

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: United States of America

This public document

2. has been signed by Andrei Perlloni

3. acting in the capacity of Branch Chief, Drug Import Export Compliance Branch

4. bears the seal/stamp of U. S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the twelfth of January, 2021

7. by Assistant Authentication Officer, United States Department of State

8. No. 2106770 33

9. Seal/Stamp:

10. Signature:


Leo J Muldoon

United States Food and Drug Administration
Center for Drug Evaluation and Research
10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America
CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950
Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: E6VP-55MY

Certificate Issue Date: August 18, 2020

Certificate Expiration Date: August 17, 2022

Importing Country: CHILE

Exporting Country: UNITED STATES of AMERICA

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: BRIDION® 200 MG/ML (2 ML PER VIAL), Injection, solution
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): sugammadex 200 MG
1.2	Is this product licensed to be placed on the market for use in the exporting country? Yes
1.3	Is this product actually on the market in the exporting country? Yes
2.A.1	Product license number & date of issue: 022225 12/15/2015
2.A.2	Product license holder name & address: Organon USA Inc., a subsidiary of Merck & Co., Inc., 2000 Galloping Hill Road, Kenilworth, NJ 07033 United States of America
2.A.3	Status of Product license holder: Neither
2.A.3.1	Manufacturer name & address: and Packaging: Patheon Manufacturing Services LLC, 5900 Martin Luther King Jr. Highway, Greenville, NC 27834 United States of America
2.A.4	Is a summary basis for approval appended? Yes
2.A.5	Is the attached product information, complete and consonant with the license? Yes
2.A.6	Applicant name & address for certificate (if different from the license holder): Merck Sharp & Dohme Corp., 351 North Summneytown pike, North Wales, PA 19454 United States of America
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Yes
3.1	Periodicity of routine inspections (years): Pursuant to section 510(h)(3) of the Federal Food, Drug & Cosmetic Act, Inspections will occur in accordance with a risk-based schedule
3.2	Has the manufacture of this type of dosage form been inspected? Yes
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): Yes, at time of inspection, site complies with FDA cGMP
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? Yes

Andrei Perlloni

Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response

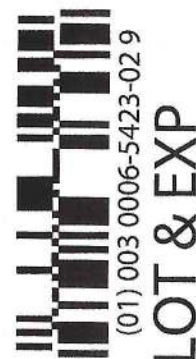


conforms to the format recommended by the World Health Organization format revised October 1, 1997. WCC

05PYR9

2 mL Single-Dose Vial NDC 0006-5423-02

Bridion[®]
(sugammadex) Injection
200 mg/2 mL
(100 mg/mL)
For Intravenous Use Only



Rx only Storage: 25°C (77°F) Protect from light
Manuf. for: Merck Sharp & Dohme Corp.

7002085400

2 mL Single-Dose Vial NDC 0006-5423-02

Bridion[®]
(sugammadex) Injection

100 mg/mL
For Intravenous Use Only

Total dose: ____ mL

Peel off &
apply to syringe



(01) 003 0006-5423-02 9

LOT & EXP

7002085400

Rx only Storage: 25°C (77°F) Protect from light
Manuf. for: Merck Sharp & Dohme Corp.

on face →



Rx only
For Intravenous Use Only
10 Single-Dose 2 mL Vials

Bridion®
(sugammadex) Injection
200 mg/2 mL (100 mg/mL)

NDC 0006-5423-12

USUAL DOSAGE: See enclosed Package Insert.
Storage: Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].
Protect from light. When not protected from light, the vial should be used within 5 days.
Bridion® is supplied as a sterile, non-pyrogenic aqueous solution that is clear, colorless to slightly yellow-brown for intravenous injection only. Each mL contains 100 mg sugammadex, which is equivalent to 108.8 mg sugammadex sodium. The aqueous solution is adjusted to a pH of between 7 and 8 with hydrochloric acid and/or sodium hydroxide. The osmolality of the product is between 300 and 500 mOsmol/kg.

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA
Manufactured by: Patheon Manufacturing Services LLC, Greenville, NC 27834 USA
Sugammadex sodium (active ingredient) Made in The Netherlands. Formulated in USA.
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7002095700



Bridion®
(sugammadex) Injection
200 mg/2 mL (100 mg/mL)

NDC 0006-5423-12

Bridion®
(sugammadex) Injection
200 mg/2 mL (100 mg/mL)

Rx only
10 Single-Dose 2 mL Vials
For Intravenous Use Only

Bridion®
(sugammadex) Injection
200 mg/2 mL (100 mg/mL)

