Reichindia®
PHARMA LIMITED

Site Master File

Document No : SMF/004

Revision No. : 03

Supersedes SMF/003

Effective Date : 17/01/2017

Dated : 17/01/2017

Enriching Society Through Healthcare

Plot No.51, TSIIC Industrial Park
Hyderabad-Warangal Highway, Bhongir –508 116
Office: +91 40 2715 8322 | +91 998 999 1234
Factory: 897 887 1234 | 9866911449

www.reichindia.com

Office

#203, Sri Sai Sampada Plaza, Habsiguda,
Hyderabad - 500 007, Telangana, INDIA

Ph:+91 40 2715 8322 | +91 998 999 1234
Fax:+91 40-2715 8352

Website: www.reichindia.com
Email: pharma@reichindia.com

Facility

Non Betalactum Facility

- ► Tablets
- ► Powders
- ► Liquid Orals

Factory

#51, TSIIC Industrial Park
Hyderabad - Warangal Highway
Bhongir -508 116
Dist. - Yadadri, Telangana, INDIA

Ph: 897 887 1234 | 9866911449

Document No.

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Approval & Authorization

Prepared By	Checked By	Approved By
V.Narasimha Manager- Production	N.Siva Reddy Plant Manager	K.V.Rama Rao Manager–Quality Operations

This Site Master File is Authorized By

Sharma Gandavarapu

Director-Technical

Table of Content

Reichindia®
PHARMA LIMITED

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REICHINDIA PHARMA LIMITED

Plot No.51, TSIIC Industrial Park
Hyderabad-Warangal Highway, Bhongir –508 116
Office: +91 40 2715 8322 | +91 998 999 1234
Factory: 555-543-5433 | 897 887 1234 | 9866911449

www.reichindia.com

Enriching Society Through Healthcare

1.0

General Information

1. GENERAL INFORMATION

1.1 BRIEF INFORMATION.

Reichindia Pharma Limited
Manufacturing Tablets, Powders & Liquid Orals at Bhongir,
Hyderabad-Warangal Highway

Since, 1997 Reichindia Pharma Ltd is enriching the society through Health

Care. Our Mission is as follows:

- To consistently adopt new technologies, system and procedures, which will enhance quality and the way our customer sees us.
- To build a highly motivated team of professionals who are committed to the total quality ethos.

MANAGING DIRECTOR

MR. CH. SYAM SUNDER:

Having vast experience in Pharmaceutical marketing since 25 years, He has established this maiden Production facility in Hyderabad, India.

We at Reichindia Pharma Ltd realize the need to co-operate as a team in providing the nation with tomorrow which is healthier and stronger.

TECHNICAL DIRECTOR

Mr. GANDAVARAPU SHARMA

Having vast experience of about 27years at various levels in various Pharmaceutical Areas

Pharmacia-Hyderabad,
Anglo French Drugs and Industries-Bangalore,
Bangalore Pharmaceutical and Research Laboratories - Bangalore
Having excellent exposure in Production, Industrial Relation, Personnel Management, Regulatory and Project experience in his entire Pharma career.

1.2 MANUFACTURING ACTIVITIES.

Reichindia Pharma limited facility is dedicated to non- beta lactum formulations in Tablets, Powders Liquid Orals and External Preparations. No other activities are carried out in the Premises.

The plant has Basement, ground floor, mezzanine, first floor, Second floor and Terrace.

- Ground Floor caters to raw material, packaging material & A/c storage for Vitamins, minerals, enzymes and for Sampling Dispensing, Packaging and Finished Goods Storage
- Mezzanine caters to Packing of liquid orals, Solid Dosage forms & Primary Packing material storage, Admin block
- First floor caters to Liquid Orals & tablet departments.
- Second Floor caters to Quality control & Assurance department, Service Block & Purified water system
- Terrace has a canteen, Conference Hall and Proposed F R&D block.
- Basement has extended packaging area.

The premises is planned to meet the requirements as per New schedule M of the Drugs & Cosmetics Act, WHO norms & as per the requirement of cGMP

1.3 OTHER ACTIVITIES:

No other activities are carried out in the premises

1.4 NAME & ADDRESS OF THE COMPANY.

FACTORY:

Reichindia Pharma Limited
#51, TSIIC-Industrial Park
Bhongir-508116
Hyderabad-Warangal Highway
Telangana-India
Ph: 897 887 1234 | 9866911449

OFFICE:

#203, Sri Sai Sampada Plaza
Habsiguda, Hyderabad-500 007
Telangana, India

Ph:040-2715 8322, 09989991234
Fax:040-2715 8352

Website: www.reichindia.com
Email:pharma@reichindia.com

1.5 LIST OF PRODUCTS LICENSED TO MANUFACTURE AT THIS SITE DOMESTIC AND EXPORT

Form - 25

MANUFACTURING LICENSE NO. : 27/NG/AP/2012/F/G
Valid up to 31.07.2017

Form - 28

MANUFACTURING LICENSE NO. : 07/NG/AP/2013/F/G
Valid up to 21.03.2018

Form NDPS - 1

NDPS LICENSE NO. : NDPS-1/163/NLG/AP/2012

Refer Annexure to SMF/00/ 003 No.001

1.6 DESCRIPTION OF THE SITE.

The manufacturing site of Reichindia Pharma Limited, Pharmaceutical formulation unit is located in Bhongir, Dist.- Nalgonda, Telangana, is about 60 km from the Rajeev Gandhi International airport.

