

CERTIFICATE OF MANUFACTURE

DRAXIMAGE MACROSALB®

Kit for the Preparation of Technetium Tc99m Albumin Aggregated Injection 5.0 mg/vial

Human Serum Albumin (HSA)

10 vials / kit

Manufacturing:

Product Number:	702815	Lot or Batch Number:	4F631
Manufacturing Date:	2024JN20	Expiry Date:	06/2026
Manufacturing Master No.	LYO-702815-20	Master effective date:	2023FE15
Batch Size:	10L	Filling date:	2024JN21

Packaging:


Product Number:	30000001020	Lot Number:	4F631A
Date of Packaging:	2024SE05	Expiry Date:	06/2026
Master Packaging No. :	PKG-30000001020-02	Master effective date:	2023NO03
Quantity:	800 kits	Format:	10 vials / kit

Certification statement:

I hereby certify that the above information is authentic and accurate. This batch of lyophilized kits has been manufactured and packaged by Jubilant HollisterStier General Partnership, tested and sold by Jubilant DraxImage Inc. in the country of origin (Canada) under Canadian Establishment License Number 101929-A and 101869-A respectively in full compliance with the GMP requirements of the local regulatory authority.

The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP and with Canadian (HPFBI) and US (21 CFR 210 and 21 CFR 211) current Good Manufacturing Practices guidelines.

This batch was not manufactured under the exemption conferred by Article 37(1) of the Canadian Food and Drug Act.


Name VALERIE BEAUHIEUX
Title QUALITY ASSURANCE SPECIALIST

2024SE24
Date

*Marketing authorization number: PL 29620/0002, PL29620/0003

Manufacturer:

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A Jubilant Pharma Company



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