

# **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.dqda.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/**1596**6

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

Drug Manufacturing License No.:

Biological -

51 Date of Issue: 23/08/1963

Non Biological -

213 Date of Issue: 23/08/1963

### 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.	<ul> <li>Sourcing &amp; procurement of RM/PM from approved sources/vendors.</li> <li>Quarantine of RM/PM in W/H</li> <li>Sampling and testing of RM/PM</li> <li>Release of RM/PM</li> <li>Formulation design &amp; development</li> <li>Material requisition and receiving from WH.</li> <li>Dispensing of RM/PM</li> <li>Control of manufacturing environment</li> <li>Production: Granulation, Compression &amp; Coating(if applicable)</li> <li>Packaging &amp; Labeling</li> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysis</li> <li>Documentation</li> <li>Batch release</li> </ul>
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.	<ul> <li>Storage of Finished Products</li> <li>Sourcing &amp; procurement of RM/PM from approved sources/vendors.</li> <li>Quarantine of RM/PM in W/H</li> <li>Sampling and testing of RM/PM</li> <li>Release of RM/PM</li> <li>Formulation design &amp; development</li> <li>Material requisition and receiving from WH.</li> <li>Dispensing of RM/PM</li> <li>Control of manufacturing environment</li> <li>Production: Granulation, Compression &amp;</li> </ul>

ifacturing Practice (GMP) for Pharmaceutical Product(s)



Page 1 of 5

E	Dosage Form (s)	Category (ies)	Activity (ies)
6			Coating(if applicable)  Packaging & Labeling
D			In process control of Intermediate, Bulk and
1			Finished products
H			<ul> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp;</li> </ul>
1			Finished product analysis
C			<ul> <li>Documentation</li> </ul>
5			<ul><li>Batch release</li><li>Storage of Finished Products</li></ul>
47	Syrup / Solution /	Chemotherapeutics, Analgesic,	Sourcing & procurement of RM/PM from
H	Suspension	Antibiotics, Antiviral,	approved sources/vendors.
		Antipyretics & Anti- inflammatory, Vitamins &	<ul><li>Quarantine of RM/PM in W/H</li><li>Sampling and testing of RM/PM</li></ul>
3		Minerals, Hematinics,	Release of RM/PM
9		Anthelmintic / Antimalarial,	■ Formulation design & development
1		antidiarrhoeal / Antiprotozoal,	Dispensing of RM/PM     Control of cont
3		Antiemetics, Antihistamines & Antiallergics, Antacids &	<ul><li>Control of manufacturing environment</li><li>Production: Preparation &amp;Filling</li></ul>
3		Antiulcerants, Laxatives,	■ Packaging & Labeling
(5)		Expectorants, Antiasthmatics &	In process control of Intermediate, Bulk and
5		Bronchodilators, Antidiarrhoeal / Antiamoebics,	Finished products  Quality Assurance: Control of Manufacturing
1		Multivitamin, Dopamine	environment, In process Quality Control &
3		Antagonist, Antispasmodics,	Finished product analysis
1		Anesthetic, Germicidal, Adrenal Corticosteroids, Antiseptic.	Documentation     Batch release
0	/ /		Storage of Finished Products
9	Pediatric Drops	Analgesic, Antipyretics &	Sourcing & procurement of RM/PM from
0		Anti-inflammatory, Vitamins & Multivitamins, Anthelmintic /	approved sources/vendors.  Quarantine of RM/PM in W/H
3		Antima <mark>lari</mark> al, Antidiarrhoeal /	Sampling and testing of RM/PM  Sampling and testing of RM/PM
1		Antipr <mark>ot</mark> ozoal, Antiemetics,	Release of RM/PM
ري		Expectorants.	<ul><li>Formulation design &amp; development</li><li>Dispensing of RM/PM</li></ul>
4			<ul> <li>Control of manufacturing environment</li> </ul>
3			Production: Preparation &Filling
चर			<ul> <li>Packaging &amp; Labeling</li> <li>In process control of Intermediate, Bulk and</li> </ul>
			Finished products
7			Quality Assurance: Control of Manufacturing
又			environment, In process Quality Control & Finished product analysis
0			Documentation
12			Batch release     Storage of Finished Breducts
34	Dry Powder for Suspension /	Antibiotics, Antidiarrhoeal /	<ul> <li>Storage of Finished Products</li> <li>Sourcing &amp; procurement of RM/PM from</li> </ul>
H	Pediatric Drops	Antiprotozoal, Dermatological	approved sources/vendors.
K		& Antifungal, Macrolides,	<ul> <li>Quarantine of RM/PM in W/H</li> <li>Sampling and testing of RM/PM</li> </ul>
9		Carbapenem, Beta-lactam antibiotics	Release of RM/PM
1			Formulation design & development
165			<ul><li>Dispensing of RM/PM</li><li>Control of manufacturing environment</li></ul>
D			Production: Preparation & Filling
5	E HEALTH & FAMILY	,	<ul> <li>Packaging &amp; Labeling</li> <li>In process control of Intermediate, Bulk and</li> </ul>
9	SERAL OF DRIVE		Finished products
7	S S S S S S S S S S S S S S S S S S S		Quality Assurance: Control of Manufacturing     Assurance
6	TAN DHAKA		environment, In process Quality Control & Finished product analysis
时	13/5/		Documentation
1			

