

Vibcare Healthcare Private Limited

Eligibility document kit for institutional and tender supply

Manufacturing plant: Khasra 6/2/2, Kot Road, Village Dabkori, Panchkula, Haryana 134103, India

Corporate office: Plot No. 4, HSIIDC IT Park, Sector 22, Panchkula, Haryana 134109 | info.vh@vibcare.co.in | +91 856

Manufacturer eligibility

WHO-GMP site certificate No. 1/182-1Drug-I-2024/10117, issued by FDA Haryana on 24 October 2024, covering tablets, capsules, oral liquids and external preparations for production, packing and quality control.

Manufacturing licences MLF252023HR000004 (Form 25) and MLF282023HR000005 (Form 28), FDA Haryana, valid to 7 May 2028.

GMP certificate under Revised Schedule M (Memo No. 1/182-1Drug-1-2024, 14 November 2024); GLP certificate for the quality control laboratories (No. 1/182-1Drug-I-2024/10589); ISO 9001:2015 (US-VTRM-25-25255390, 25 March 2025).

Plant and installed capacity

WHO-GMP plant on a 5-acre site at Dabkori, Panchkula, commissioned May 2023. Four sections: tablets 1.1 billion a year; capsules 950 million a year; oral liquids 30 million bottles a year; external preparations 40 million tubes a year. Blister and strip foil printed in-house on a 4-colour rotogravure unit. GLP certified chemical and microbiology laboratories with HPLC, GC, dissolution, UV and ICH stability chambers.

Products

750-plus formulations approved on the manufacturing licence across the four sections; 39 products approved for export to USP and BP monographs (cardiovascular, anti-infective, gastro-intestinal, CNS and pain, anti-allergic, metabolic). Products are supplied to IP, BP or USP standard as the tender schedule specifies, in institutional packs or the purchaser's brand.

Documents provided against a tender

Manufacturer's authorisation form in the tender's format for the bidder; product permission on the licence for each item quoted; certificate of analysis for every batch; stability data on request; capacity statement and other declarations in the tender's format on request; samples for evaluation; the plant open to the purchaser's inspection by appointment.

Lead time

45 to 60 days from artwork or overprint finalisation for the first consignment, then per the delivery schedule. For a product not yet on the licence, the FDA Haryana endorsement comes first.

OFFICE OF THE STATE DRUGS CONTROLLER -CUM-
LICENSING AUTHORITY FOOD AND DRUGS ADMINISTRATION,
HARYANA, PANCHKULA

SITE CERTIFICATE
(As per WHO-GMP Certification Scheme)

On the basis of the joint inspection carried out on dated 30.09.2024 & 01.10.2024 and subsequent inspection dated 21.10.2024 by Senior Drugs Control Officer, Ambala of the firm M/s Vibcare Healthcare Private Limited, Khasra No. 6/2/2, Kota Road, Dabkori, Panchkula-134103, Haryana (India), the undersigned certify that the site indicated in this certificate complies with Good Manufacturing Practices as specified under WHO-GMP certification scheme for the dosage form(s), categories and activities listed in Table 1

Name and Address of Site: M/s Vibcare Healthcare Private Limited,
Khasra No. 6/2/2, Kota Road, Dabkori,
Panchkula-134103, Haryana (India)

Manufacturer's Licence No. MLF252023HR000004 and MLF282023HR000005 valid upto 07.05.2028.

Table -1

S. No.	Dosage Form(s)	Categories	Activities
1.	Tablets	Non Beta-Lactam	Production, Packing & Quality Control
2.	Capsules	Non Beta-Lactam	Production, Packing & Quality Control
3.	External Preparations	Non Beta-Lactam	Production, Packing & Quality Control
4.	Oral Liquids	-----	Production, Packing & Quality Control

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

This Certificate is valid for three years from the date of issue and 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 as specified under WHO-GMP Certification Scheme.

Address of the Certifying Authority:
STATE DRUGS CONTROLLER-CUM-
CONTROLLING & LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION,
HARYANA, SCO No. 94, SECTOR-5, PANCHKULA.

Date of Issue:

STATE DRUGS CONTROLLER-CUM-
CONTROLLING & LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION, HARYANA

To ✓
M/s Vibcare Healthcare Private Limited,
Khasra No. 6/2/2, Kota Road, Dabkori,
Panchkula-134103, Haryana (India)

No. 1/182-1Drug-I-2024 10117

Dated: 24-10-2024

Endst. No. 1/182-1Drug-I-2024/

Dated:

A copy each is forwarded to the following for information and necessary action:-

- Deputy Drug Controller (India), Govt. of India, Central Drugs Standard Control Organization (Baddi), Directorate General of Health Services, Ministry of Health and Family Welfare. Container Corporation of India Building, Village Sheetlapur, Tehsil Baddi, District Solan (HP) 173205
- Senior Drug Control Officer, Ambala Zone.

