
fleming
LABORATORIES LIMITED

Overview

Year of Establishment	1994 (Incorporated as a Public Limited company)
Management change	2015 January
Business focus	Drug Substances & Intermediates
Team	About 316
Manufacturing Facilities	Two
Facility Category	EOU (Export Oriented Unit)
APIs Exported to	About 60 countries
Major Markets	LATAM, East Asia, CIS countries, MENA, Europe

Vision & Mission Statement

OUR VISION

To be the partner of choice for the global pharmaceutical Industry by continuously delivering top quality APIs and related services.

OUR MISSION

Profitable growth through superior customer service, operational excellence, quality and commitment, guided by the core values of the company.

Facility Details

Facility	Location / Address	Other Details
Fleming Laboratories Limited, Corporate Office	Plot No 131, Green Park Avenue, Jeedimetla, Hyderabad – 500 067, Telangana, India	DUNS Number : 65-006-8831
Fleming Laboratories Limited, Unit I	Survey No 270, Nawabpet Village, Shivampet Mandal, Medak Dist -502 313, Telangana, India	DUNS Number : 65-049-5323 GPS Co-ordinates : Latitude: 17.700817 N Longitude: 78.388133 E

Organogram


Chief Executive Officer & Managing Director
Jayamuruga Prakash
Head-Operations
L. Mohammed Rafeek
Head-EHS & Tech. Services
R. Koteeswaran
Head-Projects
R. Prabhu
Head-QA
T.Srinivas
Head-QC
T. Srinivasa Rao
Production-In charge
Head-Engineering
Head-Warehouse
Head-HR
Team Leader-RA
Head-Environment
Head-safety
Head-TechTransfer
Head-EDP
Team Leader-QA
Team Leaders
Block In charge
Dy.Head-Mech/Elec/Utilities
Shift In-charges/Block Engineer
Supervisors
Supervisors
Executives
Executives
Supervisors
Engineers
Engineers
Project Engineers
Executives
Executives
Analyst QC & Microbiologists
Chemists/Operators
Technicians/Operators
Officers
Operators
Officers

