Certificate of Analysis

Material	Description			Usage Decision		Usage Decision Date
30000001020	DRAXIMAGE MAA Kit AU (10 vials)			***Accepted (OK)***		01/17/2025
Insp. Lot	**Insp.Plan**	**Versio**	**Batch**	**Bulk Batch**	**Manuf.Date**	**Exp.Date**
10000630257	90003372	3	4K126A	4K126A	11/17/2024	11/2026

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 10019AWO04-C1
2	Resuspendability	10079	A white suspension which may separate on standing.	Conforms 10079AWO01-C1
3	pH	10005	5.2 .. 6.0	5.4 10005AWO01-C1
4	Loss on Drying	10021	<= 5 %	< 1 % 10021AWO01-C1
5	Particle Density	10088	3x10E+06 - 8x10E+06 aggregated albumin particles in each vial	Conforms 10088AWO01-C1
6	Particle Size < 10 µm	10080	<= 10 %	1 % 10088AWO01-C1
7	Particle Size >= 10 µm - <= 70 µm	10080	>= 90 %	99 % 10088AWO01-C1
8	Particle Size > 100 µm	10080	<= 0.2 %	< 0.1 % 10088AWO01-C1
9	Particle Size > 150 µm	10080	None	Conforms 10088AWO01-C1
10	Identification MAA	10000	A blue color develops.	Conforms 10000AWO01-C1, PR-258746
11	Sterility	10007	Sterile	Conforms Manufacture CoA
12	Assay - Stannous Chloride	10039	>= 0.06 mg/vial	0.12 mg/vial 10039AWO01-C1
13	Stannous Albumin Macro Aggregate Complex	10082	2.2 .. 3.0 mg/vial	2.8 mg/vial 10082AWO01-C1
14	Human Serum Albumin	10068	(or alternative method 10089) 3.5 .. 6.5 mg/vial	4.8 mg/vial 10068AWO01-C1

Jubilant DraxImage Inc., dba Jubilant Radiopharma
16751 Trans-Canada Highway
Kirkland, Québec, Canada, H9H 4J4

Certificate of Analysis

Material	Description			Usage Decision		Usage Decision Date
30000001020	DRAXIMAGE MAA Kit AU (10 vials)			***Accepted (OK)***		01/17/2025
Insp. Lot	**Insp.Plan**	**Versio**	**Batch**	**Bulk Batch**	**Manuf.Date**	**Exp.Date**
10000630257	90003372	3	4K126A	4K126A	11/17/2024	11/2026

Inspection Results

Characteristic		Insp.Method	Specification	Result
15	Sodium Chloride	10084	0.96 .. 1.44 mg/vial	1.22 mg/vial 10084AWO01-C1
16	Residual Solvents	USP<467>	Meets USP requirements (no test required).	Conforms Testing not required
17	Bacterial Endotoxins	10008	<= 16.5 EU/Vial	< 8.0 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 %	81 % 2)78% 3)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 %	1 % 2)1% 3)1%
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 % 2)1% 3)1%
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 %	97 % 2)94% 3)88%
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 %	1 % 2)1% 3)1%

Jubilant DraxImage Inc., dba Jubilant Radiopharma
16751 Trans-Canada Highway
Kirkland, Québec, Canada, H9H 4J4

Certificate of Analysis

Material	Description	Usage Decision	Usage Decision Date
30000001020	DRAXIMAGE MAA Kit AU (10 vials)	***Accepted (OK)***	01/17/2025

Insp. Lot	Insp.Plan	Versio	Batch	Bulk Batch	Manuf.Date	Exp.Date
10000630257	90003372	3	4K126A	4K126A	11/17/2024	11/2026

Inspection Results

Characteristic		Insp.Method	Specification	Result
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 % 2)1% 3)1%
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 % conforme
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 % conforme
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 % conform
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 %	4 % conform
28	Assay - Total Tin	10357	of SnCl2.2H2O <= 0.12 mg/vial	< 0.12 mg/vial ACT LAB COA Work order A24-14901-1

Usage Decision performed by: VBEAULIEU Date: 01/17/2025

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.

Jubilant DraxImage Inc., dba Jubilant Radiopharma
16751 Trans-Canada Highway
Kirkland, Québec, Canada, H9H 4J4