NAVIN Molecular

CDMO Division of Navin Fluorine

NAVIN MOLECULAR

Vision

We at Navin Fluorine are committed to be a world class customer focused, innovative organization in the filed of Fine & Speciality chemicals and partner of choice to global refrigerant, chemicals, crop science and Life science companies.

Mission

- To partner with our customers by providing world-class fluorochemical intermediates, products and services
- To continue and grow research and development as the sustenance engine of the organisation
- To innovate, build and operate chemical plants in the most safe, compliant and environment-friendly
- To continuously enhance stakeholder value by optimum utilisation of resources

PADMANABH MAFATLAL GROUP
Creating value. Sharing value.

Navin Fluorine International Limited

At a Glance

- Established in 1967, NFIL is among the first fluorochemicals companies in mainland Asia
- One of largest and fully integrated Specialty Fluorochemical Company in India offering CRO, CDMO and
- CMO services to Innovator partners
- Strong Global Partnerships with Innovators in CropScience, Life Science, Performance Materials and Semicon industry
- Strong Balance Sheet with legacy of strong governance practices & Corporate Social Responsibility

Revenue FY 24	Employees	Manufacturing sites	Global Locations
$255m	1500+	3 (Surat, Dahej, Dewas)	3 (US, UK, China)

Business Units	Market Cap.	R&D	EcoVadis rating
3 (Specialty, HPP & CDMO)	$2.14bn (as on 28th Feb 2025)	State of art facility (100+ scientists)	GOLD

57 - Year history of Navin Fluorine business

1967 — Navin Fluorine founded as the first integrated fluorochemicals company in Asia (outside of Japan), producing HF, refrigerant gases, and a range of inorganic fluorides

1978 — A speciality chemicals facility is established at our site in Dewas to produce alkylated anilines and toluidine's.

1996 — Manchester Organics is founded at University of Manchester Institute of Science and Technology (UMIST) as a provider of novel fluorinated building blocks.

2008 — Navin Fluorine wins the CHEMEXCIL Award under the 'Large Scale Sector, Chemicals Panel' for outstanding export performance.

2009 — **Dedicated CDMO business unit founded, providing contract manufacturing and development services for pharma starting materials and intermediates. Pilot plant and R&D laboratories are commissioned in Dewas.**

2011 — Navin Fluorine take a controlling stake in Manchester Organics Limited (UK) to develop expertise for more complex fluorination projects and expand our pipeline.

2015 — We commissioned a **2nd** cGMP multi-purpose plant at our Dewas site.

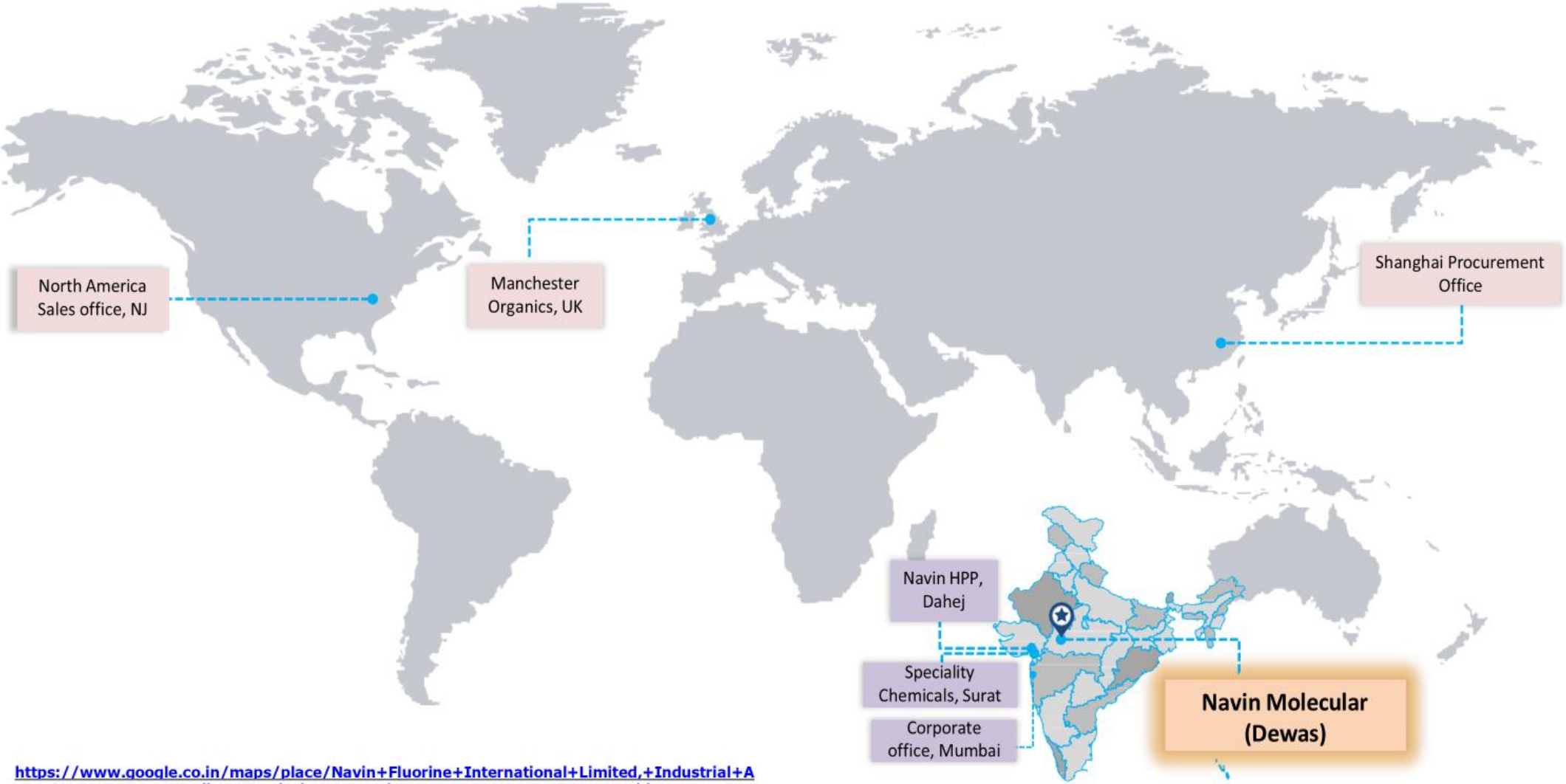
2020 — CDMO Business's third cGMP multi-purpose plant at our Dewas site begins commercial production.
Navin Fluorine is included in Forbes Asia's Best under a Billion 2020.
Recognised for their growth and innovation.