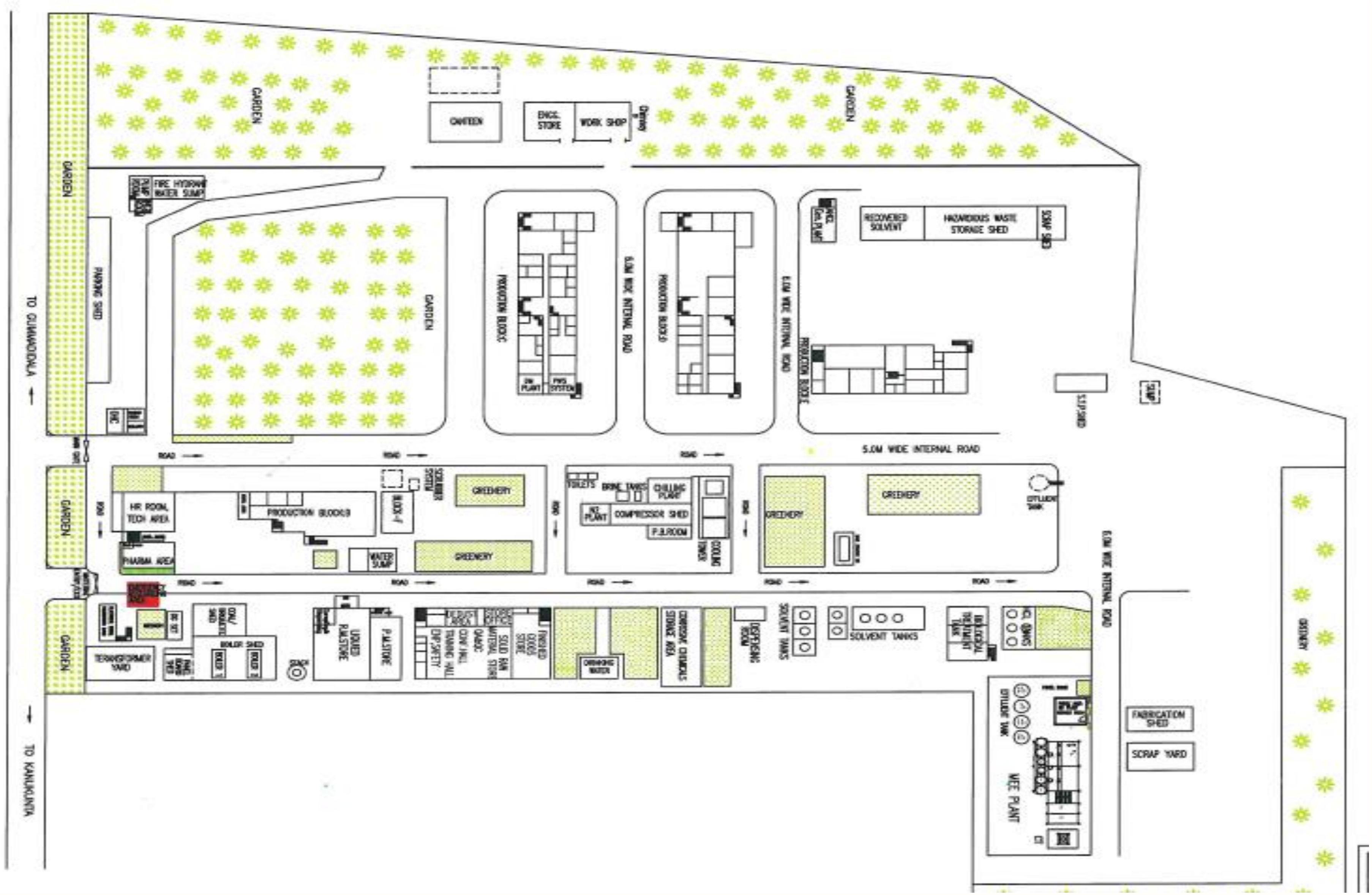
Personnel

Unit I	
Total Employees	194
Production	76
QA	14
QC	25
Regulatory	2
Warehouse / Stores	9
Engineering & Projects	57
Administration / HR	4
EHS	7

Key Personnel

Name	Department	Designation	Experience
M. Jeyamuruga Prakash	Corporate	CEO	23 Years
R. Koteeswaran	EHS & Technical Services	Head	21 Years
Mohammed Rafeek	Operations	Head	20 Years
T. Srinivas Rao	Quality Control	Head	14 Years
T. Srinivas	Quality Assurance	Head	16 years
R. Prabhu	Projects	Head	15 years
A. Balachander	Production	Head	23 Years
D. Srinivas	Engineering	Head	24 Years
A. Appa Rao	Human & Resources	Head	13 Years
S. Vijay Kumar	Warehouse	Head	14 Years

