

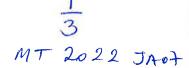
# **CERTIFICATE OF ANALYSIS**

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

# Certificate:	2022JA07-1		
Batch Number:	1M392	Manufacturing Date:	2021NO25
Lot Number (FP):	1M392B	Expiry Date:	2023 - NO
Product Number:	500150	Specification Number and Version:	500150_v15
Standard of Testing:	House, USP <sup>1</sup>	Date of Release: (Date with QA Initials)	MMN 20227A07

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	5 x 10E06 particles/vial
Particle Size		Particle Size < 10 µm: ≤ 10%	8%
	10080	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
SnCl₂.2H₂O Assay	10039	≥ 0.06 mg/vial	0.11 mg/vial
Total Tin Assay	10040	≤ 0.12 mg of SnCl₂•2H₂O/vial	<0.08 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	1.34 mg/vial

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A Jubilant Pharma Company



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Tests on the Lyophilized product				
Test Description	Analytical Method	Specifications	Results	
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	<4.0 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%
	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: 4%
			Animal 2: 89%
			Animal 3: 87%
Biological Distribution		In not less than 2 of 3 animals, at 15 – 30 minutes post labeling, not more than a total of 5% of the radioactivity	Animal 1: <1%
			Animal 2: 2%
		is found in the liver of the animal at 15 minutes post injection.	Animal 3: 1%
		In not less than 2 of 3 animals, at 15 – 30 minutes post	Animal 1: <1%
		labeling, not more than 5% of the radioactivity is found in	Animal 2: 1%
		the kidneys of the animal at 15 minutes post injection.	Animal 3: 1%

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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: 86% Animal 2: <1% Animal 3: 87%
		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	Animal 1: 1% Animal 2: <1%
		injection.	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	Animal 1: 1% Animal 2: <1%
		the kidneys of the animal at 15 minutes post injection.	Animal 3: 1%

<sup>&</sup>lt;sup>2</sup> 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.

M. Tollali'

MUSTAPHA TOLLABÍ QC Sr. Supervisor Verified by:

Name and Title Signature 2022 JA 07

Date

FAIZA MIMOUNI Approved by:

Name and Title

Signature

F. Mimound

Date

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OUR VALUES

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