Dosage Form (s)	Category (ies)	Activity (ies)
		Batch release
		<ul> <li>Storage of Finished Products</li> </ul>
Cream/Ointment/Gel	Analgesic & Anti-inflammatory,	Sourcing & procurement of RM/PM from
cream, omene, der	Antiseptic, Dermatological &	approved sources/vendors.
	Antifungal, Steroids.	• Quarantine of RM/PM in W/H
		<ul><li>Sampling and testing of RM/PM</li></ul>
		<ul><li>Release of RM/PM</li></ul>
		<ul> <li>Formulation design &amp; development</li> </ul>
t contract to the contract to		<ul><li>Dispensing of RM/PM</li></ul>
		<ul> <li>Control of manufacturing environment</li> </ul>
		<ul><li>Production: Filling</li></ul>
		Packaging & Labeling
		<ul> <li>In process control of Intermediate, Bulk</li> </ul>
		and Finished products
		<ul> <li>Quality Assurance: Control of</li> </ul>
		Manufacturing environment, In process
		Quality Control & Finished product analysi
		<ul><li>Documentation</li></ul>
		<ul> <li>Batch release</li> </ul>
		<ul> <li>Storage of Finished Products</li> </ul>
Dry Powder For Injection	Antibiotics, Antispasmodics, Steroids,	<ul> <li>Sourcing &amp; procurement of RM/PM from</li> </ul>
i on act i of injection	Antiulcerants, Carbapenem,	approved sources/vendors.
	Beta-lactam antibiotics.	<ul><li>Quarantine of RM/PM in W/H</li></ul>
	beta-factain antibiotics.	
		<ul> <li>Sampling and testing of RM/PM</li> </ul>
		Release of RM/PM
		<ul> <li>Formulation design &amp; development</li> </ul>
		<ul><li>Dispensing of RM/PM</li></ul>
		<ul> <li>Control of manufacturing environment</li> </ul>
	The second secon	Production: Filling
	As ARROY	<ul> <li>Packaging &amp; Labeling</li> </ul>
		<ul> <li>In process control of Intermediate, Bulk</li> </ul>
		and Finished products
		Quality Assurance: Control of
		Manufacturing environment, In process
		Quality Control & Finished product analysi
		<ul> <li>Documentation</li> </ul>
		Batch release
		<ul> <li>Storage of Finished Products</li> </ul>
Eye & Ear Drops/	Antibiotics, Multivitamin, Analgesic &	<ul> <li>Sourcing &amp; procurement of RM/PM from</li> </ul>
Liquid Injection	Anti-inflammatory, Antimicrobial,	approved sources/vendors.
	Antihistamine, Steroids, Antiulcerant,	<ul> <li>Quarantine of RM/PM in W/H</li> </ul>
	Antispasmodic, Iron Supplement,	<ul> <li>Sampling and testing of RM/PM</li> </ul>
	NSAID, Antivomiting, Anesthetic	Release of RM/PM
	, rmar omeng, rmescrete	Formulation design & development
		<ul> <li>Dispensing of RM/PM</li> </ul>
		• Control of manufacturing environment
		Production: Preparation, Filtration (if
		applicable) & Filling
	4	
		Packaging & Labeling
		<ul> <li>Packaging &amp; Labeling</li> <li>In process control of Intermediate, Bulk</li> </ul>
		<ul> <li>In process control of Intermediate, Bulk</li> </ul>
		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> </ul>
CHEALTH & FAMILY		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of</li> </ul>
OF BAL OF DE		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process</li> </ul>
OF HEALTH & FAMILY AND THE REPORT OF DRUG RE		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysis</li> </ul>
OF HEALTH & FAMILY AND THE REAL OF DRUG ENERGY ENER		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysi</li> <li>Documentation</li> </ul>
CHEALTH & FAMILY AND THE POPULATION OF DAILS AND THE POPULATION OF DAILS AND THE POPULATION OF THE POP		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysis</li> <li>Documentation</li> <li>Batch release</li> </ul>
OF DAILS DOMINIS DHAKA		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysi</li> <li>Documentation</li> </ul>
3 8		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysis</li> <li>Documentation</li> <li>Batch release</li> </ul>
DHAKA  OF DAILS		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> <li>Quality Assurance: Control of Manufacturing environment, In process Quality Control &amp; Finished product analysis</li> <li>Documentation</li> <li>Batch release</li> </ul>