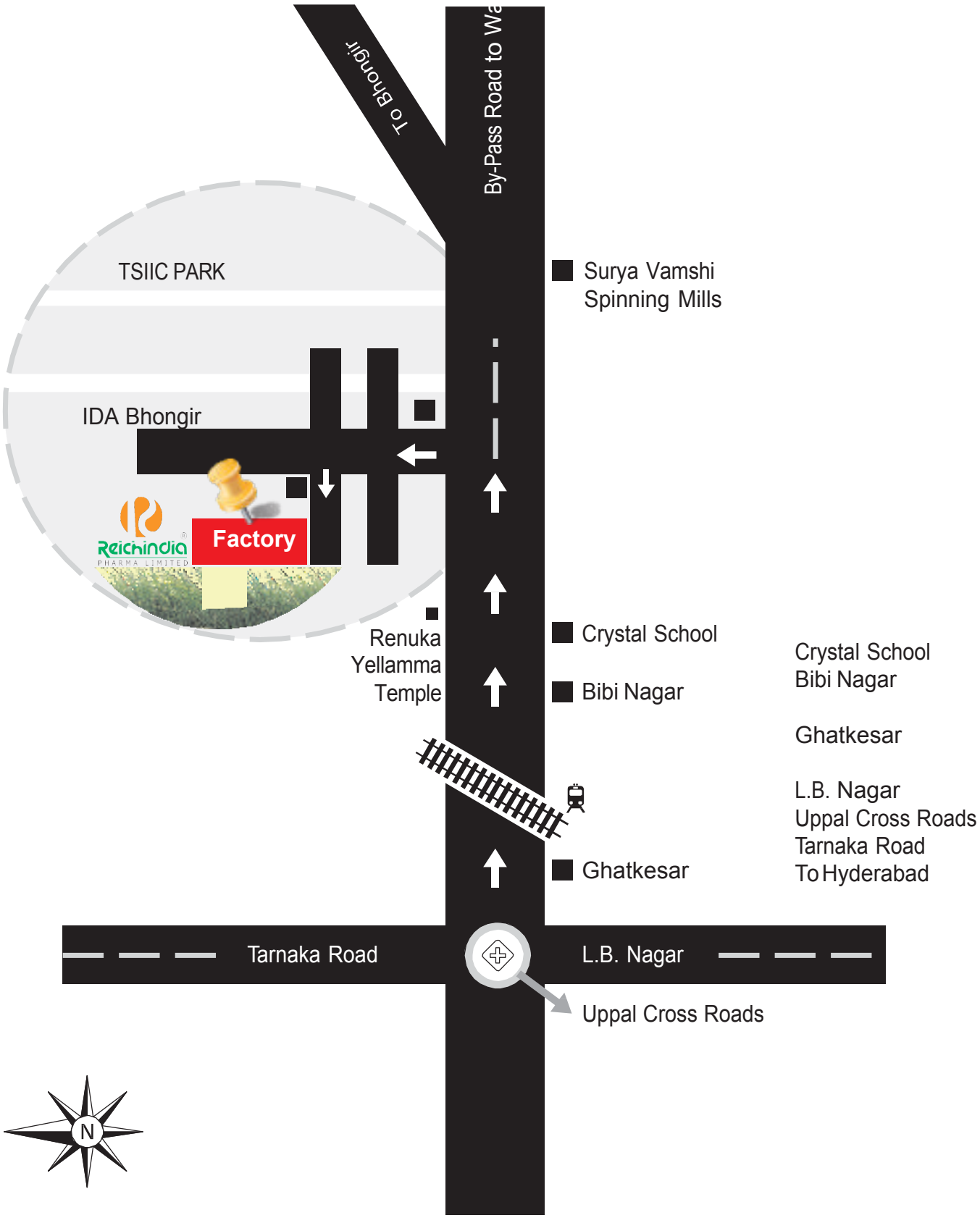
The plant is in the Industrial park surrounded by Pharma and other Industries which ensure that the area is pollution free.
The plant is located in Industrial Zone surrounded by Green Belt.

Location	Plot # 51,TSIIC-Industrial Park,Bhongir-508 116,India, On Hyderabad- Warangal Highway.
Build – up Area	3810 Sq.mtrs /41000 sq. Feet
Proximity to : Road	300 meters from State Highway
Nearest Railway Station	Bhongir Railway Station
Air	60 km from Rajiv Gandhi International airport (Hyderabad)
Standards	The factory conforms to cGMP standards.
Machineries	All machineries as per GMP standards with latest technologies in all departments.
Quality Control	Significant steps have been taken to assure the quality of products. RM/PM procurement by approved vendors. These Steps include advanced training of personnel, inspecting & analytical equipments & modernization of the quality area.

The areas surrounding the site are as below

East – Plot No.50
West – Green Belt
North – Open Plot
South - Main gate and approach road

1.6.1 ROUTE MAP DRAWING



1.6.2 Factory Area Particulars

S.No	Department / Section	Area in sq.m
1.	**Total built up area (consists of following)**	**3810**
2.	**Ground Floor**	**752**
	Stores Block	681
	Reception Block	71
3.	**Mezzanine Floor**	**657**
	Second packing line of Liquid Orals and Solid Dosage packing	526
	Primary Packing Material Storage area.	85
	Admin Block	46
4.	**First Floor**	**752**
	Tablet Section	412
	Liquid Oral Section	340
5.	**Second Floor**	**752**
	QC/QA Block	173
	Service Area	544
	Purified Water System	35
6.	**Terrace Floor**	**429**
	Canteen & Conference Hall	253
	Water System (Nano)	63
	Chillers	113
7.	**Cellar & Utility**	**468**
	DG set, Air Compressor, ETP,	
	Boiler &Panel Room	

1.7 NUMBER OF EMPLOYEES ENGAGED.

S.No	Department	Staff	Workmen
1	Production	07	50
2	Stores	04	07
3	QC/QA	18	05
4	Administration	05	05
5	Engineering Services	04	08
	Total	**38**	**75**

1.8 USE OF OUTSIDE ASSISTANCE

Manufacturing	:	No Technical assistance is used in the area of manufacturing All team is internal
Analysis	:	External Analytical services are utilised from the following approved testing laboratories

1.0 Vimala Scientific Services Pvt. Ltd.

12-12-157/A, Backside of NIN (Tarnaka),
Ravindra Nagar, Seethaphalmandi,
Secunderabad – 500 061.
Off. Ph: 040-27007561, 27016941
E-mail:vimlalab@yahoo.com
Website: www.vimlalab.com

2.0 Bio Leo Analytical Labs

Plot No.135, First Floor, OASIS Towers IX
Prashanthi Nagar, IDA Kukatpally,
Hyderabad-72,
Off. Ph: 040-23074567, 27016941
E-mail:admin@bioleolabs.com/
bioleolabs@gmail.com
Website: www.bioleolabs.com

3.0 Indian Institute of Chemical Technology

IICT, Hyderabad - 500 607.
EPABX :+91 -040 -27191234
www.iictindia.org

4.0 M.J.Lab Private Limited

7A/702, Alica Nagar,
Lokhandwala Complex, Kandivali (E)
Mumbai-401 204
8976072834/37/38/39/31; mjplab@gmail.com

