BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

CERTIFY ONLY that Brian Michael Howes who is well known to me and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter has today caused the annexed Certificate of a Pharmaceutical Product – Approved Drug Product 74UV-YBS6 for SOLU-MEDROL®, Injection, Powder for Solution to be produced to me and has represented to me on behalf of the company that the said document is an original document issued by the United States Food and Drug Administration.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 14th September 2020.

Sunita Kumeri
Notary Public
England and Wales

Protocol No. 46120

APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1.	**Country:** Pays / Pais:	United Kingdom of Great Britain and Northern Ireland
	This public document Le présent acte public / El presente documento público	
2.	**Has been signed by** a été signé par ha sido firmado por	Sunita Kumeri
3.	**Acting in the capacity of** agissant en qualité de quien actúa en calidad de	Notary Public
4.	**Bears the seal / stamp of** est revêtu du sceau / timbre de y está revestido del sello / timbre de	The Said Notary Public

Certified

Attesté / Certificado

5.	**at** á / en London	6.	**the** le / el día 15 September 2020
7.	**by** par / por	Her Majesty's Principal Secretary of State for Foreign, Commonwealth and Development Affairs	
8.	**Number** sous no / bajo el numero	APO-2041238	
9.	**Seal / stamp** Sceau / timbre Sello / timbre	10.	**Signature** Signature Firma R. Rich

FOREIGN, COMMONWEALTH & DEVELOPMENT OFFICE LONDON

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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: **74UV-YBS6**

Certificate Issue Date: **August 19, 2020**

Certificate Expiration Date: **August 18, 2022**

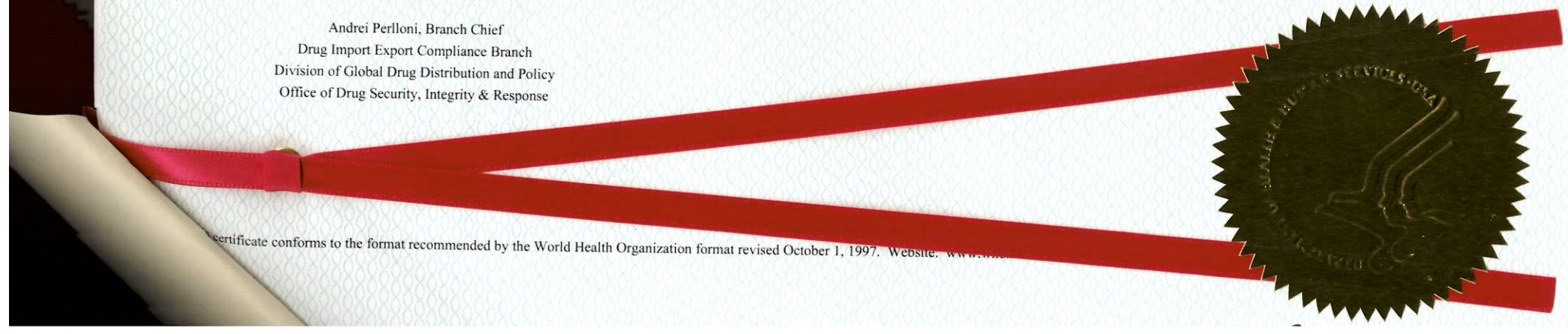
Importing Country: **CHILE**

Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **SOLU-MEDROL®, Injection, powder for solution**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **methylprednisolone sodium succinate 500 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: **011856 05/18/1959**
2.A.2	Product license holder name & address: **Pfizer Inc, 235 E 42nd Street, New York, NY 10017 United States of America**
2.A.3	Status of Product license holder: **Neither**
2.A.3.1	Manufacturer name & address: **Pharmacia and Upjohn Company LLC, 7000 Portage Road, Kalamazoo, MI 49001 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 consonent with the license? **Yes**
2.A.6	Applicant name & address for certificate (if different from the license holder): **Pfizer Inc, 235 E 42nd St, New York, NY 10017 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



ertificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.

3.2.P.1. DESCRIPTION AND COMPOSITION OF THE DRUG PRODUCT

3.2.P.1.1. Description of the Drug Product

Methylprednisolone Sodium Succinate products are sterile powders for injection containing methylprednisolone sodium succinate. They exist in a wide range of 40 to 2000 mg strengths. The sodium succinate ester of methylprednisolone is deemed to be a very useful replacement of methylprednisolone because it is highly soluble in water and permits the immediate intravenous administration of high doses of methylprednisolone in a small volume of diluent. Methylprednisolone Sodium Succinate has the same actions as methylprednisolone.

Prior to use, the lyophilized powders are reconstituted with a diluent.

Methylprednisolone Sodium Succinate products are packed in hydrolytic glass class I vials closed with rubber stoppers. Both components comply with USP requirements.

According to the United States Pharmacopoeia, Methylprednisolone Sodium Succinate products are powders for injection complying with USP monograph <1> "*Injections*".

3.2.P.1.2. Composition of the Drug Product

The composition of Methylprednisolone Sodium Succinate 500 mg Vials is presented in Table 3.2.P.1-1 with the function and quality standard applicable to each component.

Note: Total volume of each vial when reconstituted with 8.0 mL of diluent is 8.620 mL.

Table 3.2.P.1-1 Composition of Methylprednisolone Sodium Succinate 500 mg Sterile Powder (Fill 7.27 mL/vial)[a]

Name of Ingredients	Amount per Vial	Function	Quality Referenceb
Methylprednisolone Hemisuccinate [c]	683.2 mg	Active ingredient	USP-NF
Monobasic Sodium Phosphate Anhydrous	6.896 mg	Buffer	USP-NF
Dibasic Sodium Phosphate Dried	74.99 mg	Buffer	USP-NF
Sodium Hydroxide [d, e]	q.s	pH adjustment, conversion of hemisuccinate into sodium succinate	USP-NF
Water for Injection [f]	q.s	For preparation of the solution before lyophilization; removed during lyophilization	USP-NF

[a] Components 7.75% excess for overfill.
[b] References: USP-NF: the current edition of the United States Pharmacopeia-National Formulary.
[c] Equivalent to 539 mg (78.9%) of Methylprednisolone USP
[d] Prepared from Sodium Hydroxide Reagent and Water for Injection USP.
[e] To adjust pH
[f] Removed during freeze-dry process