APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Karen C. Corallo

3. acting in the capacity of Division Director, 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 ninth of February, 2017

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

8. No. 17018143-12

9. Seal/Stamp:

10. Signature:

Sonya N. Johnson

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: **999R-CMZV**

Certificate Issue Date: **January 24, 2017**

Certificate Expiration Date: **January 23, 2019**

Importing Country: **CHILE**

Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **PRECEDEX (DEXMEDETOMIDINE HYDROCHLORIDE), Injection**
1.1	Active Ingredient(s) and amounts(s) per unit dose (complete quantitative composition is preferred): **dexmedetomidine hydrochloride**
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: **021038 12/17/1999**
2.A.2	Product license holder name & address: **Hospira, Inc., 275 N. Field Drive, Lake Forest, IL 60045 United States of America**
2.A.3	Status of Product license holder: **Neither**
2.A.3.1	Manufacturer name & address: **Hospira, Inc., Highway 301 North, Rocky Mount, NC 27801 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): **Pfizer Inc, 500 Arcola Road, Collegeville, PA 19426 United States of America**
2.B.4	Remarks: **Manufacturing and Packaging Facility: Hospira, Inc., Highway 301 North, Rocky Mount, NC 27801, USA**
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**

Karen C. Corallo

Karen C. Corallo, Division Director
Drug Import Export Compliance Branch
Division of Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

BLAIR CONSULAR SERVICES LTD 819127

3.2.P Drug Product

Precedex® (Dexmedetomidine Hydrochloride Injection) is an alpha$_2$-adrenergic agonist. Dexmedetomidine Hydrochloride Injection is presented as a sterile, aqueous solution in glass vials that is further diluted with 0.9% sodium chloride prior to intravenous infusion. The drug product is comprised of a clear, colorless solution, free from visible particulates, presented in clear Type I glass vials. The vials are closed with West 4416/50, 13 mm Teflon faced stoppers and aluminum seals with plastic flip-off tops. The pH range is 4.5-7.0. This is a terminally sterilized product containing no antimicrobial preservatives.

3.2.P.1 Description and Composition of Precedex® (Dexmedetomidine Hydrochloride Injection)

The qualitative composition of the drug product is presented in Table 1. The quantitative composition on a per mL basis and per presentation basis are provided in Table 2.

Table 1. Qualitative Composition

Component	Quality Standard	Function
Dexmedetomidine HCl	In-house	Active Ingredient
Sodium Chloride	USP	Isotonicity agent
Water for Injection	USP	Vehicle

Note:
[1] Nitrogen is used to displace air during manufacturing (i.e.,to blanket the formulation and fill vial headspace).
[2] Silicone or Medical Fluid 360 (Dimethicone) is used to lubricate stoppers/closures during component preparation.

Table 2. Quantitative Composition

Component	Quantity per Milliliter (mL)	Strength: 100 mcg/mL
		200 mcg/2 mL
		Quantity per unit
Dexmedetomidine (base) Dexmedetomidine Hydrochloride		
Sodium Chloride USP		
Water for Injection, USP		
Total Volume		

A.R = As Required

Note:
[1] Nitrogen is used to displace air during manufacturing (i.e.,to blanket the formulation and fill vial headspace).