GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH
MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
OUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd

CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP) FOR PHARMACEUTICAL (PRODUCTS)

This certificate conforms to the format recommended by the World Health Organization (WHO)

Certificate Number: DA/6-31/2000/15966 Date: 22/08/2021

It is hereby certified that **M/S. Advanced Chemical Industries Limited** a drug (Pharmaceutical Products) manufacturing and marketing organization, has been given license to manufacture and sell its products freely in the People's Republic of Bangladesh as lawfully required and granted in pursuance of The Drug Act, 1940 (XXIII of 1940) and the Drugs (Control) Ordinance, 1982.

On the basis of the inspection carried out on 10-09-2020 & 24-11-2020 we certify that the site indicated on this certificate complies with Good Manufacturing Practices & regulatory norms for the dosage forms, categories and activities listed in Table 1.

The License information are as below:

1. Name & Address of Site: **M/S. Advanced Chemical Industries Limited**
   7, Hajeegonj Road, Godnyl, Narayangonj, Bangladesh
2. Drug Manufacturing License No. : Biological - 51 Date of Issue: 23/08/1963
   Non Biological - 213 Date of Issue: 23/08/1963
3. Table-1

Dosage Form (s)	Category (ies)	Activity (ies)
Tablet: Uncoated Tablet, Film Coated Tablet, Enteric Coated Tablet, Sugar Coated Tablet, Dispersible Tablet, Controlled / Sustained Release Tablet, Vaginal Tablet, Compression coated Tablet, Bi-layer Tablet.	Antibiotics & Chemotherapeutics, Antihypertensive & Cardioprotectives, Antacid & Anti-ulcerants, Hematinics, Antidiabetics, Anthelmintic/ Antimalaria /Antidiarrhoeal/ Antiprotozoal, Steroids, Antiemetics, Anti-inflammatory, Antispasmodics, Antiseptic, Antihistamines & Antiallergics, Antidepressants, Dermatological & Anti-Fungal, Anti-asthmatics & Bronchodilators, Angiolotic, Antipsychotic, Anti-viral, Hypnotic, Laxative, Stomalogical, Topical, Fungicidal, Multivitamin, Anti-schizophrenia, Antivertiginous, Supplements, Analgesic, Anti-parkinson, Anticoagulant, Anti-epileptic, cholagogue and choleretic.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Material requisition and receiving from WH. ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Granulation, Compression & Coating(if applicable) ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Capsule: Hard Gelatin Capsule, Controlled / Sustained Release Capsule	Antibiotics, Antihypertensive & Cardioprotectives, Anti-ulcerants, Hematinics, Vitamins & Minerals, Analgesic & Anti-inflammatory, Anti-parkinson, Anti-viral, Obesity management.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Material requisition and receiving from WH. ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Granulation, Compression &

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Date: 2022.09.29 10:44:32 EEST
Reason: MoldSign Signature
Location: Moldova

Dosage Form (s)	Category (ies)	Activity (ies)
		Coating(if applicable) ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Syrup / Solution / Suspension	Chemotherapeutics, Analgesic, Antibiotics, Antiviral, Antipyretics & Anti-inflammatory, Vitamins & Minerals, Hematinics, Anthelmintic / Antimalarial, antidiarrhoeal / Antiprotozoal, Antiemetics, Antihistamines & Antiallergics, Antacids & Antiulcerants, Laxatives, Expectorants, Antiasthmatics & Bronchodilators, Antidiarrhoeal / Antiamoebics, Multivitamin, Dopamine Antagonist, Antispasmodics, Anesthetic, Germicidal, Adrenal Corticosteroids, Antiseptic.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation &Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Pediatric Drops	Analgesic, Antipyretics & Anti-inflammatory, Vitamins & Multivitamins, Anthelmintic / Antimalarial, Antidiarrhoeal / Antiprotozoal, Antiemetics, Expectorants.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation &Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Dry Powder for Suspension / Pediatric Drops	Antibiotics, Antidiarrhoeal / Antiprotozoal, Dermatological & Antifungal, Macrolides, Carbapenem, Beta-lactam antibiotics	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation & Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation

