# Admiron Life Sciences
## Private Limited

**Plot No. 11, Jawaharlal Nehru Pharma City,**
**Thadi Village,Parawada Mandal,**
**Visakhapatnam- 531019.Andhra Pradesh, India.**

# Our Mission & Core Values

**Mission:**

To manufacture and market API's of the highest quality at affordable prices any where in the world.

**Vision:**

To become a leading player in offering integrated solutions to global pharmaceutical needs.

**Driving Forces:**

- Quality and services.
- Innovation and Research.
- Strategic partnerships.
- Transparency in operations.
- Commitment coupled with determination, dedication and discipline.
- Continual improvement through Customer Satisfaction

## Core Values and Beliefs:

- Customer satisfaction.
- Integrity.
- Empowerment.
- Networking.
- Creativity and innovation.
- Diversity in specialization

# Facility Address

## Corporate Office:

M/s. Admiron Life Sciences Private Limited
Vertex Corporate 2nd Floor Plot No 8&9, Jubilee Enclave,
Opp Hitex Entrance, Madhapur Hyderabad- 500081 Telangana India
Phone Nos : +91-40-30853000, +91-40-23552146
Contact Person: Mr. Pratap Reddy, Director
Phone:+918978723456
Email: pratap@admironls.com

## Manufacturing facility:

M/s Admiron Life Sciences Private Limited
Plot No. 11, Jawaharlal Nehru Pharma City,
Thadi Village,Parawada Mandal,
Visakhapatnam- 531019.Andhra Pradesh, India.
Phone Nos: +91-8924-236232,
Fax Nos: 0+91-8924-23623
Contact person: P. Raviteja Reddy, DGM – Operations.
Telephone number: +91-8924-236232; Mobile: +91-9949334981
E-mail: info@admironls.com.

# Brief Details about the Facility

- The manufacturing facility is located at Jawaharlal Nehru Pharma city, Visakhapatnam.
- It is about 600 kilometers from Hyderabad
- Admiron Life established in 2010 by a team of scientists who had a passion towards chemistry & to ensure a better health to everyone.
- Admiron Life is committed to maintain best Quality standards in Research & Development and Manufacturing of pharmaceutical products.
- Well-equipped standalone Research and Development lab with professional scientists with strong knowledge of chemistry.
- The production facility is divided into two major blocks and three minor blocks.

# Brief Details about the Facility

- Production block-I having 4 clean rooms; operations are performing under ISO class 8 specified area (class 100,000).
- Production block-II is designed to manufacture intermediates.
- Production block-III is having small reactors ranging from 50 liters to 630 liters for pilot scale purpose.
- Production block-IV is specially designed for hydrogenation reactions.
- Production block-V is a solvent recovery system having two distillation columns of height and diameter of 16 m and 600 mm respectively.
- The total reactors volume is 107.82 KL
- Stainless steel reactors total volume: 78.91 KL (capacities ranging from 50 litres to 4000 litres).
- Glass line reactors total volume: 28.91 KL (capacities ranging from 100 litres to 6300 litres).