2022 — Dedicated hydrogenation block commences operation at our Dewas site.

2023 — Navin Molecular brand is launched for our CDMO business unit.

2024 — US$ **35 Mn** investment for New GMP-4 Manufacturing block.

Global Footprint of Navin Fluorine



https://www.google.co.in/maps/place/Navin+Fluorine+International+Limited,+Industrial+Area+No.2,+Dewas,+Madhya+Pradesh+455111/@22.9309936,76.0195216,17z/data

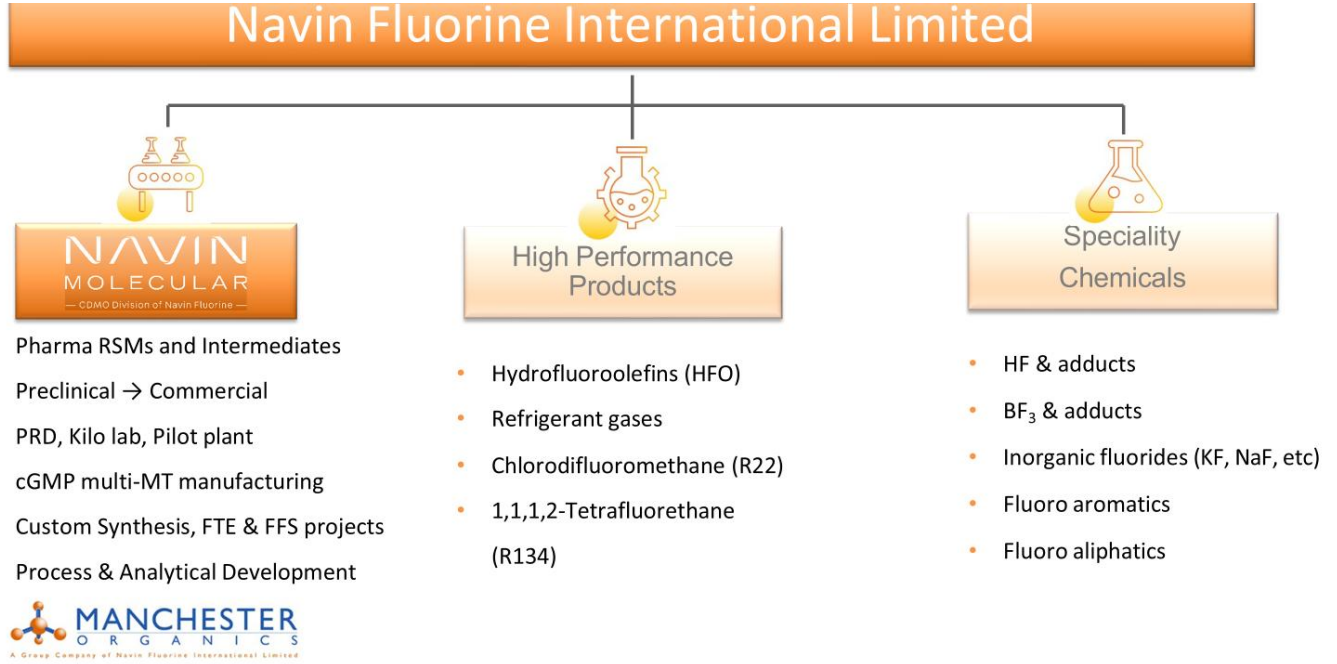
Services offered by Navin Molecular

- **Custom Synthesis**
  1. Fee For Service (FFS): a quick solution to your material requirements, whether gram to kg-scale manufacturing of a key building block, or mg to gram-scale supply of impurities or reference standards.
  2. Full-time Equivalent (FTE): collaborative approach and work in partnership with customer technical team to solve complex route, process, and analytical development challenges.

- **Process Development**
  1. Development of both new synthetic routes and the optimization of existing processes as suitable for scale-up.
  2. Experience in full range of classical small-molecule synthetic transformations.
  3. Isolation and handling of reactive intermediates.
  4. Process safety assessments.
  5. Stoichiometry and process stream optimization.
  6. Waste reduction.
  7. Impurity profiling and synthesis.

- **Analytical Development**
  1. Analytical method development.
  2. Optimization, qualification, verification, validation, and method transfer.
