



An Overview

About the Team

About the Promoter



Moksha has done his Chemical Engineering from Institute of Technology, Nirma University where his team won four national awards including one from Government of India for the work done on process development of “Aceclofenac”. He has earned his MBA from Rutgers Business School, NJ, USA where he was a Beta, Gamma, Sigma Invitee, a business honor society. Before founding Lewens Labs, Moksha has worked with the Investment banking team of Yes Bank Ltd. where he was part of the team providing advisory services on Mergers and Acquisitions and Equity fund raising activities to its clients.



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Nirma techies' work may make key arthritis medicine cheaper

DNAHM36708 | 10/20/2010 | Author : Kinjal Desai | WC :257 | Health

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Here is some good news for patients suffering from acute arthritis. The non-steroidal pain-killer, aceclofenac, which is preferred by doctors and patients alike because of its fewer side effects, may soon become cheaper, thanks to the research acumen of three students of Nirma University.

The three students — Moksha Udani, Shreya Gupta and Antrix Patel — graduated in chemical engineering this year. The research done by them in their final years was so successful that the trio have decided set up an industrial unit in Dahej four years from now to produce a cheaper formulation of aceclofenac. And there is a strong possibility that Nirma University itself may fund their effort to produce their product on a commercial scale. The trio did the research for their project, titled, 'Process Development of an Active Pharmaceutical Ingredient (API) - Aceclofenac.' Their project guide was Dr SS Patel, head of the chemical engineering department.

"The main aim of the project was to develop an alternative process for aceclofenac," said Udani. "Another drug, diclofenac, is more widely used as a pain-killer but it can cause various gastrointestinal problems. Aceclofenac is known to be more efficient in giving relief from pain and has relatively no side effects." Udani added that they would be applying for land in Dahej GIDC to set up their industry.

Gupta explained that their product was basically a derivative of diclofenac, but as it has almost no side effects it is the better drug.

"By a stroke of luck, we found raw materials in Ankleshwar," Gupta said. This helped bring down cost.

Board of Directors Consisting Industry Veterans



Mr. H. T. Patel is a Management Graduate with a rich experience of over 35 years in the pharmaceutical industry, which includes **25 years at Alembic Pharma and 10 years at Zydus Cadila**. He recently retired as **President of API Business at Zydus Cadila** and is currently also a Member of the Board of Management at CHARUSAT University, Gujarat. He is an integral part of the the Company and has been the main guiding force from day one. To give back to the society and to work for students, he founded Yuvalay – An organization which aims at training students for real life challenges and helping them unlock their true potential.



Mr. Kamlesh Udani serves as an **Executive Director in J.B.Chemicals and Pharmaceuticals Ltd.** and brings over 3 decades of experience in pharmaceutical industry to the table. He has been the past **president of IDMA-GSB**, Ankleshwar Industries Association, Rotary Club of Bharuch and various other prestigious organizations. He is also associated with several charitable organizations and NGOs and runs many social projects for development of the society. He has done his electrical engineering from LE Engineering college and earned his MBA from B.K. School of Management.

Key Highlights of the Company

Why Lewens Labs?

Strong In-House R&D Setup

- Highest number of personnel in R&D with a team of 1 PhD and 3 MSc qualified scientists
- Experienced leader guiding the team to develop products at a fast pace
- Strong Technical Advisory Team overlooks each product development

Focused on Entering Regulated Markets by 2019-20

- Developing products with proper methodology by adopting GMP from lab level, designing experiments based on the concept of QBD and performing validations from lab to plant scale
- Forming a strong QA team to create proper control and check on all activities

Independent Management Team

- Company is led by a young entrepreneur with understanding and experience in the field of Engineering and Finance
- Production and R&D departments are led by experience professionals for quicker growth of the organization

Industry Veterans mentoring the Company

- Company is supported and mentored by two industry veterans having combined experience of more than seven decades
- In-depth understanding of the potential market and overall business steers the Company in the right direction


Greenfield Facility At Dahej – Details on Land




Details about the Land

Location	<ul style="list-style-type: none">GIDC Dahej
Area	<ul style="list-style-type: none">10,000 Sq. Mt.
Accessibility	<ul style="list-style-type: none">45 kms from Bharuch railway station50 kms from NH-8140 kms from Hazira port
Other Key Industries in the region	<ul style="list-style-type: none">GSFC, GNFC, GACL, Sun Pharma. Torrent, Glenmark etc.