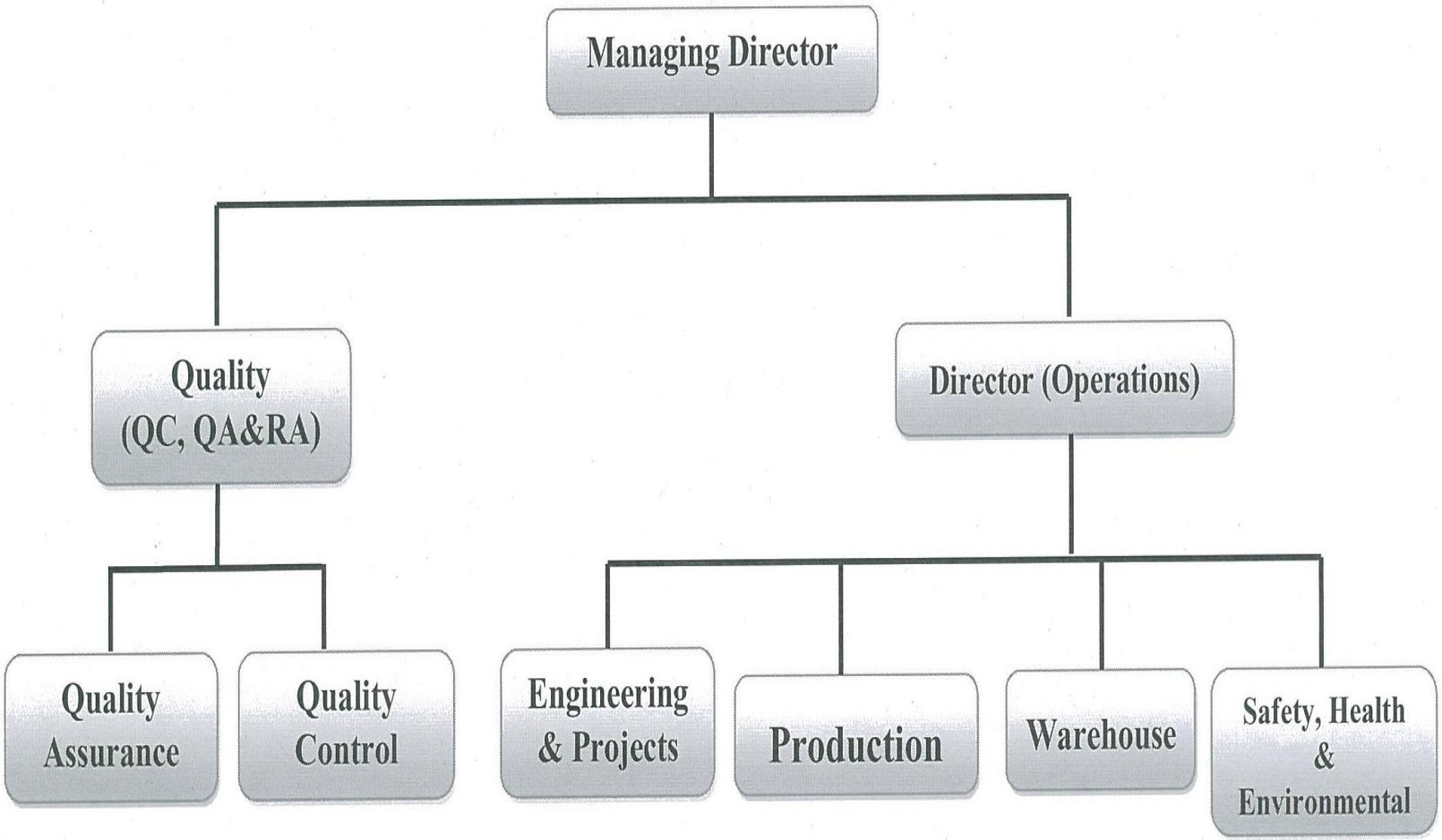
# Quality Policy

M/S Admiron Life Sciences Private Limited, Vishakhapatnam, AP, India is committed to produce Active Pharmaceutical Ingredients (API's i.e. Bulk drugs) to meet predetermined standards as specified by various National and International regulatory guidelines.

We shall also committed to implement all required cGMP (Good Manufacturing Practices) norms as per Schedule 'M', WHO-TRS guidelines and also allied guidelines for the production of purity, Identity, Strength, Safe, Efficacy and Quality API's for the benefit of customers at affordable prices in health care sector.