Dosage Form (s)	Category (ies)	Activity (ies)
MDI / Nebulizer / Nasal	Anti-asthmatics, Anti-histamine,	<ul><li>Sourcing &amp; procurement of RM/PM from</li></ul>
Spray/Sub lingual Spray	, ,	approved sources/vendors.
	Anti-anginal, Nose preparations.	<ul><li>Quarantine of RM/PM in W/H</li></ul>
		<ul> <li>Sampling and testing of RM/PM</li> </ul>
		<ul><li>Release of RM/PM</li></ul>
		<ul> <li>Formulation design &amp; development</li> </ul>
	*	<ul> <li>Dispensing of RM/PM</li> </ul>
		<ul> <li>Control of manufacturing environment</li> </ul>
		• Production: Preparation, Filtration (if
		applicable), Filling & Autoclave (if applicable
		Packaging & Labeling
		<ul> <li>In process control of Intermediate, Bulk and</li> </ul>
		Finished products
		<ul> <li>Quality Assurance: Control of Manufacturing</li> </ul>
		environment, In process Quality Control &
		Finished product analysis
		<ul> <li>Documentation</li> </ul>
		Batch release     Grand G
ODI (Dave e	A-111111	Storage of Finished Products
DPI (Dry powder for	Anti-asthmatics	<ul> <li>Sourcing &amp; procurement of RM/PM from</li> </ul>
nhalation)		approved sources/vendors.
		<ul><li>Quarantine of RM/PM in W/H</li></ul>
		<ul><li>Sampling and testing of RM/PM</li></ul>
		<ul><li>Release of RM/PM</li></ul>
		<ul> <li>Formulation design &amp; development</li> </ul>
	/ All 4 & Market	<ul><li>Dispensing of RM/PM</li></ul>
		<ul> <li>Control of manufacturing environment</li> </ul>
		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
nsulin	Anti-Diabetic	Storage of Finished Products     Source of PM (PM 6)
iisuiiii	Allu-Diabetic	Sourcing & procurement of RM/PM from
		approved sources/vendors.
		Quarantine of RM/PM in W/H
		<ul> <li>Sampling and testing of RM/PM</li> </ul>
		Release of RM/PM
		<ul> <li>Formulation design &amp; development</li> </ul>
		<ul><li>Dispensing of RM/PM</li></ul>
		<ul> <li>Control of manufacturing environment</li> </ul>
		<ul><li>Production: Preparation, Filling &amp; Sealing</li></ul>
		<ul><li>Packaging &amp; Labeling</li></ul>
		<ul> <li>In process control of Intermediate, Bulk and</li> </ul>
		Finished products
		<ul> <li>Quality Assurance: Control of Manufacturing</li> </ul>
	****	environment, In process Quality Control &
		Finished product analysis
WEALTH & F.		<ul><li>Documentation</li></ul>
JOY OAL OF DELLA	*	Batch release
18 Services		Storage of Finished Products
1\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\		
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Docago Form (a)	Cotogowy(isa)	
Dosage Form (s) Bio-tech Injectable	Category (ies)	Activity (ies)
(Erythropoietin,	Glycoprotein Hormone,	Sourcing & procurement of RM/PM from
Filgrastim)	Granulocyte colony-stimulating	approved sources/vendors.
riigrasumj	factor (G-CSF)	Sampling and testing of RM/PM
		Release of RM/PM
	A STATE OF THE STA	Control of manufacturing environment
		Production: Filling & Sealing
		<ul> <li>Packaging &amp; Labeling</li> </ul>
		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> </ul>
		<ul> <li>Quality Assurance: Control of Manufacturing</li> </ul>
		environment, In process Quality Control &
		Finished product analysis
	1	<ul><li>Documentation</li></ul>
		Batch release
		<ul><li>Storage of Finished Products</li></ul>
Suppository	Analgesic, Anti-Pyretic and	<ul><li>Sourcing &amp; procurement of RM/PM from</li></ul>
	Anti-Inflammatory, Laxatives.	approved sources/vendors.
	9	<ul><li>Quarantine of RM/PM in W/H</li></ul>
	- Marian - M	<ul><li>Sampling and testing of RM/PM</li></ul>
		<ul><li>Release of RM/PM</li></ul>
		Formulation design & development
		<ul><li>Dispensing of RM/PM</li></ul>
-		Control of manufacturing environment
		<ul><li>Production: Filling &amp; Sealing</li></ul>
		<ul><li>Packaging &amp; Labeling</li></ul>
		<ul> <li>In process control of Intermediate, Bulk and Finished products</li> </ul>
		Quality Assurance: Control of Manufacturing
		environment, In process Quality Control &
/		Finished product analysis
1		Documentation
Total State of the		Batch release
		Storage of Finished Products
		Storage of Hillshou Houdels

