



GOVERNMENT OF THE PEOPLE'S REPUBLIC OF BANGLADESH

MINISTRY OF HEALTH & FAMILY WELFARE
DIRECTORATE GENERAL OF DRUG ADMINISTRATION
AUSHAD BHABAN, MOHAKHALI
DHAKA-1212, BANGLADESH
www.dgda.gov.bd



CERTIFICATE OF GOOD MANUFACTURING PRACTICE (GMP)
FOR PHARMACEUTICAL (PRODUCT(S))

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

Certificate Number: DA/6-87/04/ 19242

Date: 04 / 11 / 2024

It is hereby certified that **M/s. JMI Syringes & Medical Devices Ltd.** a drug (Disposable Syringe, Auto Disable Syringe, Medical Devices & Surgical 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 Provision of chapter-VII, of the Drug & Cosmetics Act, 2023 (xxix of 2023) or any Rule made there under.**

On the basis of the inspection carried out on 10-11-2023 & 03-07-2024 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the capacity forms, categories and activities listed in Table -1.

1. Name and Address of site : **JMI Syringes & Medical Devices Ltd.**
Rajendrapur, Chauddagam, Cumilla, Bangladesh.
2. Manufacturer's license Number : Biological-237
and Date of issue Date: 16-07-2001
3. Table-1 :

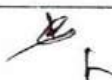


| Form(s) of Product(s) | Category (ies) | Activity (ies) |
|---------------------------|---|---|
| Auto Disable (AD) Syringe | Auto Disable (AD) Syringe 0.05ml Auto Disable (AD) Syringe 0.1 ml Auto Disable (AD) Syringe 0.5 ml Auto Disable (AD) Syringe 0.5 ml (Unibody) Auto Disable (AD) Syringe 1 ml Auto Disable (AD) Syringe 2 ml Auto Disable (AD) Syringe 3 ml Auto Disable (AD) Syringe 5 ml Auto Disable (AD) Syringe 10 ml | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Disposable Syringe | Disposable Syringe 1 ml Disposable Syringe 2 ml Disposable Syringe 3 ml Disposable Syringe 5 ml Disposable Syringe 10 ml Disposable Syringe 20 ml Disposable Syringe 30 ml Disposable Syringe 50 ml | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Ribbon Packing/ Blistering, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |

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| <i>Form(s) of Product(s)</i> | <i>Category (ies)</i> | <i>Activity (ies)</i> |
|-------------------------------------|---|---|
| Insulin Syringe | Insulin Syringe 1 ml (U- 40) Insulin Syringe 1 ml (U- 100) | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Ribbon Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Infusion Set | Intravenous Infusion Set | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Poly Packing/ Ribbon Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Blood Transfusion Set | Blood Transfusion Set | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Poly Packing/ Ribbon Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| JMI Hypodermic Needle / Luer Needle | Hypodermic Needle / Luer Needle | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Intravenous Cannula (I.V Cannula) | Intravenous Cannula (I.V Cannula) | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Suction Catheter | Suction Catheter | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |

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| <i>Form(s) of Product(s)</i> | <i>Category (ies)</i> | <i>Activity (ies)</i> |
|---|---------------------------|--|
| Urine Drainage Bag | Urine Drainage Bag | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Eye Gel Set (Syringe with stopper & Eye Gel Cannula) | Eye Gel Set | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Copper – T 380-A | Copper – T 380-A | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Umbilical Cord Clamp | Umbilical Cord Clamp | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Toomey Syringe | Toomey Syringe | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Disposable Dental Syringe | Disposable Dental Syringe | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |

| <i>Form(s) of Product(s)</i> | <i>Category (ies)</i> | <i>Activity (ies)</i> |
|--|--|---|
| Disposable Stomach Tube | Disposable Stomach Tube | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Scalp Vein Set | Scalp Vein Set | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Scalp Vein Set | Scalp Vein Set | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| First Aid Bandage | First Aid Bandage | Quality Control of Incoming Materials, In-process Control, Manufacturing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Disposable Feeding Tube | Disposable Feeding Tube | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Blood Lancet | Blood Lancet | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| 3-Way Stopcock (With or without Extension Tube) | 3-Way Stopcock (With or without Extension Tube) | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing , Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |

