

Certificate: 2021JA25-2

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:	OM383
Manufacturing Date:	2020NO24	Expiry Date:	11/2022
Manufacturing Master No.	LYO-702815-17	Version:	2020OC07
Batch Size:	5L	Filling date:	2020NO24

Packaging:

Product Number:	3000001020	Lot Number:	0M383A
Date of Packaging:	2020DE03	Expiry Date:	11/2022
Master Packaging No. :	PKG-30000001020-01	Version:	2020SE01
Quantity:	563 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 Faiza Mimouni

Title

20 A L F E II

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

Manufacturer:

External Laboratories:

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A Jubilant Pharma Company



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