5.0 Sigma Analytical Testing House Pvt Ltd

47-1/B, Sri Sai Colony, Chintal, Hyderabad-54
Tel/Fax:040-23085055, Cell: 9346517264
sigmatestlab@gmail.com

6.0 Sreechem Analytical Services Pvt Ltd, Plot No. 62, 2nd & 3rd Floor,
Ayyanna Commercial Building,
Prasanthi Nagar, Kukatpally, Hyderabad 500072
sreechemanalyticalservices@gmail.com
Ph:040-42306516

3.1 QUALITY MANAGEMENT.

1.9.1 QUALITY POLICY

Manufacture

"QUALITY HEALTHCARE FORMULATIONS"

Strive for

"CONSTANT INNOVATION"

Provide

"EXCELLENT WORK CULTURE"

Thereby

Enriching Society Through Healthcare

1.9.2 Quality Control & Assurance

Role of Reichindia Pharma Ltd. Quality Assurance in Quality Management

- Define Systems, Standards and Procedures to be followed.
- Ensure availability of authorized procedures specification at required Place and time.
- Document control including issue control & Batch Manufacturing Record.
- Authorize Master Formula Record.
- Authorize Master Validation Protocol.
- Provide Support for Validation.
- Provide Technical support for Documents/ System/ Procedure.
- Change Control.
- Verify Implementation of system/ procedure etc.,
- Ensure that personal working are trained.
- Experienced Qualified Staff in respective field of activities.
- Audit for all systems of Plant.
- Process control including in-process checks/ inspection/ line clearance.
- In-process / Finished product sampling.
- Inspection of final pack.
- Equipment Qualification of New Machines and Equipment.
- Verification of Quality of work.
- Internal Audit.
- Prevent Product/ Process/ System Nonconformity.
- Initiate corrective / preventive action.
- Identify problems relating to Product/ Process/ System.
- Handling of customer complaints.

- ► Ensure compliance to local statutory requirements and to drug Authorities.
- ► Ensure amendments in Specifications and procedures reflect current Pharmacopeial Standards.
- ► Specifications, cGMP and other regulatory standards and requirements.
  Stability study.
- ► To review Batch Manufacturing Record and to verify Reconciliation of Batch inputs and Batch yields.
- ► To investigate product recall and initiate corrective/ preventive action Deviation control.

Implementation of Quality Policy:

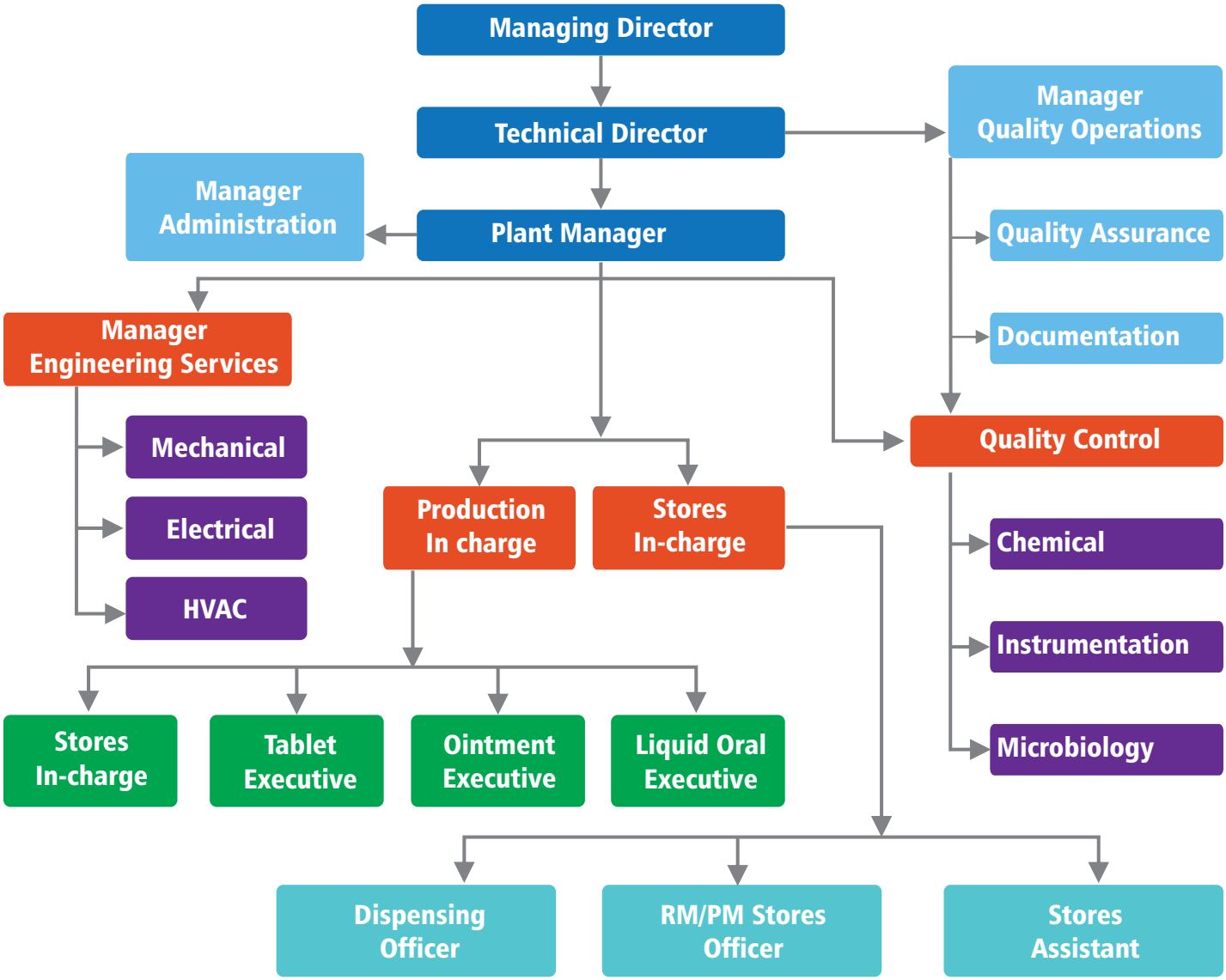
► To achieve quality objective a strong Quality Assurance Team has been formulated to incorporate Good Manufacturing Practices & Good Laboratory Practices.