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| <i>Form(s) of Product(s)</i> | <i>Category (ies)</i> | <i>Activity (ies)</i> |
|------------------------------|--|--|
| Disposable Nelaton Catheter | Disposable Nelaton Catheter | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Disposable Wound Drain Tube | Disposable Wound Drain Tube | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Ribbon/Poly Packing, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Spinal Needle | Spinal Needle | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Packing, Sterilizing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |
| Oral Dispenser | Oral Dispenser 1 ml , Oral Dispenser 2ml, Oral Dispenser 3ml, Oral Dispenser 5ml, Oral Dispenser 10ml, Oral Dispenser 30ml Oral Dispenser 50ml | Quality Control of Incoming Materials, In-process Control, Manufacturing, Assembling, Blistering/Poly Packing, Packing, Finished Product Analysis, Finished Product Release, Storage and Finish Product Delivery. |

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

The manufacturing plant in which the pharmaceutical products (Disposable Syringe, Auto Disable Syringe and Medical Devices & Surgical Products) are produced is subject to inspection at suitable intervals.

The manufacturer conforms to the requirements for good practices in the manufacture and quality control (GMP) of drugs, as required under law in this country, as well as recommended by the World Health Organization (WHO) in respect of pharmaceutical products to be manufactured, sold or distributed within the country of origin or to be exported.

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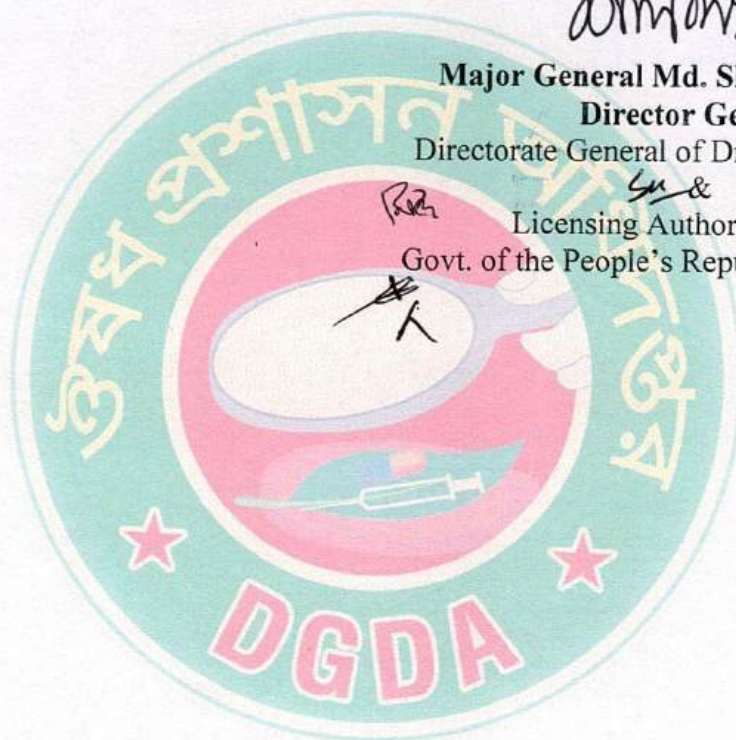
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This Certificate will remain valid for a period of 2 (Two) years from the date of issue.

It becomes invalid if the activities and/or categories certified hereby are changed or if the site is no longer considered to be in compliance with GMP.

Name of Authorized Person : **Major General Md. Shameem Haidar**
Address of Certifying Authority : **Directorate General of Drug Administration**
Mohakhali, Dhaka-1212, Bangladesh
Telephone : +88-022222-80803
Fax : +880-2-9880854
Email : dgda.gov@gmail.com
Web : www.dgda.gov.bd

Stamp and date:



[Signature]
Major General Md. Shameem Haidar
Director General

Directorate General of Drug Administration

[Signature]
Licensing Authority (Drugs)

Govt. of the People's Republic of Bangladesh

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