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Dosage Form (s)	Category (ies)	Activity (ies)
		▪ Batch release ▪ Storage of Finished Products
Cream/Ointment/Gel	Analgesic & Anti-inflammatory, Antiseptic, Dermatological & Antifungal, Steroids.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Dry Powder For Injection	Antibiotics, Antispasmodics, Steroids, Antiulcerants, Carbapenem, Beta-lactam antibiotics.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Eye & Ear Drops/ Liquid Injection	Antibiotics, Multivitamin, Analgesic & Anti-inflammatory, Antimicrobial, Antihistamine, Steroids, Antiulcerant, Antispasmodic, Iron Supplement, NSAID, Antivomiting, Anesthetic	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation, Filtration (if applicable) & Filling ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products

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Dosage Form (s)	Category (ies)	Activity (ies)
MDI / Nebulizer / Nasal Spray/Sub lingual Spray	Anti-asthmatics, Anti-histamine, Analgesics & Anti-inflammatory, Anti-anginal, Nose preparations.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation, Filtration (if applicable), Filling & Autoclave (if applicable) ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
DPI (Dry powder for Inhalation)	Anti-asthmatics	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Mixing & Encapsulation. ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Insulin	Anti-Diabetic	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Preparation, Filling & Sealing ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products

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Dosage Form (s)	Category (ies)	Activity (ies)
Bio-tech Injectable (Erythropoietin, Filgrastim)	Glycoprotein Hormone, Granulocyte colony-stimulating factor (G-CSF)	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Control of manufacturing environment ▪ Production: Filling & Sealing ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products
Suppository	Analgesic, Anti-Pyretic and Anti-Inflammatory, Laxatives.	▪ Sourcing & procurement of RM/PM from approved sources/vendors. ▪ Quarantine of RM/PM in W/H ▪ Sampling and testing of RM/PM ▪ Release of RM/PM ▪ Formulation design & development ▪ Dispensing of RM/PM ▪ Control of manufacturing environment ▪ Production: Filling & Sealing ▪ Packaging & Labeling ▪ In process control of Intermediate, Bulk and Finished products ▪ Quality Assurance: Control of Manufacturing environment, In process Quality Control & Finished product analysis ▪ Documentation ▪ Batch release ▪ Storage of Finished Products

The responsibility for the quality of individual batches of pharmaceuticals products manufactured through this process lies with the manufacturer.

This certificate remains valid for a period of 02 (two) years from the date of issue. It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name of authorized person : **Major General Md Mahbubur Rahman**
Address of certifying authority : Directorate General of Drug Administration
Mohakhali, Dhaka-1212
Telephone : + 880-2-222280803
Fax no. : + 880-2-9880854
E-mail : dgda.gov@gmail.com
Web-site : www.dgda.gov.bd

Date of 1st Issue of GMP Certificate:

Stamp and Date:

MINISTRY OF HEALTH & FAMILY WELFARE ★ GOVT. OF THE PEOPLES REPUBLIC OF BANGLADESH ★ DIRECTORATE GENERAL OF DRUG ADMINISTRATION ★ DHAKA

Major General Md Mahbubur Rahman
Director General 22 AUG 2021
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

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CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

Certificate Number: DA/6-31/2000/ 8443 Date: 19.09.22

Exporting (certifying) country : **BANGLADESH**

Importing (requesting) country : **MOLDOVA**

1. Name and dosage form of the product:

A. In Bangladesh : **SOFOMAX DUO FC TABLET**
B. In Moldova : **SOFOMAX DUO FC TABLET**

1.1 Active ingredient (s)[2] and amount(s)[3] per unit dose:

Active Ingredient (s)	Quantity (mg) / Tablet
Sofosbuvir INN	400.00 mg
Ledipasvir Acetone Solvate INN	90.00 mg (Eqv. To 90.00mg Ledipasvir)

For complete qualitative composition including excipients, see attached. [4]

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]

Yes [✓] No [ ]

1.3 Is this product actually on the market in the exporting country?

Yes [✓] No [ ]

If the answer to 1.2. is **yes**, continue with section 2A and omit section 2B. If the answer to 1.2 is **no**, omit section 2A and continue with section 2B[6] :

2.A.1. Number of product license[7] and date of issue: **DAR No. 005-1087-032 Date of Issue 13.06.2016**