  3. Impurities identification, tracking and isolation.
  4. Release and ICH stability studies.
  5. GTI & Nitrosamine Studies
  6. WS & impurities qualification and management
  7. Forced degradation studies
  9. Material characterization
  10. Elemental impurities ICH Q3D

- **Commercial Manufacturing:** Our state-of-the-art manufacturing facility in India is equipped to handle valuable projects from pilot to commercial scale. Extensive experience in custom manufacturing of complex small molecule starting materials and intermediates.



Site Introduction

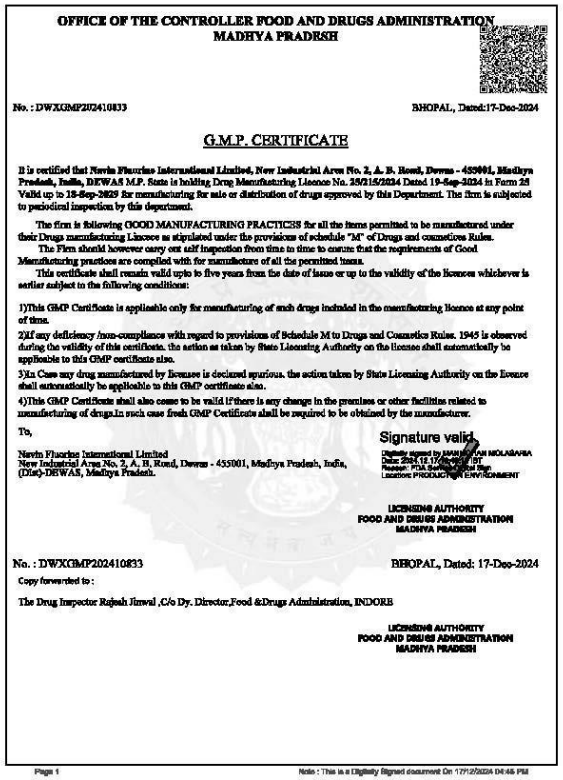
- Plot size is about 47 acres (190202 sq. m)
- CDMO business commenced in 2011 in Dewas, India
- Contract Development and Manufacturing of starting material & intermediate for drug substances.
- Facility located in notified industrial area, Dewas at national highway (NH_3)
- Nearest airport (Indore) about 45 km.
- Nearest railway (Dewas) station about 8 km
- State capital (Bhopal) is about 150 km

Latitude: 22°55’55.095"N,

Longitude: 76°1’14.839"E

Accreditations & licenses

- Registered with US FDA (Establishment Number 3013920886) to be prepared for potential FDA inspections as part of customer’s approval process
- cGMP ICH Q7 certified by SGS
- DUNS Number 725432913
- Responsible Care company
- EcoVadis CSR Rating-
- Audited by PSCI
- Certified by Indian Chemical Council.
- Site audited for EHS & GMP by major global pharma Innovators.