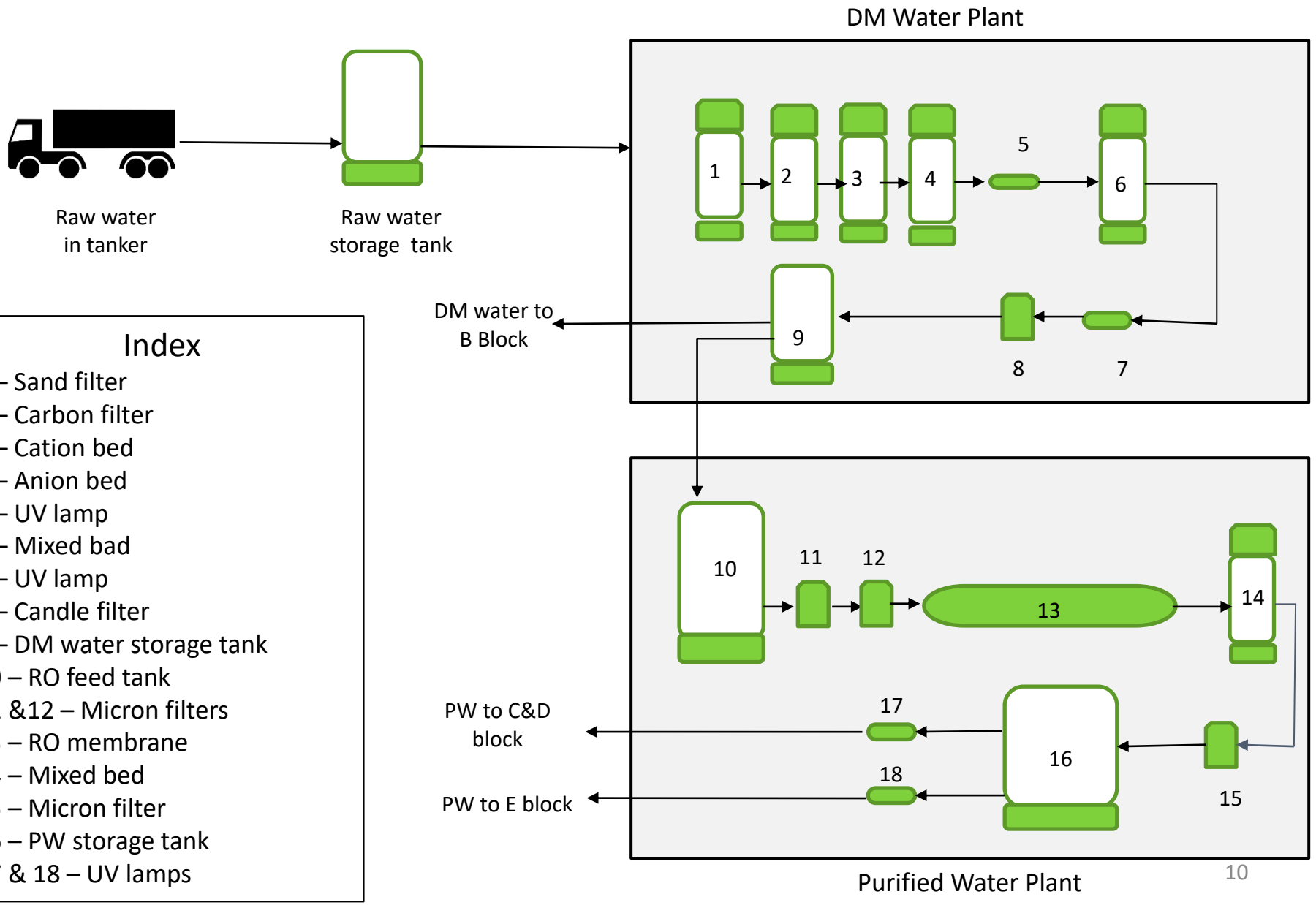
Site Layout


GARDEN
CANTEEN
ENGG. STORE
WORK SHOP
FIRE HYDRANT WATER SUMP
PARKING SHED
TO GUMMADIDALA
PRODUCTION BLOCK
5.0M WIDE INTERNAL ROAD
PRODUCTION BLOCKS
RECOVERED SOLVENT
HAZARDOUS WASTE STORAGE SHED
5.0M WIDE INTERNAL ROAD
ROAD
GREENERY
HR ROOM, TECH AREA
PRODUCTION BLOCKS
PHARMA AREA
WATER SUMP
TOILETS
BRINE TANKS
CHILLING PLANT
COMPRESSOR SHED
P.B.ROOM
COOLING TOWER
EFFLUENT TANK
TRANSFORMER YARD
BOILER SHED
LIQUID RM STORE
P.M.STORE
SOLID RAW MATERIAL STORE
FINISHED GOODS STORE
DRINKING WATER
CORROSIVE CHEMICALS STORAGE AREA
SOLVENT TANKS
MEE PLANT
FABRICATION SHED
SCRAP YARD
TO KANUKUNTA