Key Certifications



Food & Drugs Control Administration
 BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
 GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



Certificate No. : **S-GMP/1802596**

G.M.P. CERTIFICATE

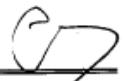
This is to certify that M/s. LEWENS LABS PVT. LTD., PLOT NO. D-2/CH376/377, GIDC, DAHEJ, Dist -BHARUCH is holding valid drug manufacturing licenses in Form No. 25 bearing No. G/25/2241 issued by this administration under the provisions of Drugs & Cosmetics Act 1940 & Rules there under. Under the said licenses the firm is permitted to manufacture & sell drugs covered under the following categories


Dosage Form (s)	Category (ies)
Bulk Drugs (APIs)	General

The firm has employed competent technical staff to undertake manufacturing & testing of the permitted drugs. They are following **GOOD MANUFACTURING PRACTICES** in manufacturing and testing as laid down under the **REVISED SCHEDULE-M** of Drugs & Cosmetics Act 1940 & Rules There under.

The manufacturing plant is subjected to inspection at suitable intervals by competent authority.

This certificate is valid from Dt : **06/02/2018** to **05/02/2020**.


 (Dr. H. G. KOSHIA)
 Commissioner
 Food & Drugs Control Administration
 Gandhinagar, Gujarat State



Email : comfdca@gujarat.gov.in
 Phone : 91-79-23253437, Fax : 91-79-232-53400



Food & Drugs Control Administration
 BLOCK NO. 8, 1ST FLOOR, Dr. JIVRAJ MEHTA BHAVAN,
 GANDHINAGAR, GUJARAT STATE, INDIA. PIN: 382010



No.Certi/GLP/Lewens Labs/2018/15238 /B, Date. 08 FEB 2018

GLP. CERTIFICATE

This is to certify that M/s. LEWENS LABS PVT. LTD, Plot No. D-2/CH376/377, G.I.D.C., Dahej, Dist. Bharuch is holding drugs manufacturing license in form No. 25, bearing No. G/25/2241 under Drugs & Cosmetics Act, 1940 & Rules thereunder.

The firm is having its own testing laboratory as per Drugs & Cosmetics Act, 1940. The firm is complying with the **Good Laboratory Practices (GLP)** requirements of **Schedule L1** of the Drugs and Cosmetics Rules 1945.

This certificate is issued on the basis of the inspection report and documents available in this office as on today and issued for Export & participation in tender for State and Central Governments.

This Certificate is valid from: **06/02/2018** to **05/02/2020**.




 For Commissioner,
 Food & Drugs Control Administration,
 Gandhinagar, Gujarat State

Key Certifications

Food & Drugs Control Administration
 BLOCK NO. 8, 1ST FLOOR, DR. JIVRAJ MEHTA BHAVAN,
 GANDHINAGAR, GUJARAT STATE, INDIA. PIN : 382010

Certificate No. : **19011156**

On the basis of the inspection carried out on 19/20/11/2018 & 03/01/2019 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table :

1 Name & Address of site : **LEWENS LABS PVT. LTD.**
PLOT NO. D-2/CH376/377, GIDC.,
City : DAHEJ, Dist, BHARUCH, GUJARAT STATE, INDIA

2 Manufacturer's Licence number : **G/25/2241**

3 Table : 1

Dosage Form (s)	Category (ies)	Activity (ies)
Bulk Drugs (APIs)	General	Manufacturer

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

This certificate remains valid until **06/01/2022**. 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

Format of this certificate is as per WHO TRS No. 908 of 2003.