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:



Major General Md Mahbubur Rahman Director General 7 Directorate General of Drug Administration

Licensing Authority (Drugs) Government of the People's Republic of Bangladesh

tificate of Good Manufacturing Practice (GMP) for Pharmaceutical Product





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



060	्र ति	, <u>s</u>			Caro	100°	000
CERTIFI	CATE	<b>OF A</b>	PHAR	MACE	UTIC	AL PR	ODUCT

This certificate conforms to the format recommended by the World Health Organization

	(General	al instructions an	d explanatory notes attached)
Certifi	cate Number: DA/6-31/2000/	8443	Date: 19,09.22
Export	ing (certifying) country	:	BANGLADESH
Import	ing (requesting) country		MOLDOVA
1.	Name and dosage form of the p	roduct:	
A.	In Bangladesh	ATOM (	SOFOMAX DUO FC TABLET
B.	In Moldova	' <b>\ \</b>	SOFOMAX DUO FC TABLET
1.1	Active ingredient (s) (2) and amo	unt(s) <sup>(3)</sup> per unit	dose:
Activ	re Ingredient (s)	A STATE OF THE PARTY OF THE PAR	Quantity (mg) / Tablet
	buvir INN pasvir Acetone Solvate INN		400.00 mg 90.00 mg (Eqv. To 90.00mg Ledipasvir )
1.2	Is this product actually on the m	arket in the expo	Yes No No
If the 2A	he answer to 1.2. is <u>yes</u> , continue v and continue with section 2B <sup>6</sup> :	vith section 2A a	and omit section 2B. If the answer to 1.2 is <u>no</u> , omit section
2.A.1.	Number of product license <sup>(7)</sup> and	date of issue:	DAR No. 005-1087-032 Date of Issue 13.06.2016
2.A.2.	Product licence holder (name an Rego	d address): Plant: I. Office:	Advanced Chemical Industries Limited. 7 Hajeegonj Road, Godnyl, Narayanganj, Bangladesh 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 t	he manufacturer producing the dosage form is (9):
			Not Applicable

