

Certificate of Analysis



Material	Description	Usage Decision			Usage Decision Date	
30000001020	DRAXIMAGE MAA Kit AU (10 vials)	Accepted (OK)			07/22/2022	
Insp. Lot	Insp. Plan	Versio	Batch	Bulk Batch	Manuf. Date	Exp. Date
10000506079	90003372	2	2F629		04/26/2022	04/2024

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	5.3
4	Loss on Drying	10021	<= 5 %	< 1 %
5	Particle Density	10088	3x10E+06 - 8x10E+06 aggregated albumin particles in each vial	Conforms conform
6	Particle Size < 10 µm	10080	<= 10 %	5 %
7	Particle Size >= 10 µm - <= 70 µm	10080	>= 90 %	95 %
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
12	Assay - Stannous Chloride	10039	>= 0.06 mg/vial	0.09 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	4.6 mg/vial
16	Sodium Chloride	10084	0.96 .. 1.44 mg/vial	1.33 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 Test not 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 % 98 % 2)91%; 3)90%	
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%; 3)1%	
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%; 3)1%	
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 % 87 % 2)94%; 3)95%	
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 % 2 % 2)2%; 3)2%	

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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%; 3)1%
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 % conforme
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 % conforme
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 %	6 % conforme
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 %	5 % conforme

Usage Decision performed by: FMIMOUNI Date: 07/22/2022

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.