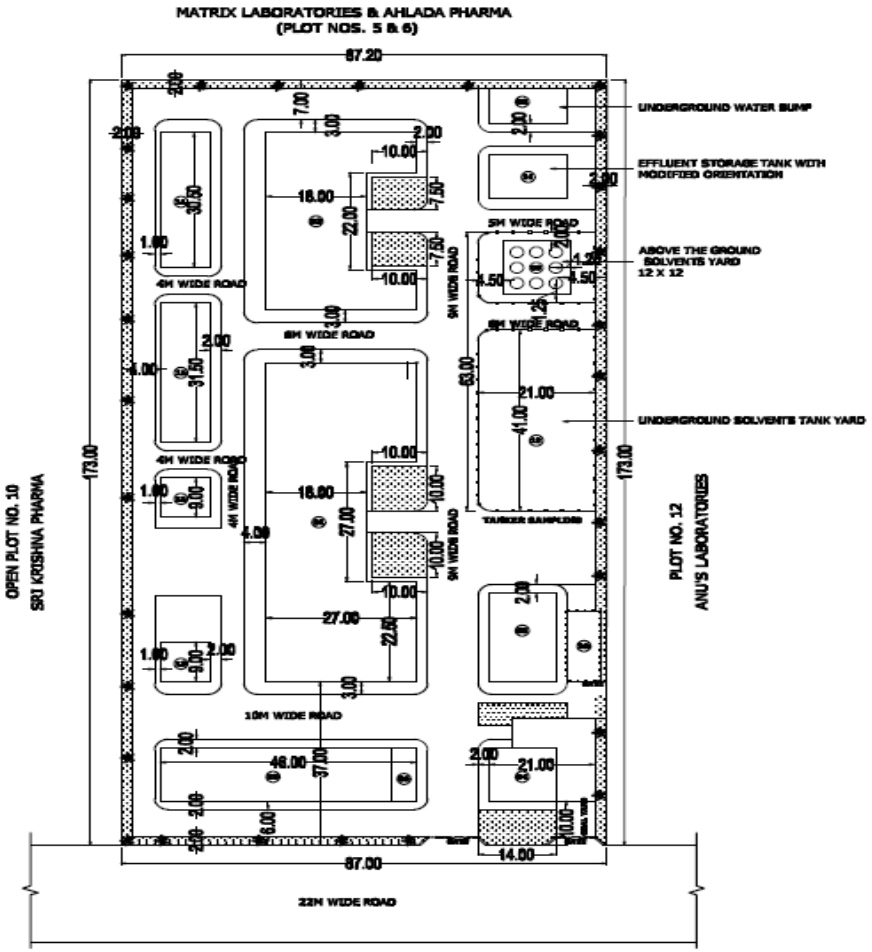
We are also committed to implement total Quality Management System (TQM), Good Laboratory Practice (GLP), Good Manufacturing Practice (GMP), Good Engineering Practice (GEP) and Good Storage Practice (GSP) at our site to meet the required specifications as per IP/BP/USP/EP/NF texts

# Organogram


Managing Director
Quality (QC, QA&RA)
Director (Operations)
Quality Assurance
Quality Control
Engineering & Projects
Production
Warehouse
Safety, Health & Environmental

# Site Layout

**SITE LAYOUT OF PROPOSED FACTORY BUILDINGS BELONGS TO M/s ADMIRON LIFE SCIENCES PVT. LTD.**
**SITUATED IN PLOT NO.11 OF SURVEY NOS PART OF 118,138,139 & 161 OF THADI (V), PARWADA (MDL) JAWAHARLAL NEHRU PHARMACITY - VISAKHAPATNAM (DIST) AP.**




**REFERENCE**

| SNo. | DESCRIPTION | SIZE IN METRES | AREA (SQ.MT) |
|---|---|---|---|
| 01 | PRODUCTION BLOCK-I | 2X27.00 X 32.00<br>18.00 X 27.00 | 1215.00<br>486.00 |
| 02 | PRODUCTION BLOCK-II | 2X27.00 X 8.00<br>18.00 X 32.00 | 486.00<br>396.00 |
| 03 | WARE HOUSE | 41.00 X 12.00 | 492.00 |
| 04 | BOILER HOUSE | 12.00 X 12.00 | 144.00 |
| 05 | D.G.SET & PANEL ROOM | 12.00 X 20.00 | 240.00 |
| 06 | SECURITY | 4.00 X 12.00 | 54.00 |
| 07 | CYCLE SHED & CAR PARKING | 16.00 X 6.00 | 96.00 |
| 08 | UNDERGROUND WATER SUMP | 14.00 X 8.00 | 112.00 |
| 09 | ABOVE THE GROUND SOLVENTS YARD | 12.00 X 12.00 | 144.00 |
| 10 | UNDERGROUND SOLVENTS TANK YARD | 21.00 X 44.00 | 861.00 |
| 11 | PILOT PLANT BLOCK | 9.00 X 30.00 | 274.00 |
| 12 | HYDROGENATION PLANT | 9.00 X 9.00 | 81.00 |
| 13 | SOLVENT RECOVERY COLUMN | 9.00 X 9.00 | 81.00 |
| 14 | EFFLUENT STORAGE TANK ABOVE GROUND LEVEL | 14.00 X16.00 | 148.00 |
| 15 | UTILITIES BLOCK | 9.00 X 31.00 | 289.00 |
| 16 | TRANSFORMER YARD | 6.00 X 16.00 | 96.00 |