2.0

General Personnel

2. PERSONNEL

2.1 ORGANOGRAM:



2.2 QUALIFICATIONS & EXPERIENCE OF KEY PERSONNEL.

Refer Annexure to SMF/00/ 003 No.002

2.3 IN-HOUSE TRAINING

All Employees involved in Production, QC, Distribution etc, are trained (Induction and on the job training).

Appropriately qualified individuals impart training. Their assigned functions are monitored.

Their training covers:

a. Company policies with respect to the area of operation

b. Brief training in all the departments with whom they will be interacting during day-to-day work.

c. Training on their responsibility and about their job (The Specific operation that the employee performs).

d. Relevant aspects of cGMP, Good Laboratory Practice & Good Engineering Practice.

e. Personal Hygiene & Safety.

Technical magazines Books & Pharma literatures are made available to keep abreast of latest happenings in the industry

► **FREQUENCY:**

Frequency of training is every year to ensure that employees are familiar with current GMP requirements and have knowledge and skills necessary for their assigned duties and responsibilities.

► **DOCUMENTATION:**

Training files & records are maintained to demonstrate that:

- All personnel are capable of performing their assigned duties.
- Appropriately qualified and trained personnel carryout all processes.

2.4 HEALTH

- All the new employees are sent for medical checkup before recruitment. All Employees should report any open wounds, rashes or boils on the exposed surface of the body. Such employees are prevented from entering production areas.
- Annual Health checks shall be carried out for all factory personnel with Special attention to given communicable disease and all relevant records are maintained. They are not allowed to work until they are cured and checked & certified by Registered Medical Practitioner. They have to produce medical fitness certificate at the time of resuming work.

2.5 PERSONNEL HYGIENE.

- All employees are imparted basic training related to personal hygiene.
- Food & drinks are not permitted to be stored and consumed in manufacturing Packing, QC and stores.
- Employees working in the Plant are required to change into factory uniform & footwear as per SOP.
- Visitors are requested to wear protective garments & Shoe- covers before entering into the Plant as per SOP.
- Employees handling powders, organic solvents for processing are given additional protection like nose-masks, safety goggles.
- No one is permitted to go out of the factory with the factory garments and Footwear.
- No one is permitted to enter the production area without factory garments & footwear. Adequate changing & rest areas are provided in the premises
- The Department Heads are responsible for the training on personal hygiene

3.0

Premises and Equipment

Please refer the drawing attached

Refer Annexure to SMF/ 003 No.DWG/GPL/00/002

3.2 NATURE OF CONSTRUCTION AND FINISH.

The facility consists of a well-designed RCC structure

(Floor Strength is 750 kg/sq.m)

Kota stone on the floor corridors for packing and finished goods storage

PU flooring on all core areas of each department

All internal wall surfaces of core areas are PU paint.

Raw material storage areas have PU flooring and PU wall paint.

Liquid Oral manufacturing and Microbiology areas have Epoxy floor and PU wall paint.

Finishing of all areas is done with PU covings.

All functional doors are clean room doors.

A/c Ducting, wiring etc are either concealed or run above false ceiling.

Service floor is on the second floor with PU coated flooring and maximum electrical controls are provided there to make the servicing operations easy and to control men entry in the manufacturing area (refer the Men Movement drawing)

Refer Annexure to SMF/ 003 No.DWG/GPL/00/002

3.2.1 Electrical System:

Electrical system is in place taking into consideration of the pharma clean room requirements.

- SS316 panel boards are provided in core areas.
- All the wiring is concealed in core areas.
- Safety systems are as per TS electrical authority norms.
- Separate systems for HVAC, common lighting, emergency lighting, UPS for critical equipments.
- Generator (320 KVA & 30KVA) along with separate invertors for lighting, emergency lighting, Intercom and UPS for sensitive equipments are provided.

3.2.2 Safety System:

Safety systems with respect to machinery, fire escape corridor, flame proof systems in flame susceptible and critical areas, separate solvent storage areas is provided. Safety equipments are provided in general areas.

3.3 VENTILATION SYSTEM.

The factory has well equipped forced air ventilation system in which the air is filtered through primary 10 micron, 5 micron and final HEPA filters and used in all operational area. The critical areas are Air conditioned and dehumidified. (Critical areas are of class 100,000 quality) Different air handling units are used in different areas to avoid cross contamination.

Differential air pressure is maintained in areas to avoid cross contamination of air born particles. Air locks and interlocks are provided in appropriate areas and maintained at higher pressure than the adjacent areas to avoid any cross contamination of the air from the process area.

Corridors are at a higher-pressure gradient than the process area to avoid the flow of air from the process area to the corridor. This is ensured on daily basis by monitoring the differential pressure using manometers provided in respective area. Temperature and humidity is monitored as per the laid down procedures.

a. Temperature of all core areas is designed to have not more than 25 degree Centigrade and relative humidity of not more than 55%.
b. Other operational area and storage area has Forced air ventilation system, Exhaust Air handling system, Fan coil unit.
c. Air-cooled scroll chiller (80TR) is available reducing the dependency on water.

Totally 14 Air Handling units are provided to cater the requirement. Additionally 6 Ventilation Air Handling units, 6 Exhaust Air Handling units, 10 Fan Coil units 7 CCK Modules provide effective air handling system.

Refer the following annexures for more details

Annexures

a. Classification of area drawing

Refer Annexure to SMF/ 003 No.DWG/GPL/00/002

b. HVAC System details Room wise

Refer annexure to SMF/00/ 003 No. 002

c. Differential pressure details

Refer annexure to SMF/00/ 003 No.003

3.4 STORAGE AND HANDLING OF MATERIAL

Necessary care is taken in handling and storing of material. In Raw material and Packing Material storage area, German Based BITO storage racks are provided on which the materials are stored. Pallets are provided to store the material on the ground level. To move the material with the pallets from one place to other, pallet trolleys are used.

Air-conditioned area is provided to store thermo-labile material if it has to be stored for a longer time. To store aluminum foil, Air conditioned area is provided.

- Separate entry for material is available.