Site Infrastructure

Total Area	19 Acres
Built up Area	6.0 Acres
Production Blocks	5 (B, C, D, E, F & PG)
Block Utilisation	
B Block	Starting materials
C Block	Intermediates & APIs
D Block	Intermediates & APIs
E Block	Intermediates & APIs
F Block	New products
PG Block	New products
Total Reactor capacity	120 KL
Utility Details	
Boiler	4 MT, (2 MT Back up)
Chilled Brine	83 TR (-10 ^{o}C), (50 TR Back up)
Chilled Water	80 TR (+5 ^{o}C)
Power	950 KVA (750 KVA back up)
Nitrogen Plant	15 NM^3/Hr
Thermic Fluid Heater	200,000 K Cal/Hr

Water system: Schematic



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1 – Sand filter
2 – Carbon filter
3 – Cation bed
4 – Anion bed
5 – UV lamp
6 – Mixed bad
7 – UV lamp
8 – Candle filter
9 – DM water storage tank
10 – RO feed tank
11 &12 – Micron filters
13 – RO membrane
14 – Mixed bed
15 – Micron filter
16 – PW storage tank
17 & 18 – UV lamps

Products & Facilities

S. No	NAME OF THE MANUFACTURING BLOCK	NAME OF THE PRODUCT		
		Regular	Not Regular	Optional
1	Block B	1. 4-Chlorobenzhydryl Piperazine 2. Buclizine HCl (Stage-II)	Not applicable	Cinnarizine (Stage-I, II, III, IV) Flunarizine Di HCl (Stage-I, II, III, IV)
2	Block C	1. Meclizine HCl 2. Buclizine HCl 3. Flunarizine Di HCl 4. Loperamide HCl 5. Cyproheptadine HCl 6. Etodolac	1. Etidronate Disodium 2. Oxatomide 3. Cyclizine HCl 4. Diltiazem HCl 5. Clopidogrel Bisulphate 6. Hydroxyzine HCl	Not applicable
3	Block D	Carisoprodol	Not applicable	Not applicable
4	PG Block	Prostaglandins	Not applicable	Not applicable
5	Block E	Cinnarizine	Pentoxifylline	Carisoprodol
6	Block F	New Products	Cilostozol	Cilostozol

Regulatory Status – Products

Product	Regulatory Approvals
Buclizine HCl	COFEPRIS, WHO GMP, WC, UK MHRA, HPRA(Ireland), TFDA(Taiwan)
Cinnarizine	EDQM, CEP, COFEPRIS, WHO GMP, WC, IDL(China), MOH(Russia)
Cyproheptadine	COFEPRIS, WHO GMP, IDL(China)
Meclizine HCl	PMDA Japan, WHO GMP, WC, COFEPRIS, CEP, MEP (Netherlands), TDMF
Carisoprodol	COFEPRIS, WHO GMP, ANVISA
Etodolac	CEP, WHO GMP
Pentoxifylline	WHO GMP, CEP (U/R)
Diltiazem HCl	GMP
Flunarizine HCl	COFEPRIS, WHO GMP, WC, CEP, ANVISA, IDL (U/R), TDMF
Loperamide HCl	CEP, WHO GMP, COFEPRIS, MOH(Russia)

Note: WC- Written confirmation

Regulatory status - Facility

S. No.	Name of Regulatory Authorities(National and International)	Inspection dates	Inspected Product(s)	Certificate	Validity	Inspection outcome
1	European Union (EU) Written Conformation	29/11/2018 30/11/2018	Cinnarizine BP/Ph. Eur. Etodolac USP Buclizine Hydrochloride BP Carisoprodol USP/Ph. Eur. Cyproheptadine Hydrochloride Ph.Eur/BP/USP Flunarizine Dihydrochloride BP/Ph. Eur. Loperamide Hydrochloride BP/Ph. Eur./USP Meclizine Hydrochloride USP Meclozine Hydrochloride BP/Ph.Eur Pentoxifylline USP/Ph.Eur Hydroxyzine Hydrochloride USP Cyclizine hydrochloride Ph.Eur Diltiazem Hydrochloride Ph.Eur/USP	EU WC	13/08/2022	Approved
2	DCA & CDSCO	29/11/2018 30/11/2018	1. Buclizine Hydrochloride BP 2. Carisoprodol USP/Ph. Eur. 3. Cinnarizine BP/Ph. Eur. 4. Cyproheptadine Hydrochloride Ph. Eur. 5. Flunarizine Dihydrochloride Ph. Eur. 6. Loperamide Hydrochloride BP/Ph. Eur./USP 7. Meclizine Hydrochloride USP 8. Meclozine Hydrochloride BP/Ph.Eur 9. Pentoxifylline USP	WHO GMP	14/02/2022	Approved
3	Federal Agency for Medical & Health Product AIMPS (FAGG), Belgium.	06/02/2019 07/02/2019 08/02/2019	Cinnarizine	EDQM/EUGMP	NA	Approved
4	DCA & CDSCO	26/12/2019 27/12/2019 28/12/2019	Etodolac EP/USPDiltiazem HCl USP/EPCyclizine EPPentoxifylline EPHydroxyzine HCl USP	WHO GMP	13/05/2023	Approved
5	ISO 9001:2015By DNV. GL	11/06/2020 12/06/2020	Quality Management System	ISO 9001:2015	01/07/2022	Approved
6	DCA	25/11/2020	GMP(Schedule-M)	GMP	15/12/2021	Approved

