

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.

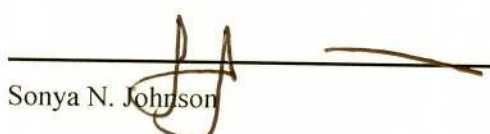
6. the ninth of February, 2017

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 Issue Date: January 24, 2017

Certificate Number: 999R-CMZV

Importing Country: CHILE

Certificate Expiration Date: January 23, 2019

Exporting Country: UNITED STATES OF AMERICA

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: PRECEDEN (DEXMEDETOMIDINE HYDROCHLORIDE), Injection
1.1	Active Ingredient(s) and amount(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



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CONSULAR SERVICES LTD

3.2.P Drug Product

Precedex[®] (Dexmedetomidine Hydrochloride Injection) is an α_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).