Refer annexure to SMF/00/ 003 No.DWG/MAT/00/002

- Material movement is done by special GMP material hoists.
- There are three hoists catering to Raw material, Packing materials & Finished Goods movement separately.
- Static pass boxes SS304 for material transfer into specified clean room areas. Suitable change rooms are provided with airlocks for men movement into the production area. Toilets for ladies & gents are provided separately outside to the core area.
- Cool rooms provide for storage of vitamins and special material storage requirements. Sampling booth & Dispensing booths provide for sampling and dispensing under clean conditions with separate AHU.

3.5 SELF-INSPECTION SYSTEM

The system detects deficiencies at any stage self-audit or inspection requires Good house-keeping, work conditions, personal hygiene, safety, etc. Self-audit Team consist of QA Manager, Production Manager & concerned department Executive. After completion of inspection a detailed observation report is prepared. Audit report is reviewed at a scheduled date to verify compliance. Besides this QA also carry out day to day inspection of various activities.

QUALITY AUDIT TEAM

Separate audit team towards inspection is done, which comprises personnel from QA, Production, Stores & Engineering Departments to comply with GMP standards which includes Personnel, Premises, Maintenance Building, Equipment, Storage Inprocess checks, Quality Control, Documentation, Sanitation, Validation, Calibration & Label Control etc...

3.6 WATER SYSTEM:

The major requirement of water is collected from a single Bore well and Tanker (Outside Agency). Water is transferred from Bore well into storage sump from where it is again pumped to the overhead tanks.

Water from the overhead tank is directly used for toilets and wash rooms (For initial washing). Pre-treatment of water is done by Nano filtration and supplied to utilities (Boiler, Compressed Air, Potable water line).
Nano filtered water is then passed through Reverse Osmosis & DM plants. It is circulated using continuous flow in loop system having PLC controls.

3.6.1 Purified Water System

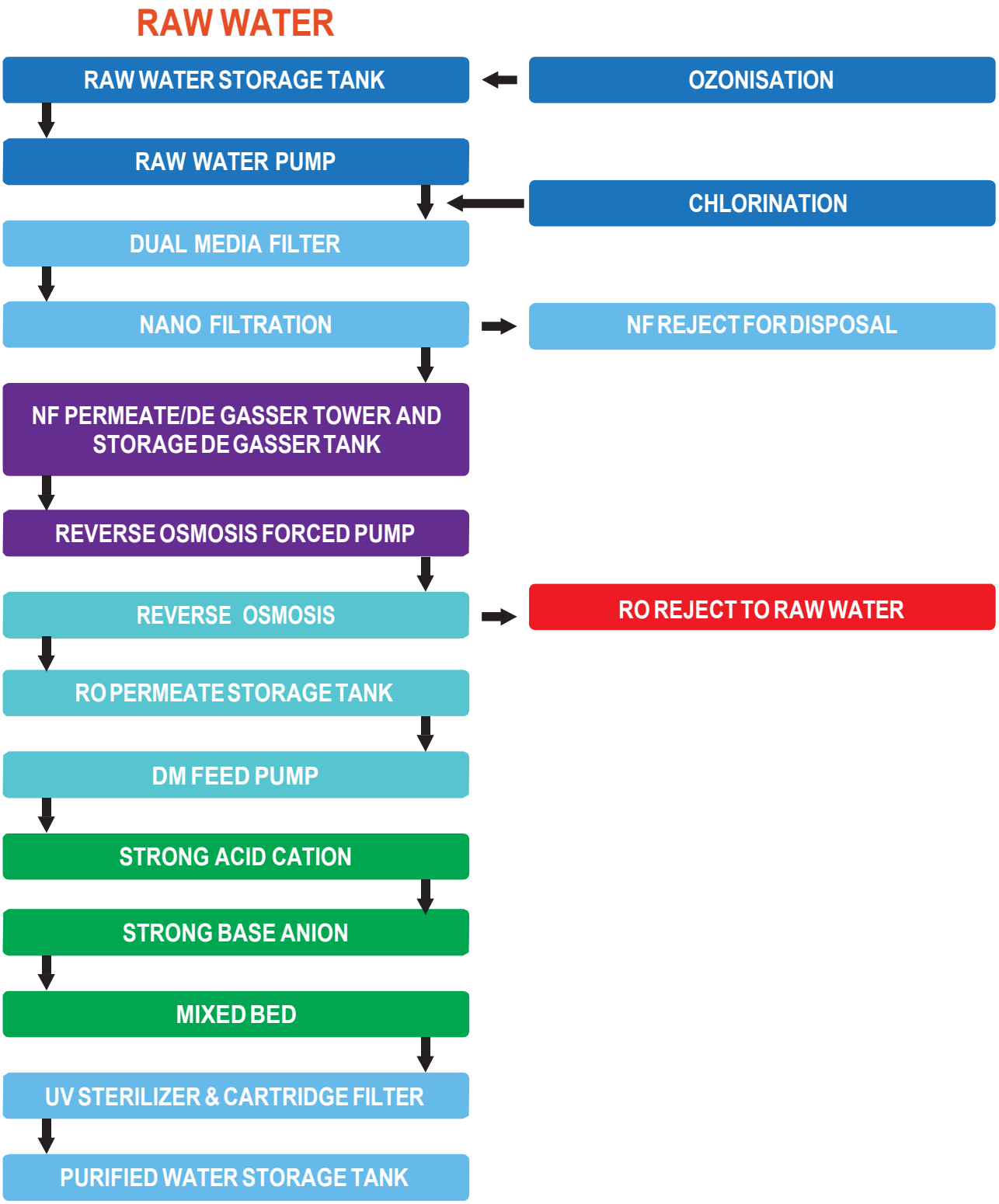
Refer annexure to SMF/00/ 003 No.DWG/PWG/00/002

Refer annexure to SMF/00/ 003 No.DWG/PWD/00/002

Raw water treated suitably (Nano Filtration-Reverse Osmosis Purified Water system 2000Litres per hour) to meet the specifications of Purified water as per Indian Pharmacopoeia.

- Loop system for distribution of Purified water using electro polished SS316L lines to respective department is in place.
- The plant is also designed for recirculation of potable water to minimize losses and save water wherever possible.

PROCESS FLOW DIAGRAM



PURIFIED WATER GENERATION SYSTEM

Brief Description:

- The Raw Water from the source (Bore well/ Tanker) is feed to Raw Water Storage Tank.
- Ozone is dosed in raw water.
- The Ozonated Raw Water is chlorinated before feeding to dual media filter and de chlorinated after dual media filter
- This Water is feed to Nano Filtration (NF) block through Raw Water Pump(RWP).