Brief Regulatory History of the site

Key Events	Year
Year of Establishment of company	1994
Year of establishment of Unit 1	1995
Original CEP filings	2005
First USDMF filing	2007
Change in Management	2015
EDQM, EUGMP approval after re-inspection	2016
EDQM, EUGMP re-inspection	2019

Major Improvements in the last 5 years (2016 – 2020) Quality Systems

- Migration of QMS events (OOS, Change control, Deviation, CAPA, Risk assessment and Customer complaint) from paper to paperless documentation through online “ERP based system”
- Implemented Integrity Manual in line with USFDA procedure & WHO guideline for data integrity (Document No: FLL/IM/001, Effective: 15/03/2017)
- Computer system validation in line with GAMP5 (CSV)
- Requalification policy, re-qualification of analytical instruments, Process equipment, and AHUs. Completion of qualification of water system.
- Solvent recovery and reuse policy (Solvent Management Policy)
- Updated the Cleaning validation procedure in line APIC and EUGMP guidelines
- Updated the OOS procedure (Including Hypothesis study)

Major Improvements in the last 5 years (2016 – 2020) – Quality control

- Migration of non networking system (HPLC, GC, GCHS, UV & FTIR) to networking system through “Lab Solution CS software”
- Annual maintenance contract for analytical instruments (HPLC,GC,UV,FTIR)
- SOP for Good Chromatographic Practices & Good Integration Practices, resulting in drastic reduction of invalid OOS reporting (Zero Invalid OOS since April 2018)
- SOP for Review of Audit trail, electronic raw / meta data, System Suitability failure
- Migration from “reusable HPLC / GC vials” and sampling bottles to “Single use and throw HPLC / GC vials”
- Extraneous matter filtration test (EMFT) for all the batches of finished product
- Facility improvement including : Incoming Sample storage, Sample preparation room for GC & HPLC, Particle size analyzer, Microbiology lab modification

Major Improvements in the last 5 years (2016 – 2020)– Manufacturing & Facility

- Replacement of old equipment like Tanks, Reactors, Sifters, Sparkler filters for compliance improvement
- Installation of new Utility systems (New boiler, New Chilling plant, Nitrogen plant)
- Access control of clean rooms ,Quality Control & Finished goods storage through biometric system
- Replaced the concrete & damaged epoxy floors with granite floors in manufacturing area
- Demolished the A block due to compliance inadequacies
- Additional Facility created for rejected material storage.
- New Facility created for PG Block.

Have a safe Visit

- Visitors shall be accompanied by Fleming representative during the visit
- Visitors shall be advised about specific safety precautions, if any, for entering the hazardous areas by the FLL personnel
- In case of emergency, siren shall be sounded and Visitors shall move along with Fleming personnel to a safe assembly point
- Visitors shall be provided with and advised about personnel protective equipment suitable to the area of the visit
- Photography is permitted for Visitors. Area shall be cleared as safe for photographing by Safety personnel prior to taking the pictures.
- Entire site premise is a non smoking zone

Thank You …

Contact Us

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