OFFICE OF THE CONTROLLER FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. : DWXGMP202410833 BHOPAL, Dated:17-Dec-2024

G.M.P. CERTIFICATE

It is certified that Navin Fluorine International Limited, New Industrial Area No. 2, A. B. Road, Dewas - 455001, Madhya Pradesh, India, DEWAS M.P. State is holding Drug Manufacturing Licence No. 25/15/2024 Dated 19-Sep-2024 in Form 25 Valid up to 18-Sep-2029 for manufacturing for sale or distribution of drugs approved by this Department. The firm is subjected to periodical inspection by this department.

The firm is following GOOD MANUFACTURING PRACTICES for all the items permitted to be manufactured under their Drugs manufacturing Licence as stipulated under the provisions of schedule "M" of Drugs and cosmetics Rules.

The Firm should however carry out self inspection from time to time to ensure that the requirements of Good Manufacturing practices are complied with for manufacture of all the permitted items.

This certificate shall remain valid upto to five years from the date of issue or up to the validity of the licences whichever is earlier subject to the following conditions:

1)This GMP Certificate is applicable only for manufacturing of such drugs included in the manufacturing licence at any point of time.

2)If any deficiency /non-compliance with regard to provisions of Schedule M to Drugs and Cosmetics Rules, 1945 is observed during the validity of this certificate, the action as taken by State Licensing Authority on the licence shall automatically be applicable to this GMP certificate also.

3)In Case any drug manufactured by licensee is declared spurious, the action taken by State Licensing Authority on the licence shall automatically be applicable to this GMP certificate also.

4)This GMP Certificate shall also cease to be valid if there is any change in the premises or other facilities related to manufacturing of drugs.In such case fresh GMP Certificate shall be required to be obtained by the manufacturer.

To,

Navin Fluorine International Limited
New Industrial Area No. 2, A. B. Road, Dewas - 455001, Madhya Pradesh, India,
(Dist)-DEWAS, Madhya Pradesh.

Signature valid

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

No. : DWXGMP202410833 BHOPAL, Dated: 17-Dec-2024

Copy forwarded to :

The Drug Inspector Rajesh Jiswal ,C/o Dy. Director,Food &Drugs Administration, INDORE

LICENSING AUTHORITY
FOOD AND DRUGS ADMINISTRATION
MADHYA PRADESH

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Overall score
80/100
Percentile
98th

GOLD | Top 5%
ecovadis
Sustainability Rating
NOV 2024

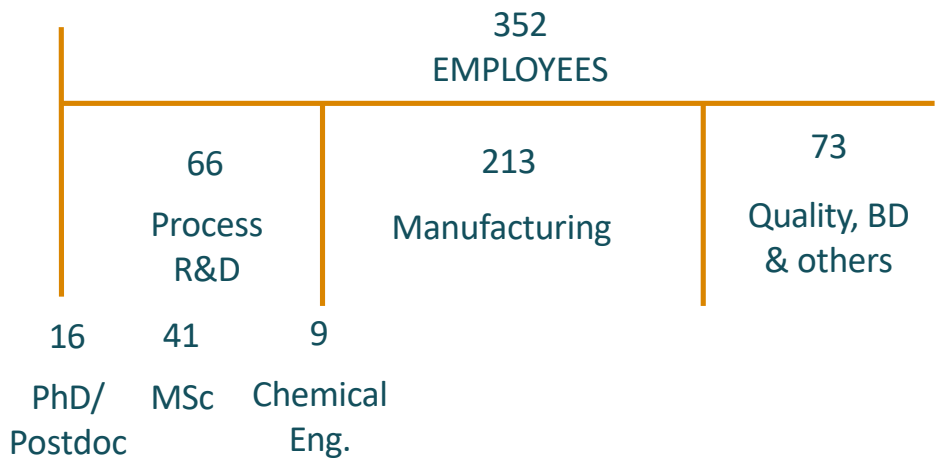
Responsible Care®
OUR COMMITMENT TO SUSTAINABILITY

Indian State FDA GMP Certificate
Certificate issue date: 12 December 2024
Validity: 18 September 2029

PSCI PHARMACEUTICAL SUPPLY CHAIN INITIATIVE
Building responsible supply chains

R&D: Strong Pool Of Scientific Talent- Dewas, India & Runcorn, UK

- "State of the art" R&D development facility at Dewas, India.
- Dedicated flow chemistry Laboratory & Process safety labs.
- +55 fume hoods in various suites
- PhD/Post-docs project leads
- PhD/MSc chemists ratio 1:3
- Minimum 10 years of experience post PhD (project leads)
- Minimum qualification of bench chemists (FTEs) is Masters in chemistry
- 2-15 years of experience in process development (bench chemist FTEs)