{Nanofiltration(NF) is a cross-flow filtration which ranges between ultra-filtration (UF) and reverse osmosis(RO). The nominal pore size of the membrane is typically below 100 nanometers, thus Nanofiltration membrane are typically rated by molecular weight cut-off(MWCO) rather than nominal pore size. The trans membrane pressure (pressure drop across the membrane) required is considerably lower than the one used for RO, reducing the operating cost significantly.
This technique can be seen as a coarse RO (reverse osmosis) membrane. Because nano filtration uses less fine membranes, the feed pressure of the NF system is generally lower compared to RO systems.}

- The NF permeate water passes through the De Gasser Tower (DGT) where Carbon Dioxide is Scrubbed Off.
- De carbonated water is then stored in the Storage Degasser Tank (SDG).
- De-gassed water is feed to Reverse Osmosis (RO) through Reverse Osmosis Forced Pump (ROFP)
- The permeate from RO is collected in RO permeate storage tank and from here it is pumped to De-mineralization (DM) unit through DM feed pump.
- DM unit consist of Strong Acid Cation (SAC), Strong Base Anion (SBA) & Mixed Bed(MB).
- The outlet of the MB is passes through UV sterilizer and cartridge filter before entering to the Purified Water Storage Tank (PWST).

PURIFIED WATER DISTRIBUTION SYSTEM

Brief Description:

- The PW storage and distribution system is designed for continuous recirculation.
- PLC based controlled panel is provided for automatic operation and controlling the system through Human Machine Interface (HMI)
- The system is designed to work at a temperature of around 85°c during sanitization.
- Distribution tank and loop is made of SS316L and the fabrication is Close Head Orbital Welding.
- The user point valve is of manual Zero dead leg block diaphragm valve.
- The return line of the distribution loop is connected to the PW storage tank through a spray ball in the tank. In the normal operating condition, a velocity of 1.2m/sec shall be maintained in the return loop.

SANITIZATION OF TANKS: Routine cleaning schedule is made for cleaning the overhead tanks and sumps and recorded.

3.7 EFFLUENT TREATMENT:

After feasibility study report submitted to Pollution Control Board, and subsequent permission an efficient Combined Effluent treatment plant is set up.

The effluents are tested and treated by Effluent Treatment Plant as per the Pollution Control Board norms. Recirculation of treated and tested effluents is utilized for gardening and toilet flush.

Refer annexure to SMF/00/ 003 No.DWG/ETP/00/002

I. Effluent treatment plant:

Base Line Data for Design:

Trade effluent quantity considered for the design - 6.0 KLD

Quantity of sewage considered for the design - 4 KLD

Proposal - Combined Effluent Treatment Plant

Capacity of plant - 10 KL/Batch

Purpose - To use treated effluent for lower secondary uses

Plant Process - SBR with pre-treatment for trade effluent

The plant is designed to deliver the treated effluent characteristics as follows

S.No	Parameters	Raw effluent	Treated effluent
1	pH	5.5 to 9.0	7.0 to 8.0
2	Suspended solids	150 - 300 mg/L	< 10 mg/L
3	TDS	1500 to 1600 mg/L	< 2100 mg/L
4	BOD5	350 mg/L	< 20 mg/L
5	COD	550 - 650 mg/L	< 150 mg/L

COMBINED EFFLUENT TREATMENT PLANT DETAILS

CETP is designed for 10 KL/Batch of combined effluent (Trade effluent – 6 KLD & Domestic effluent – 4 KLD) to meet treated effluent quality as per TSPCB standards and to use for lower secondary uses, such as Gardening, Plantation, ETP chemical solution preparation and Toilet flushing. The proposed treatment plant comprising of Physical treatment units, chemical treatment processes & Biological treatment processes. The schematic units are listed below.

Treatment units:

Pre-treatment for washing effluent:

1.Bar Screen Chamber – 1 (For trade effluent)	-1 no.
2.Equalization Tank – 1 (For trade effluent)	-1 no.
3.Reaction cum settling tank	-1 no.

Pre-treatment for domestic sewage:

4.Bar Screen Chamber – 1 (For Domestic effluent)	-1 no.
5.Equalization Tank – 1 (For Domestic effluent)	-1 no.

Secondary treatment for combined effluent:

6.Sequential Batch Reactor (SBR)	-1 no.

Tertiary treatment:

7.Dual media Filter	-1 no.
8.Chlorinator	-1 no.
9.Sludge drying beds	-2 no.
10.Post-filtration tank	-1 no.

Treatment description:

The generated washing effluent will pass through Bar screen chamber – 1 for removal of coarse solids, the screened effluent will collect in Equalization tank - 1 to equalize the strength of the effluent. The equalized effluent will be pumped to Reaction cum settling tank once 6 KL effluent collects, where chemicals like Lime/ Caustic soda, Ferrous sulphate/ HCL & Poly will dose at required dose and allow for chemical reaction for about 45 min, then, allow the reacted effluent to settle for about 3 hours for solid – liquid separation, the settled chemical sludge will be pumped to drying beds for drying and dewatering. The cleared/ clarified effluent will be combined with sewage at Equalization tank – 2.

Whereas the domestic sewage will pass through Bar screen chamber – 2 for removal of coarse and floating solids, the screened effluent will collect in Equalization tank – 2, where pretreated washing effluent will combine the sewage.

The combined effluent is then pumped to SBR tank, the detailed process of SBR is explained as follows.

Process Description of Sequencing Batch Reactor (SBR)

A sequencing batch reactor (SBR) is a Fill – and – Draw Activated – Sludge Treatment System. The unit processes involved in the SBR and conventional activated – sludge systems are identical. Aeration and sedimentation /clarification are carried out in both systems. However, there is one important difference. In conventional plants, the processes are carried out simultaneously in separate tanks, whereas in SBR operation the processes are carried out sequentially in the same tank.

