

Certificate of Analysis



Material	Description	Usage Decision			Usage Decision Date	
30000001020	DRAXIMAGE MAA Kit AU (10 vials)	Accepted (OK)			12/12/2022	
Insp. Lot	Insp. Plan	Versio	Batch	Bulk Batch	Manuf. Date	Exp. Date
10000531482	90003372	2	2H013	2H013	08/29/2022	08/2024

Inspection Results				
Characteristic		Insp. Method	Specification	Result
1	Description	10019	A white freeze-dried plug or powder, clean and free of foreign matter. The flip-off cap is blue. Vendor item number: Not applicable	Conforms
2	Resuspendability	10079	A white suspension which may separate on standing.	Conforms
3	pH	10005	5.2 .. 6.0	5.4
4	Loss on Drying	10021	<= 5 %	< 1 %
5	Particle Density	10088	3x10E+06 - 8x10E+06 aggregated albumin particles in each vial	Conforms 3x106 part/vial
6	Particle Size < 10 µm	10080	<= 10 %	7 %
7	Particle Size >= 10 µm - <= 70 µm	10080	>= 90 %	93 %
8	Particle Size > 100 µm	10080	<= 0.2 %	< 0.1 %
9	Particle Size > 150 µm	10080	None	Conforms
10	Identification MAA	10000	A blue color develops.	Conforms
11	Sterility	10007	Sterile	Conforms JHS Certificate of Manufacture
12	Assay - Stannous Chloride	10039	>= 0.06 mg/vial	0.11 mg/vial
13	Assay - Total Tin	10040	of SnCl ₂ .2H ₂ O <= 0.12 mg/vial	0.08 mg/vial
14	Stannous Albumin Macro Aggregate Complex	10082	2.2 .. 3.0 mg/vial	2.5 mg/vial
15	Human Serum Albumin	10068	(or alternative method 10089) 3.5 .. 6.5 mg/vial	4.7 mg/vial
16	Sodium Chloride	10084	0.96 .. 1.44 mg/vial	1.30 mg/vial

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Inspection Results				
Characteristic	Insp. Method	Specification	Result	
17	Residual Solvents	USP<467>	Meets USP requirements (no test required). Conforms No test required	
18	Bacterial Endotoxins	10008	<= 16.5 EU/Vial < 4.0 EU/Vial	
19	Biological Distribution - Lungs 15-30min	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. >= 80 % 97 % 2)92.17% 3)97.83%	
20	Biological Distribution - Liver 15-30min	10044	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. <= 5 % 1 % 2)1.22% 3)1.11%	
21	Biological Distribution - Kidneys 15-30min	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. <= 5 % 1 % 2)1.11% 3)1.06%	
22	Biological Distribution - Lungs 12-24hrs	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. >= 80 % 94 % 2)88.70% 3)86.17%	
23	Biological Distribution - Liver 12-24hrs	10044	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. <= 5 % 1 % 2)1.48% 3)1.51%	

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Inspection Results				
Characteristic	Insp. Method	Specification	Result	
24	Biological Distribution -Kidneys 12-24hr	10044	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. ≤ 5 %	1 % 2)1.01% 3)1.04%
25	Radiochemical Purity 15-30 min (US-AU)	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. ≥ 90 %	100 % conforms
26	Radiochemical Purity at least 12 hrs	10043	Not less than 90% of the total radioactivity is found as aggregated albumin at the point of application, at least 12 hours post labeling. ≥ 90 %	100 % conforms
27	Centrifugation 15 - 30 min (US-AU)	10087	Not more than 10% of the total radioactivity is found in the supernatant liquid, at 15 - 30 minutes post labeling. ≤ 10 %	3 % conforms
28	Centrifugation Procedure at least 12 hrs	10087	Not more than 10% of the total radioactivity is found in the supernatant liquid, at least 12 hours post labeling. ≤ 10 %	3 % conforms

Usage Decision performed by: LAYOUAZ Date: 12/12/2022

This batch of product has been tested by Jubilant DraxImage Inc., dba Jubilant Radiopharma Quality Control Laboratory under Canadian Establishment License Number 101869-A and complies with the specification requirements.