Address of certifying authority

Food & Drugs Control Administration,
 Block No. 8, 1ST floor, Dr. Jivraj Mehta Bhavan, Gandhinagar, Gujarat State, India. – Pin : 382010

Name & function of responsible Person : **(Dr. H.G. KOSHTIA)**
Commissioner

Email : comfdca@gujarat.gov.in

Phone : 91-79-23253417, Fax : 91-79-232-53400

Date : **07/01/2019**



Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 9001:2015

This is to certify that: **Lewens Labs Pvt. Ltd.**
 D2/CH/376-377
 GIDC, Dahej,
 Dist, Bharuch
 Gujarat
 India

Holds Certificate No: **FM 701269**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

Research, Development and Manufacturing of API and Intermediates,

For and on behalf of BSI:

A

Chris Cheung, Head of Compliance & Risk – Asia Pacific

Original Registration Date: 2019-01-03
 Latest Revision Date: 2019-01-03

Effective Date: 2019-01-03
 Expiry Date: 2022-01-02

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...making excellence a habit.

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated www.bsi.com. Printed copies can be validated at www.bsi.com/ClientDirectory or telephone +91 11 2692 9000. Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2015 requirements may be obtained by emailing the organization. This certificate is valid only if provided original copies are in complete set.

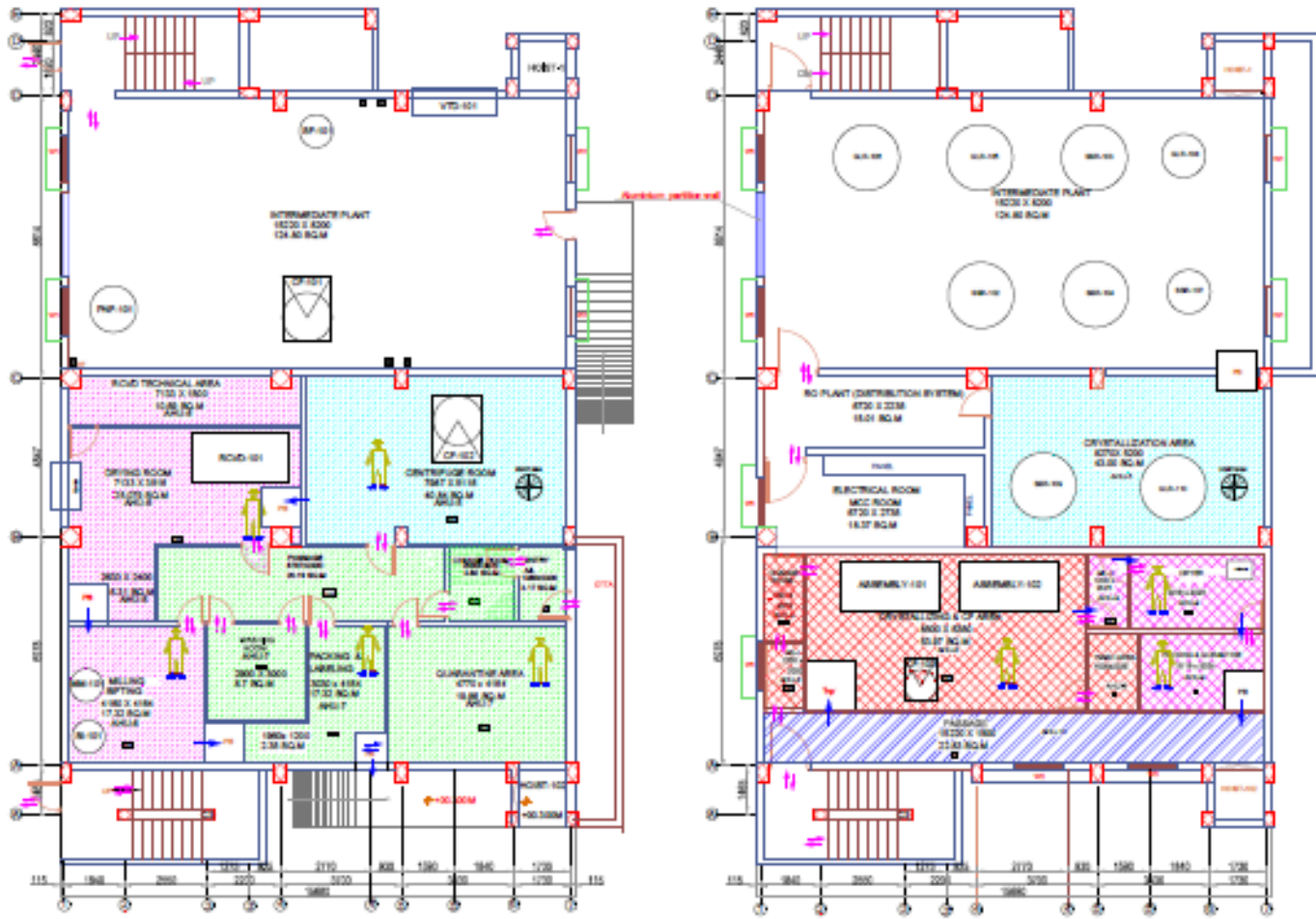
Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlton, Milton Keynes MK8 9PS, UK + 44 345 080 9000
 BSI Assurance UK Limited, registered in England under number 7505221 at 389 Chiswick High Road, London W4 4AL, UK.
 A Member of the BSI Group of Companies.