As currently used, all SBR systems have five steps in common that are carried out in sequence as follows

1. Fill
2. React (aeration)
3. Settle (sedimentation/clarification
4. Draw (decant)
5. Idle

Sludge wasting is another important step in the SBR operation that greatly affects performance. Wasting is not included as one of the five basic process steps because there is no set time period within the cycle dedicated to wasting. The amount and frequency of sludge wasting is determined by performance requirements, as with a conventional continuous – flow system. In an SBR operation, sludge wasting usually occurs during the settle or idle phases. A unique feature of the SBR system is that there is no need for a return activated – sludge (RAS) system. Because both aeration and settling occur in the same chamber, no sludge is lost in the react step, and none has to be returned from the clarifier to maintain the sludge content in the aeration chamber

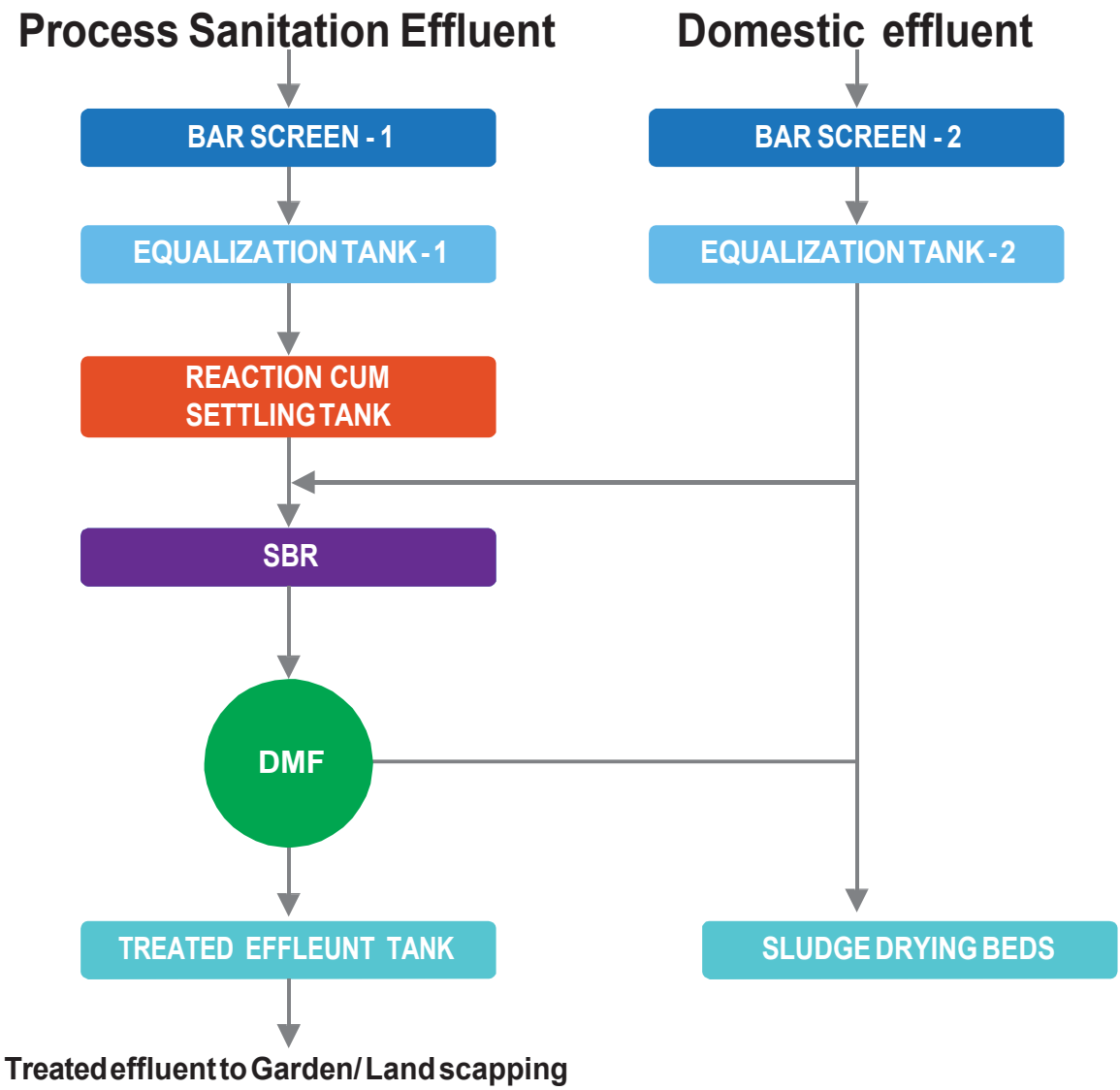
The clarified effluent from the SBR will be pass through Dual media filter to remove minute suspended solids, color and odor if any. The filtered effluent will be chlorinated on line for Disinfection purpose and treated effluent will be collected in post-filtration tank and treated effluent used on land for Gardening, Plantation and other lower end secondary uses.

The settled excess sludge will be pump to sludge drying beds for dewatering and drying purpose. The dried sludge will be used as manure for garden and plantation.

Design:

Flow	-	10 KLD
Retention time	-	24 hours
Tank volume	-	10 m3
Depth of the existing tank	-	1.5 m LD (2.0 m TD)
Area of the tank	-	6.6 m2
Existing tank size	-	4.0 m x 1.6 m x 1.5 m SWD

CETP PROCESS FLOW SHEET



3.8 HOUSE KEEPING:

We have a good team of Housekeeping personnel by which the plant and the premises are maintained hygienically. Regular sanitation programme / schedule for the area are drawn and adhered to the instructions.

3.8.1 PEST CONTROL

We have entered into a contract with external agency for pest management programme like rodent control, insect control, which is carried out at regular intervals.

3.9 DESCRIPTION OF MAJOR EQUIPMENT.

Refer Annexure to SMF/00/ 003 No.DWG/EQP/00/003(SMF GF EQP-09-1 to 5)

3.9.1 PRODUCTION

3.9.1.1 Tablets & Powders

a. Rapid Mixer Granulator 100 Kg.