TOTAL BUILTUP AREA = 5688.00 SQ.MT (OR) 37.75 %

OPEN AREAS:-
1. GREENARY : 1458.00 SQ.MTS 9.68 %
2. ROADS AREA : 3035.00 SQ.MTS 20.14 %
3. OPEN AREA : 4858.00 SQ.MTS 32.19%

TOTAL PLOT AREA =15068.30 SQ.MT (OR) 1.5068 HECTARE OR 3.72 ACERS

| SL.NO | DRG.NO | REV. NO | DATE |
|---|---|---|---|
| 1. | | | |

CLIENT:

**M/s ADMIRON LIFE SCIENCES PVT. LTD.**
J.N.PHARMACITY,VISAKHAPATNAM.

TITLE: SITE LAYOUT

EXISTING : PROPOSED :

SCALE: 1:400 DRG NO: LC/ADMR/ARCH/SL/01 DATE : 01-06-2013

FIRM:
M/S LEEV CONSULTANTS
178/14 R.No.34,
V.V.Nagar Colony,
Kukatpally,
HYDERABAD-500072.

PREPARED BY: JYOTHI.T. D.C.E

DESIGNED & CHECKED BY:

V.V. RAO

OWNER'S SIGNATURE

APPOROVED BY

# List of Products

- ❖ Etoricoxib
- ❖ Dobutamine Hydrochloride
- ❖ Tadalafil
- ❖Levetiracetam
- ❖Pentosan Polysulfate Sodium

# Certifications

GOVERNMENT OF ANDHRA PRADESH
*DRUGS CONTROL ADMINISTRATION*

L.Dis.No. 08/DCA/AP/2018 Dated: 26-05-2018

From:
M.B.R.Prasad, M.Pharm, M.Phil ,AIC,
Director & Licensing Authority
O/o. the Director General,
Drugs Control Administration
Chuttugunta,
Guntur -522 004.

To
M/s Admiron Life Sciences Pvt.Ltd.,
Plot No. 11,
Jawaharlal Nehru Pharma City,
Parawada (M),
Visakhapatnam District
Andhra Pradesh, India

Sirs,

Sub:- Drugs and Cosmetics Act, 1940 and rules made there under – Issue of **World Health Organization G.M.P. Certificate** – Reg.

Ref: 1.Your application Dt. 04-01-2018
2.Your Letter Dt.20-03-2018
3.Joint Inspection Dated: **20-03-2018 & 21-03-2018**

I, forward herewith **WORLD HEALTH ORGANISATION GOOD MANUFACTURING PRACTICE** Certificate for the products mentioned in the Joint Inspection Report of the Officers of Drugs Control Administration, Andhra Pradesh and CDSCO, Hyderabad.

This Certificate is **Valid for a period of Three Years** from the date of issue and this certificate is meant for Export of Drugs only.

