Certificate of Analysis

Material	Description			Usage Decision		Usage Decision Date
30000001020	DRAXIMAGE MAA Kit AU (10 vials)			***Accepted (OK)***		03/10/2023
Insp. Lot	**Insp.Plan**	**Versio**	**Batch**	**Bulk Batch**	**Manuf.Date**	**Exp.Date**
10000541070	90003372	2	2K129		11/28/2022	11/2024

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	5.5
4	Loss on Drying	10021	<= 5 %	< 1 %
5	Particle Density	10088	3x10E+06 - 8x10E+06 aggregated albumin particles in each vial	Conforms 5x106part/vial
6	Particle Size < 10 µm	10080	<= 10 %	9 %
7	Particle Size >= 10 µm - <= 70 µm	10080	>= 90 %	91 %
8	Particle Size > 100 µm	10080	<= 0.2 %	< 0.1 %
9	Particle Size > 150 µm	10080	None	Conforms none
10	Identification MAA	10000	A blue color develops.	Conforms
11	Sterility	10007	Sterile	Conforms CofA Manufacturer
12	Assay - Stannous Chloride	10039	>= 0.06 mg/vial	0.10 mg/vial
13	Stannous Albumin Macro Aggregate Complex	10082	2.2 .. 3.0 mg/vial	2.5 mg/vial
14	Human Serum Albumin	10068	(or alternative method 10089) 3.5 .. 6.5 mg/vial	4.6 mg/vial
15	Sodium Chloride	10084	0.96 .. 1.44 mg/vial	1.35 mg/vial
16	Residual Solvents	USP<467>	Meets USP requirements (no test required).	Conforms Testing not required

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Inspection Results

Characteristic		Insp.Method	Specification	Result
17	Bacterial Endotoxins	10008	<= 16.5 EU/Vial	< 4.0 EU/Vial
18	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 %	94 % aNIMAL2:97%,ANIMAL3:91%
19	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 %	2 % ANIMAL2:2%,ANIMAL3:2%
20	BiologicaDistribution - 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 % ANIMAL2:1%,ANIMAL3:2%
21	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 %	84 % AIMAL2:96%,ANIMAL3:83%
22	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 % ANIMAL2:2%,ANIMAL3:2%
23	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 % ANIMAL2:1%,ANIMAL3:1%

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Inspection Results

Characteristic		Insp.Method	Specification	Result
24	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 % comforme
25	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 % comforme
26	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 %	4 % comforme
27	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 % comforme
28	Assay - Total Tin	10040	of SnCl2.2H2O <= 0.12 mg/vial	0.10 mg/vial

Usage Decision performed by: LAYOUAZ Date: 03/10/2023

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.

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