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CONTROLLING & LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION, HARYANA

**OFFICE OF THE STATE DRUGS CONTROLLER, HARYANA
FOOD AND DRUG ADMINISTRATION,
HARYANA, PANCHKULA**

G.M.P. CERTIFICATE

This is to certify that M/s Vibcare Healthcare Private Limited, Khasra No. 6/2/2, Kota Road, Dabkori, Panchkula-134103 (Haryana) INDIA, is holding Drug Manufacturing Licenses on Form 25 & 28 bearing no. **MLF252023HR000004** and **MLF282023HR000005** under the Drug and Cosmetic Act, 1940 and the Rules 1945 there under, which are valid up to **07.05.2028** respectively for manufacturing for sale or for distribution of **Tablets (Non-Beta lactam), Capsule (Non-Beta lactam), Oral Liquids and External Preparations (Non-Beta lactam).**

The firm, by and large, is following **GOOD MANUFACTURING PRACTICES** as stipulated under the provisions of **Revised Schedule 'M'** of Drug Rules, 1945.

The firm shall, however, carry out self-inspection from time to time to ensure that the requirements of **Good Manufacturing Practices** are complied with.

This certificate is valid for three years from the date of issue

Dated:
Place: Panchkula

To ✓
M/s Vibcare Healthcare Private Limited,
Khasra No. 6/2/2, Kota Road, Dabkori,
Panchkula-134103, Haryana (India)

Memo. No. 1/182-1Drug-1-2024/ 10587

Dated: 14-11-2024

Endst. No. 1/182-1Drug-1-2024/

Dated:

A copy is forwarded to Senior Drug Control Officer, Ambala w.r.t. his office letter no. FDA/SDCO/Zone/Ambala/2024/2577 dated 21.10.202

**OFFICE OF THE STATE DRUGS CONTROLLER, HARYANA
FOOD AND DRUG ADMINISTRATION,
HARYANA, PANCHKULA**

G.L.P. CERTIFICATE

Certified that M/s Vibcare Healthcare Private Limited, Khasra No. 6/2/2, Kota Road, Dabkori, Panchkula-134103, Haryana (India) is holding Drugs Manufacturing Licenses No. MLF252023HR000004 and MLF282023HR000005 on Form 25 & 28 which are valid up to 07.05.2028 for carrying out Manufacturing of drugs.

The firm is following Good Laboratory Practices as stipulated under provision of Schedule L-1 appended to Drug Rules, 1945.

The firm shall carry out internal quality audits periodically as per requirements of above said schedule.

This certificate is valid for three years from the date of issue.

Dated:
Place:-Panchkula

To
✓ M/s Vibcare Healthcare Private Limited,
Khasra No. 6/2/2, Kota Road, Dabkori,
Panchkula-134103, Haryana (India)

Memo. No. 1/182-1Drug-1-2024/ 10589

Dated: 14-11-2024

Endst. No. 1/182-1Drug-1-2024/

Dated:

A copy is forwarded to Senior Drug Control Officer, Ambala w.r.t. his office letter no. FDA/SDCO/Zone/Ambala/2024/2577 dated 21.10.2024 for information and necessary action.



Certificate of Registration

This is to certify that

VIBCARE HEALTHCARE PRIVATE LIMITED

**KHASRA NO. 6/2/2, KOTA ROD, DABKORI, PANCHKULA –
134103, HARYANA, INDIA**

*has been independently assessed by IAB accreditation and is compliance
with the requirement of the standard*

ISO 9001:2015 **Quality Management System**

For the following scope of activities

**MEDICAMENTS (EXCLUDING GOODS OF HEADING 3002, 3005 OR 3006)
CONSISTING OF MIXED OR UNMIXED PRODUCTS FOR THERAPEUTIC
OR PROPHYLACTIC USES, PUT UP IN MEASURED DOSES (INCLUDING
THOSE IN THE FORM OF TRANSDERMAL ADMINISTRATION SYSTEMS)
OR IN FORMS OR PACKINGS FOR RETAIL SALE.**

Certificate Number: US-VTRM-25-25255390

To verify this certificate please visit at www.uscertifications.uk

Date of Certification	25 TH MAR 2025
Issuance Date	25 TH MAR 2025
1st Surveillance Due	24 TH MAR 2026
2nd Surveillance Due	24 TH MAR 2027
Re-Certificate Due	24 TH MAR 2028



CAB Address : Merry Terrace Woking, London FU21 3EH UK Validity of this certificate is subject to annual surveillance audits to be done successfully This certificate is the property of U.S. Certification and shall be returned immediately on request U.S. Certification is an independent Systems Products and Personal assessment Body, U.S. Certification is an accredited by IABCERT.US