Warehouse – Capable to handle all storage requirement



- Segregated Areas for Quarantine, Under Test, Approved and Reject
- FIFO followed
- Labels stored under lock and key

Production Plant Layout – Complying All International Standards



- Separate Man and Material Movement
- Powder Processing area restricted with bio matrix

W-F-M	W-F-M NO.	ROOMS COVERED	PLANT ALT.
[Light Blue Box]	H-1	OFFICE ROOMS	0.5 M
[Pink Box]	H-2	POWDER PROCESSING ROOMS	0.5 M
[Green Box]	H-3	UTILITY ROOMS	0.5 M
[Red Checkered Box]	H-4	ASSEMBLY ROOMS	0.5 M
[Purple Box]	H-5	POWDER PROCESSING ROOMS	0.5 M
[Blue Hatched Box]	H-6	PASSAGE	3.0 M

LEGEND:-

- MAN WITH APRON CAP & FOOT WEAR
- MAN MOVEMENT
- MATERIAL MOVEMENT

GROUND FLOOR PLAN EFL -0.30M LVL TO 10.45M

FIRST FLOOR PLAN EFL +5.30M LVL TO 10.45M

List of Equipments and Facilities

Manufacturing	Nos	Quality Control	Nos	Utilities	Nos
Reactors (Intermediate Block)	07	HPLC with UV Detector	02	Boiler	01
Reactors (GMP Area)	02	HPLC with PDA Detector	01	Chilling Plant (50 TR)	02
Centrifuge	03	GC with Head Space	01	Cooling Tower (250 TR)	02
Vacuum Tray Dryer/Tray Dryer	03	UV	01	Vacuum Pumps	03
RCVD	01	IR	01		
100 Liter glass assembly (GMP)	01	Analytical Balance	02		
50 Liter glass assembly (GMP)	01				
Purified Water System (500 LPH)	01				