2.A.2. Product licence holder (name and address):
Plant: Advanced Chemical Industries Limited.
7 Hajeegonj Road, Godnyl, Narayanganj, Bangladesh
Regd. Office: 245, Tejgaon Industrial Area, Dhaka-1208, Bangladesh

2A.3. Status of product licence holder[8]: **Manufactures the dosage form**

2A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

Not Applicable

Continued to page-2

2A.4.	Is a summary basis for approval appended?[10]	Yes		No	✓
2A.5.	Is the attached, officially approved product information complete and consonant with the licence?[11]:	Yes	✓	No	
2A.6.	Applicant for certificate, if different from licence holder (name and address)[(12)]:	**Not Applicable**			
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [(14)]	Yes	✓	No	
3.1	Periodicity of routine inspections (years) :	**Every Two Years**			
3.2	Has the manufacture of this type of dosage form been inspected?	Yes	✓	No	
3.3	Do the facilities and operation conform to GMP as recommended by the World Health Organization?[(15)]	Yes	✓	No	
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[(16)]:	Yes	✓	No	

Name of authorized person : **Md. Eyahya**

Address of certifying authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka-1212

Telephone : + 880-2-9880897 ext.: 112
Fax no. : + 880-2-9880854
E-mail : dgda.gov@gmail.com
Web-site : www.dgda.gov.bd

Stamp and Date:

Md. Eyahya
Director (C.C.)
For Director General
Directorate General of Drug Administration 19 SEP 2022
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh

MINISTRY OF HEALTH & FAMILY WELFARE
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CERTIFICATE OF A PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General instructions and explanatory notes attached)

Certificate Number: DA/6-31/2000/ 8441 Date: 19.09.22

Exporting (certifying) country : **BANGLADESH**

Importing (requesting) country : **MOLDOVA**

1. Name and dosage form of the product:

A. In Bangladesh : **SOVEL FC TABLET**
B. In Moldova : **SOVEL FC TABLET**

1.1 Active ingredient (s)[2] and amount(s)[3] per unit dose:

Active Ingredient (s)	Quantity (mg) / Tablet
Sofosbuvir INN	**400.00 mg**
Velpatasvir INN	**100.00 mg**

For complete qualitative composition including excipients, see attached. [4]

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]

Yes [✓] No [ ]

1.3 Is this product actually on the market in the exporting country?

Yes [✓] No [ ]

If the answer to 1.2. is **yes**, continue with section 2A and omit section 2B. If the answer to 1.2 is **no,** omit section 2A and continue with section 2B[6] :

2.A.1. Number of product license[7] and date of issue: **DAR No. 005-1208-032 Date of Issue 24.09.2019**

2.A.2. Product licence holder (name and address): Advanced Chemical Industries Limited.
Plant: 7 Hajeegonj Road, Godnyl, Narayanganj, Bangladesh
Regd. Office: 245, Tejgaon Industrial Area, Dhaka-1208, Bangladesh

2A.3. Status of product licence holder [8]: **Manufactures the dosage form**

2A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

Not Applicable

Continued to page-2

2A.4.	Is a summary basis for approval appended?[10]	Yes		No	✓
2A.5.	Is the attached, officially approved product information complete and consonant with the licence?[11]:	Yes	✓	No	
2A.6.	Applicant for certificate, if different from licence holder (name and address)[12]:	**Not Applicable**			
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14]	Yes	✓	No	
3.1	Periodicity of routine inspections (years) :	**Every Two Years**			
3.2	Has the manufacture of this type of dosage form been inspected?	Yes	✓	No	
3.3	Do the facilities and operation conform to GMP as recommended by the World Health Organization?[15]	Yes	✓	No	
4.	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]:	Yes	✓	No	

Name of authorized person : **Md. Eyahya**

Address of certifying authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka-1212

Telephone : + 880-2-9880897 ext.: 112
Fax no. : + 880-2-9880854
E-mail : dgda.gov@gmail.com
Web-site : www.dgda.gov.bd

Stamp and Date:

Md. Eyahya
Director (C.C.)
For Director General 19 SEP 2022
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Government of the People's Republic of Bangladesh