Yours faithfully,

O/o Director DCA Govt of A.P Guntur

**DIRECTOR & LICENCING AUTHORITY**
**DRUGS CONTROL ADMINISTRATION**
**Camp at VISAKHAPATNAM**

Director & Licensing Authority
Drugs Control Administration
Govt. of A.P
Chuttugunta, Guntur-522004

Copy to : The Joint Director, Visakhapatnam

GOVERNMENT OF ANDHRA PRADESH
DRUGS CONTROL ADMINISTRATION

Office of the Joint Director,
Licensing & Approving Authority,
Drugs Control Administration,
Visakhapatnam Region, Visakhapatnam, A.P

L.Dis.No. 08/DCA/AP/2018 Dated: 26-05-2018

LIST OF PRODUCTS APPROVED UNDER WHO GMP CERTIFICATION SCHEME FOR EXPORT PURPOSE

1. **Dobutamine Hydrochloride USP**
2. **Etoricoxib In-House**
3. **Etoricoxib IP**

Manufacturer : M/s Admiron Life Sciences Private Limited, Plot No. 11, Jawaharlal Nehru Pharma City, Parawada (M), Visakhapatnam, Andhra Pradesh, India.

Drug Licence No. : **32/VP/AP/2013/B/G,**
***Dt.22-11-2013 Valid up to 21-11-2018***
**In Form-25**

It is also certified that

a) The manufacturing plant in which the products are produced is subject to inspection at suitable intervals.

The unit **M/s Admiron Life Sciences Private Limited,** Plot No: 11, Jawaharlal Nehru Pharma City, Parawada (M), Visakhapatnam District, Andhra Pradesh, India **was Jointly inspected by Smt.D.Suneetha, Drugs Inspector, Visakhapatnam (Mfg) and Mr. R.Srinivasan, Assistant Director, CDSCO, Hyderabad on dated: 20-03-2018 to 21-03-2018**

b) The Manufacturer conforms to requirement for Good Manufacturing Practices in the manufacture and quality control (As recommended by the World Health Organization) in respect of products mentioned above (**Three Numbers**) for Export in the International Market.

This Certificate is **Valid for a period of Three Years** from the date of issue and this certificate is meant for Export of Drugs only.

O/o Director DCA Govt of A.P Guntur

**DIRECTOR & LICENCING AUTHORITY**
**DRUGS CONTROL ADMINISTRATION**
Camp at VISAKHAPATNAM

Director & Licensing Authority
Drugs Control Administration
Govt. of A.P
Chuttugunta, Guntur-522004

To
M/s Admiron Life Sciences Private Limited,
Plot No. 11, Jawaharlal Nehru Pharma City,
Parawada (M), Visakhapatnam District.
Andhra Pradesh, India.

# Area Details in the Facility

| S.No. | Facility | Size in mtr. | Area (Sq.mt) |
|---|---|---|---|
| 01 | Ware House | 46.00X12.00 | 552.00 |
| 02 | Boiler House | 12.00X12.00 | 144.00 |
| 03 | D.G.Set & Panel Room | 12.00X24.00 | 240.00 |
| 04 | Transformer Yard | 6.00X16.00 | 96.00 |
| 05 | Production Block-I | 2X27.00X22.50,18.00X 27.00 | 1215.00,486.00 |
| 06 | Production Block-II | 2X27.00X9.00,18.00X2 2.00 | 486.00,396.00 |
| 07 | Production Block-III (Pilot Plant) | 9.00X30.50 | 274.50 |
| 08 | Production Block-IV (Hydrozination Plant) | 9.00X9.00 | 81.00 |
| 09 | Production Block-V (Solvent Recovery Column) | 9.00X9.00 | 81.00 |
| 10 | Underground solvents tank yard | 21.00X41.00 | 861.00 |
| 11 | Tankers Sampling Shed | 16.00X6.00 | 96.00 |
| 12 | Effluent Storage area | 14.00X10.00 | 140.00 |
| 13 | Underground water sump | 14.00X8.00 | 112.00 |
| 14 | Utilities Block | 9.00X31.50 | 283.50 |

# Manufacturing Capacities

**The total volumes of the reactors:**

| | |
|---|---|
| **PB-I (Reaction Area):**<br><br>**SS Reactors- 21.00 KL**<br>**GL Reactors- 8.25 KL**<br>**Total- 29.25 KL** | **PB-I (Clean Rooms):**<br><br>**SS Reactors- 14.00 KL**<br>**GL Reactors- 3.00 KL**<br>**Total- 17.00 KL** |
| **PB-II:**<br><br>SS Reactors- 35.26 KL<br>GL Reactors- 16.93 KL<br>**Total- 52.19 KL** | **PILOT PLANT (PB-III):**<br><br>SS Reactors- 1.15 KL<br>GL Reactors- 0.73 KL<br>**Total- 1.88 KL** |