Continued to page-2



# Page "-2-"

2A.4.	Is a summary basis for appro	oval appended?10	Yes		No	<b>V</b>
04.5	T. (1 1. 1. 07 1.11				1 .1 11 011	
2A.5.	Is the attached, officially ap	proved product info	mation complete and co Yes	onsonant wit	h the licence?":	
			ies		NO	
2A.6.	Applicant for certificate, if o	lifferent from licenc	e holder (name and addr	ress) <sup>(12)</sup> :	Not Applicable	
3.	Does the certifying authority	arrange for periodi	c inenection of the many	ifacturing n	ant in which the	
· ·	dosage form is produced? (14		Yes	✓	No	
	accage rosses to produces.					
3.1	Periodicity of routine inspec	tions (years):		Eve	ery Two Years	
3.2	Has the manufacture of this	type of dosage form	heen inspected?			
	1140 010 114101000010 01 0115	eype or dosage form	Yes	V	No	
3.3	Do the facilities and operatio	n conform to GMP		World Healt		(15)
			Yes		No	
	D. 4.10 6 1				II	
4.	Does the information submit manufacture of the product?		Yes	thority on a	n aspects of the	
	manufacture of the product?		165		NO	
			XUA			
		The state of the s				
Name of	f authorized person	Md. Eya	hya			
A 44	-C	D:	A CONTRACTOR			
Address	of certifying authority		ate General of Drug A lli, Dhaka-1212	aministrati	on	
Telepho	ne l		9880897 ext.: 112			
Fax no.		: +880-2-				
E-mail			@gmail.com			
Web-site	e \	: www.dg	da.gov.bd			
				01		

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





Certificate Number:

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



Date: 19.09.22

660	2053	300	3000	60	SC E	6000	9
CERTIF	CATE	OFAP	HARN	JACEI	UTICAL	PRODUC	T

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

DA/6-31/2000/ 8441

Exporting (certifying) country	BANGLADESH
Importing (requesting) country :	MOLDOVA
1. Name and dosage form of the product:	M N
A. In Bangladesh :	SOVEL FC TABLET
B. In Moldova	SOVEL FC TABLET
1.1 Active ingredient (s) (2) and amount(s)(3) per	r unit dose:
Active Ingredient (s)	Quantity (mg) / Tablet
Sofosbuvir INN	400.00 mg
Velpatasvir INN	100.00 mg
2A and continue with section 2B <sup>6</sup> :	Yes No
2.A.1. Number of product license <sup>(7)</sup> and date of iss	
2.A.2. Product licence holder (name and address):  Plant:  Regd. Office:	Advanced Chemical Industries Limited. 7 Hajeegonj Road, Godnyl, Narayanganj, Bangladesh 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	ss of the manufacturer producing the dosage form is (9):
	Not Applicable
	Continued to page-2



Page "-2-"

2A.4.	Is a summary basis for approval appended? <sup>10</sup>	Yes No 🗸					
2A.5.	Is the attached, officially approved product in	formation complete and consonant with the licence? <sup>11</sup> :  Yes  No					
2A.6.	Applicant for certificate, if different from lice						
3.	Does the certifying authority arrange for periodosage form is produced? (14)	odic inspection of the manufacturing plant in which the  Yes  No					
3.1	Periodicity of routine inspections (years):	Every Two Years					
3.2	Has the manufacture of this type of dosage for	orm been inspected? Yes ✓ No					
3.3	Do the facilities and operation conform to GM	P as recommended by the World Health Organization? <sup>(15)</sup> Yes V No					
4.	Does the information submitted by the applic manufacture of the product? <sup>(16)</sup> :	ant satisfy the certifying authority on all aspects of the  Yes  No					
	12						
Name o	of authorized person : Md. I	Cyahya					
Address	Address of certifying authority : Directorate General of Drug Administration Mohakhali, Dhaka-1212						
Telepho	one : +880	-2-9880897 ext.: 112					
Fax no. E-mail		-2-9880854					
Web-sit		gov@gmail.com dgda.gov.bd					
Web sit		Subjective .					
		PANSINGS					
Stamp a	and Date:	Md. Eyahya					
		Director (C.C.) For Director General 19 SEP 2022					
		For Director General 19 SEP 2022 Directorate General of Drug Administration					
	o Calo	&					
	OF DE	Licensing Authority (Drugs)					
		Government of the People's Republic of Bangladesh					
	1818/ \EBI						
	MILITAL DHAM (O) [5]						