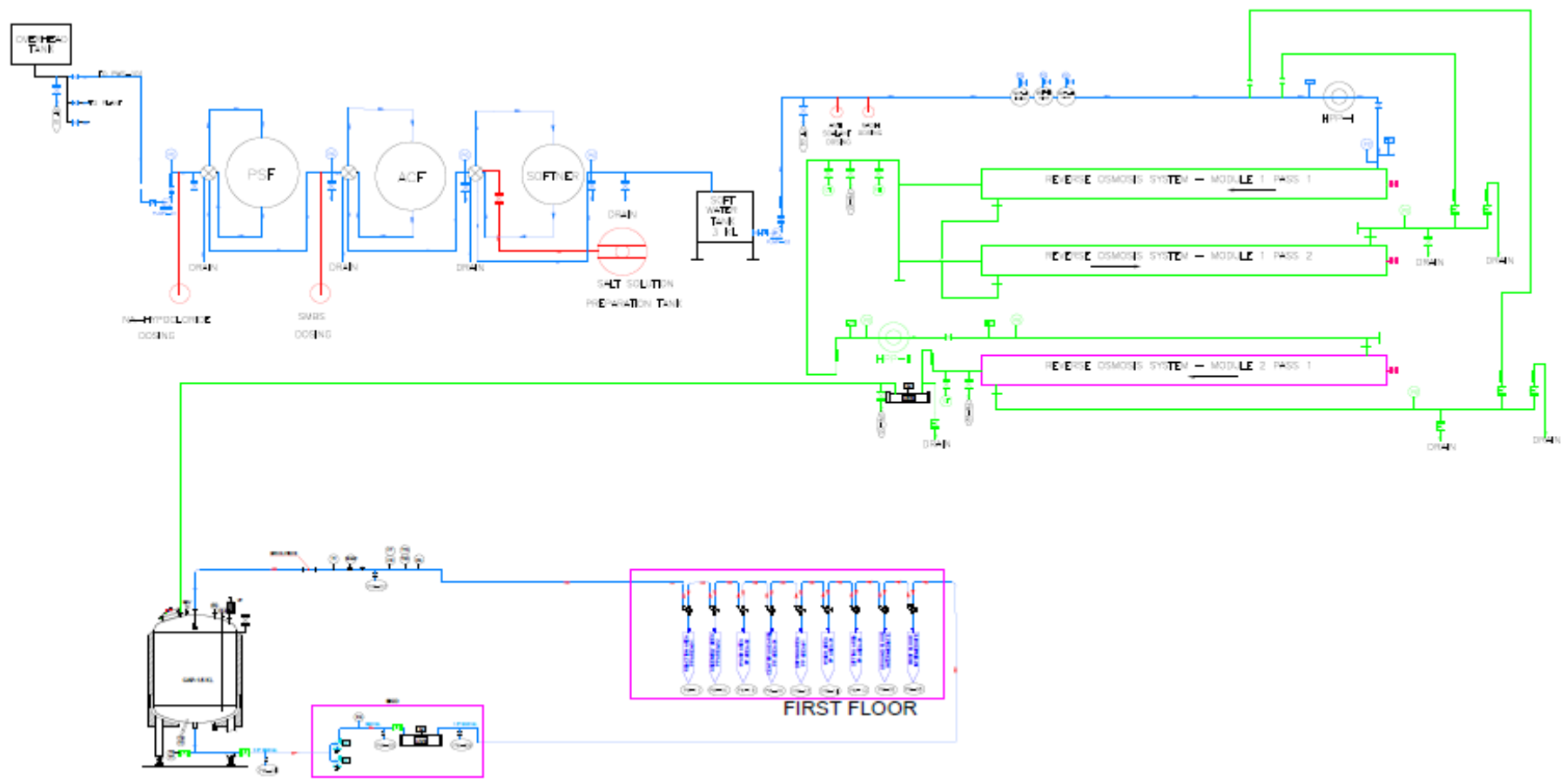
- Total GMP Blocks: 02
- Installed Capacity: 20 KL

QC Overview

Key Instruments	Particulars	Make
HPLCs	21 CFR Compliant	Shimadzu
GC	21 CFR Compliant	Shimadzu
IR	21 CFR Compliant	Shimadzu
UV	21 CFR Compliant	Shimadzu
Detector	UV	Shimadzu
Detector	PDA	Shimadzu
Stability Chambers	4 Conditions including storage of 2-8	Newtronic

- In-House AMV Capability
- Stability Chambers – 21 CFR compliant

Two Pass RO Water System



Quality Policy

Quality establishes the faith in the brands of the company therefore it cannot be compromised at any cost. Quality is the prime focus, as we inculcate the spirit of Quality in every employee at all levels. Our quality standards meet all international norms, as they are supported by well-written SOPs, which are continuously updated.

It is our commitment to design and Manufacture products that respect the people and environment.

Thank You