**Total Volume is : 107.82 KL** **(PB-IV: Hydrogenator: 3.0 KL)**

| Production Block | Minimum Volume | Maximum Volume |
|---|---|---|
| PB-I | 0.25 KL | 4.0 KL |
| PB-II | 0.63 KL | 6.3 KL |
| Pilot Plant | 0.05 KL | 0.63 KL |

# Equipment Details in Quality Control

| Quality Control Instruments | | | |
|---|---|---|---|
| S.No. | Name of the instrument | No. of Instruments | Make |
| 01. | UV-Vis Spectrophotometer | 1 | Agilent Technologies |
| 02. | FT- IR Spectrophotometer | 1 | Agilent Technologies |
| 03. | Gas Chromatograph | 2 | Agilent Technologies |
| 04. | High Performance Liquid Chromatographs | 4 | Waters |
| 05. | Polarimeter | 1 | Jasco |
| 06. | Stability Chambers | 3 | Newtronic |
| 07. | pH meters | 2 | Polmon |
| 08. | Melting Point Apparatus | 2 | Polmon |
| 09. | Conductivity/ TDS meter | 1 | Polmon |
| 10. | Karl- Fischer Titrator | 1 | Polmon |
| 11. | Analytical Balance | 2 | Sartorius |
| 12. | Tapped Density tester | 1 | Electrolab |
| 13. | Water purification system | 1 | Millipore |
| 14. | Laboratory Balance | 1 | Sartorius |

# Employees Details

| | |
|---|---|
| Total Site Area | 15297.12 m2 |
| Total Built up Area | 5992.33 m2 |

| | |
|---|---|
| Ware House | 4 |
| Production | 38 |
| Quality Control | 11 |
| Safety Health & Environment | 2 |
| Quality Assurance | 10 |
| R&D | 2 |
| Engineering Services | 17 |
| Operations | 3 |
| HR | 3 |
| TOTAL | 90 |

# Equipment Details

| Equipment | PB-I | PB-II | PB-III | PB-IV | PB-V | Total |
|---|---|---|---|---|---|---|
| Reactors | 20 | 21 | 9 | 2 | 2 | 54 |
| Centrifuges | 9 | 5 | 2 | 0 | 0 | 16 |
| Tray Dryers | 0 | 6 | 0 | 0 | 0 | 6 |
| Vacuum Tray Dryers | 1 | 2 | 2 | 0 | 0 | 5 |
| Rotocone Vacuum Dryer | 2 | 0 | 0 | 0 | 0 | 2 |
| Multi miller | 4 | 3 | 0 | 0 | 0 | 7 |
| ANFD | 0 | 0 | 0 | 0 | 0 | 0 |
| Leaf Filter | 3 | 2 | 0 | 1 | 0 | 6 |
| Nutsche Filter | 2 | 2 | 0 | 0 | 0 | 4 |
| Sifter | 4 | 2 | 0 | 0 | 0 | 6 |
| Micronizer | 0 | 0 | 0 | 0 | 0 | 0 |
| Blender | 4 | 0 | 0 | 0 | 0 | 4 |
| Lyophilizer | 0 | 0 | 0 | 0 | 0 | 0 |
| Distillation Column | 0 | 0 | 0 | 0 | 2 | 2 |
| Total Volume of the Reactors ~ 107.82 KL | | | | | | |

# Site Overview

# Manufacturing Capabilities (facilities)




# Manufacturing Capabilities (facilities)




# Quality Assurance Practices

- Suppliers/ vendors are assessed through in-house quality system procedure.
- Declarations will be taken to ensure that products received from vendors are complaint with TSE.
- The company does not routinely use contract testing facilities, but as and when such services are needed, cGMP audit of the contract testing facility is carried out and then their services are utilized. Contract services are used for analytical purpose. Suppliers of key components (starting materials), key services (pest control) are assessed based on defined Standard Operating Procedure.
- Admiron Life Sciences Private Limited can manufacture the products on contract/ job work or loan license basis.
- Admiron will develop an in-house procedure to offer a systematic approach for Quality Risk Management of the product. .