R&D Services: Runcorn, UK & Dewas, India

- 65 PhD/Post Docs/MSc Chemists
- 23 + 32 Fume hoods across 6 + 4 laboratories, respectively
- High pressure chemistry facility including fluorination, carbonylation, & hydrogenation
- Vessel size up to 30 L (glass & stainless steel)
- non-GMP kilo lab

- NMR
- UPLC
- HPLC
- Detectors – UV, PDA and ELSD
- GC HS
- GC
- LCMS 5500 QTRAP
- GCMSMS
- IR spectrometer
- Potentiometer
- UV instrument
- Coulometer
- Melting point

- Route scouting
- Process development
- Scalable processes
- Sustainability through lowering risks involved in the processes
- Intrinsically safe processes
- Green processes through reduction in effluents
- Optimization, stress studies and process hold points
- Analytical development, impurity identification and marker preparation
- Quality & Safety Risk Assessment (QRA) studies.
- Process Engineering & Process safety studies.
- Stability Studies

Expertise & Capabilities

Our dedicated facilities comprise dedicated PR&D and kilo-labs, and four GMP manufacturing plants, including a standalone hydrogenation block. Process development is supported by bespoke analytical development and process safety labs.

- Strong research and development team at site
- On-site process development team for process establishment and trouble-shooting
- Development using quality by design principles
- Technology transfer team assist process development and take process into piloting
- Advanced analytical development capabilities
- 4 Manufacturing blocks, included dedicated hydrogenation facility. Total 220 kl multi-purpose plant capacity
- SF4, HF, Mafron, Halex etc. fluorinations at site from gram scale to 500 kg batch size depending on volume occupancy
- High pressure reaction capabilities up to 80 kg/cm2 pressure and temperature from -175 to 295 °C
- Various sizes & material of construction reactors (100 mL - 10 kl; Glass lined, SS-316, Hastelloy and Inconel)

Facility Overview

- Manufacturing Plant:
  - cGMP Manufacturing Plant-1
  - cGMP Manufacturing Plant-2
  - cGMP Manufacturing Plant-3
  - Dedicated Hydrogenation Block
- Process development and analytical development laboratory
- Quality Control and Microbiology Laboratory
- Warehouse
- Utility Blocks
- Effluent Treatment Facility & MEE (ZLD)
- Administration and Technical wing (Including training hall & QA dept.)
- Occupational Health Centre, Canteen and Recreation Centre

Manufacturing plants

- Total 220 kL reactor capacity over 4 manufacturing blocks
- Design as per cGMP requirements (ICH Q7)
- Controlled access (closed plant)
- Separate areas for chemical synthesis and powder processing
- Filtered air in chemical and powder processing areas
- Dedicated day stores attached with each plant
- Rodent and pest control system
- Qualified equipment
- Preventive maintenance and calibration system for equipment/instruments

cGMP Manufacturing Plant-1

cGMP Manufacturing Plant-2

cGMP Manufacturing Plant-3

cGMP Hydrogenation Block

Expansion plans: cGMP-4

- US$ 35 Mn investment at the Dewas site adding 200 m^3 reactor capacity
- Design as per cGMP requirements (ICH Q7)
- Reactor sizes up to 10,000 L
- Groundbreaking in March 2024; facility expected to come online in Q4 2025
- Sustainable design at the heart of the project:
  - Highly efficient motors for material transfer to reduce energy use
  - Gravity flow used wherever possible to reduce need for pumps
  - Solar panels on carpark roof to provide green electricity
  - Dedicated solvent charging station to reduce emissions and manual handling requirements
  - High-efficiency (hydrofoil) agitation systems to be used where possible for reduced energy consumption

Quality control Laboratory- Instrument




Microbiology Laboratory- Instrument

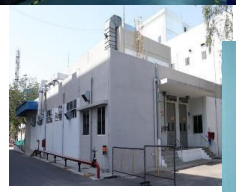


Utilities

EHS Management system

Warehouses






Process safety lab


Industrial Hygiene


Why Navin Molecular ??

Core expertise in fluorination, pressure chemistry and all kind of hazardous and complex chemistry

One stop solution to develop, scale up and commercialize products (GMP & non-GMP) in well-integrated R&D and manufacturing facilities at Dewas, India.

Established company, with both UK/India locations. Supply chain assurance

Highly experienced team, with effective project management to achieve 100% OTIF

Continued investment in new equipment & facilities

Strong commitment to employee health, safety and environment

Successfully audited by many global pharma companies for quality (GMP) & safety

Thank You