13

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