# Quality Assurance Practices

- Effective Quality Risk Management can facilitate better and more informed decisions which was made applicable to intermediates / drug substances manufactured under the purview of cGMP or as agreed in the Quality agreement.

- Procedure is in place for the preparation, review and approval of product quality review (PQR) in order to assess/ evaluate the adequacy of process controls in place, to monitor the consistency in yield and quality of each product that are manufactured.

# Process Validation Policy at Admiron

- Before a new or modified process is introduced, a process validation protocol is prepared, reviewed and approved by the production and Quality Assurance Head. The protocol addresses specifications, methods, critical parameters, validated test equipment calibration data, test methods, assessment of the results, conclusions and final agreed process details.

- At least three consecutive successful validation batches shall be carried out to assess the validity of the process. The final release for sale is accorded if the product meets its quality profile.

- Cleaning validation protocol is prepared for each stage or product changeover which includes sampling areas, acceptance criteria etc. Cleaning validation studies are accordingly undertaken, results are evaluated and on compliance of acceptance criteria, cleaning procedure is declared validated.

# Frequency of Revalidation System

- Number of air changes/Air velocity test (Once a year).
- Room Pressure differential Test (Once a Year).
- HEPA filter integrity/leak test (Once a year).
- Temperature mapping (Once a year).
- Air Borne particle count test (Once a Year).
- Particle count recovery test (Once a Year).
- Visualization Test/Air flow pattern (Smoke) Test (Two Year).

# Contract Manufacturing Details

**Contract Manufacturing:**

- We are not given any contract manufacturing products to outside and at the same time we are in the contract business with the following customers to manufacture their products at our facility.

  1. M/s. Aurobindo Pharma Limited
  2. M/s. GVK Bio Limited
  3. M/s. Alivira Animal Health Limited.

**Contract Analysis:**

- Some of the analysis has been given outside for which the in-house facility is not available. At present, microbial analysis only outsourcing with the following laboratories.

  1. M/s. Startech Laboratories Limited
  2. M/s. Cheminos Analytical Solutions.

# Employee Training Methodology

- Training need for each employee is identified by departmental heads, depending on their job responsibilities. cGMP training needs are identified by Head –QA or designee in consultation with respective functional head.
- All new employees are given induction training. This involves introduction to the company, its product and policies and the concept of current Good Manufacturing Practices.
- The cGMP training sessions are usually interactive and take the form of a presentation delivered by a qualified trainer from quality assurance department.
- Written training evaluation is carried out for all cGMP training programs as per the laid down standard operating procedure.
- On the job training takes place usually under the guidance of immediate supervisor or departmental head. For specialized training, in house or external courses are organized.
- Efficacy of cGMP training is assessed through written training questionnaires.
- Re-training needs are identified through these assessments or as a result of audit deficiencies noted.
- Individual training records including qualification acquired, external trainings attended etc., are documented and maintained by QA.

# Utilities at Admiron

- The captive consumption of electricity at the site is 800 KVA. 100% power back-up facility is available from two generators of 500 KVA each.
- Three chilling plants are facilitated at site with individual 100 TR cooling tower. Out of three, two of -25˚C cooling and the third one is +5 ˚C cooling capacity.
- A coal fired boiler is facilitated with 3 ton capacity.
- Ten numbers of vacuum pumps are facilitated with 1 torr vacuum pressure capacity (each production block is having five vacuum pumps).
- Two air compressors with 7.5 bar capacity.
- Four cooling towers of 300 TR, one for PB-I, two for PB-II and one for SRS block.

# Environment, Health & Safety

- Effluent Pre-Treatment and disposal to CETP in Pharma city.
- HW disposal to TSDF/Cement industries
- Fire Detection and Alarm system
- Fire Hydrant system with Diesel Driven Back-up.
- Spill Control Kits
- Bulk Foam stock in the site
- Periodical Medical Check up of employees

# Environment, Health & Safety




Thank You