Made up of SS 316 and GMP Model

Used for dry mixing of the powder and to granulate the same at a faster speed thus by reducing process time.

b. Fluid Bed Drier 120 Kg. G.M.P Model.
Made up of S.S of 316 quality with retarding chamber to ensure easy removal of filter bags for cleaning.
For uniform drying of processed granule inlet air is filtered through 20 micron, 5 micron and HEPA filter 0.3 micron.

c. Tray drier

d. Vibro sifter (03 Nos) Made up of SS 316

e. Multi mill (02 Nos) Made up of SS 316

f. Octagonal Blender 500 Kg and 750kg Made up of SS 316

To blend the milled granules

g. Double Cone Blender 100 Kg. Made up of SS 316

To blend the milled granules

h. GMP Model Compression Machines (45 & 27 Stn D-Tooling& 8Stn Spl-Tooling)

To compress the granule into tablets

i. Coating Pan 48" and 60" Made up of SS 316

j. Blister Packing Machine BPV-234 and Rapid
Pack Mach-1 GMP Model made up of SS 316
Consists of Flat and Normal Forming in a single machine

k. Electronic weighing scales with Data capturing unit and printer.
Data like Gross weight; Net weight etc. is recorded and printed on real time basis. In packing to weigh the shippers on line

l. Roll compactor for compaction made of SS316L

m. Augar filling machine for powder filling made of SS316L

Other Accessory equipment required for productions are provided

3.9.1.2 Complete Oral Liquid cGMP Manufacturing Plant-

(Working capacity 2000Liters) consisting of

a 2000 liters. Liquid Mfg. Vessel With Jacket for heating and cooling, Top agitator with std. fittings and nozzles.

b. 1800 liters. Sugar Melting Vessel With Jacket for heating and cooling, Top agitator with std. fittings and nozzles. With 100 Liters Basket Type Sugar Filter

c. 1000 Liters mixing tank with jacket

d. 500 Liters mixing tank with jacket

e. 2000 liters. Liquid Storage Vessel Without jacket.

f. Inline Homozinizer – 7.5 HP

g. Zero Hold Up Filter Press – SS 316

h. Colloid Mill for Suspensions.

i. SS pipe line (Interconnecting) from sugar melting vessel to mfg. vessel to storage vessel, SS working platform

j. Storage tank 2000ltrs. Without jackets & with internal pipe connection

Complete Oral Liquid GMP Packing Machinery 120/BPM consisting of

a. Rotary Bottle Washing Machine-64 (02 Nos) with In built pre inspection with magnifying dome (02 Nos) Automatic 6 Head filling (02 Nos) and 6 head ROPP sealing (02 Nos) Automatic high speed labelling machine (02 Nos)

Provision for post nitrogen bubbling Online bottle inspection machine
Suitable SS turn tables and packing conveyors for two packing lines.

3.9.2 PLANT CAPACITY BASED ON TWO SHIFT BASIS

S.No	Description	Quantity	No. of Days	Per Shift Month	Per Shift Annum	Per Two Shifts Month	Per Two Shifts Annum
1	Tablets	1.2 Millions	25	30 Millions	360 Millions	60 Millions	720 Millions
2	Powders	10000nos (50gm)	25	0.25 Millions	3 Millions	0.5 Millions	6 Millions
3	Liquids	60,000 bottles	25	1.5 Millions	18 Millions	3 Millions	36 Millions

3.9.3 LIST OF MAJOR EQUIPMENTS.

Machinery/Equipment

S. No	Name Of Equipment **TABLET&POWDERSECTION**	Make	No of Units	Capacity	Equipment ID
1	SS 316 Tray Drier-GMP	Ahlada Industries,Hyderabad	1	48 Trays	TA/TRA/01
2	FBD 120KG Steam	Gem Pharma Machineries,Navi Mumbai	1	120kg	TA/FBD/01
3	Rapid Mix Granulator	Gem Pharma Machineries,Navi Mumbai	1	250lts (100KG)	TA/RMG/01
4	Paste Kettle	Gem Pharma Machineries,Navi Mumbai	1	100 Liters	TA/KET/01
5	Octagonal Blender 500KG	Gem Pharma Machineries,Navi Mumbai	1	1400 Liters	TA/OBL/01
6	Octagonal Blender 750KG	Winmax, Hyderabad	1	1600 Liters	TA/OBL/02
7	Multimill	Gansons, Nashik	2		TA/MML/01
8	Sifter 750MM/30INCH	Gansons, Nashik	3		TA/SFT/01
9	Compression Machine 27 Stn	Karnavati Engg,Gujarat	1	27STN-D Tooling	TA/CMP/01
10	Compression Machine 45 Stn	Cadmach Engg,Gujarat	1	45 STN-D Tooling	TA/CMP/03
11	Compression Machine 8 Stn	Karnavati Engg,Gujarat	1	8 STN-SP Tooling	TA/CMP/02
12	Coating Pan	Gem Pharma Machineries,Navi Mumbai	1	48 Inch	TA/COT/01
13	Coating Pan	Gem Pharma Machineries,Navi Mumbai	1	60 Inch	TA/COT/02
14	Blister Pkg M/C	Rapid Pack	1	Mach-1	TA/BLP/02
15	Blister Pkg M/C	Nutan Technologies,Bangalore	1	BPV 234	TA/BLP/01
16	Double Cone blender 100Kg.	Gem Pharma Machineries,Navi Mumbai	1	250 Ltrs.	TA/DCB/01
17	Roll Compactor	Karnavati,Ahmedabad	1	60Kg	ST/RCR/01
18	Augar Filling machine	Canflex,Hyderabad	1	15-500gms	MZ/AFM/01
19	Ink Jet Printer	Control Prints,Hyderabad	2		OP/IJP/01

S. No	Name Of Equipment	Make	No of Units	Capacity	Equipment ID
	LIQUID ORALS				
1	Complete Liquid Oral manufacturing	SK Pharma,Gujarat	1	2000litres	LO/MFG/01
	machinery - 2000litres				
2	Complete Liquid Oral six head filling	Konark Engineering,Ahmedabad	1	120BPM	LO/PKG/01
	line- 120Bottles per min(100ml)				
	STORES				
1	SAMPLING BOOTH -GMP	Supra Control Systems,Hyderabad	1		ST/SMB/01
2	DISPENSING BOOTH - GMP	Supra Control	2		ST/DSB/01

QUALITY CONTROL DEPARTMENT

S. No	Name Of Equipment	Make	No of	Capacity	Equipment
1	Laminar Air Flow Bench (Class 100)	Laminar Flow Systems	1		QC/LAF/01
2	Autoclave-Steam Sterilizer (GMP Model)	Osworld	1	175 Liters	QC/ATC/01
3	Autoclave	Equitron	1	25 Liters	MB/ATC?02
4	BOD incubator GMP model	Osworld	1	120 Liters	QC/BOD/01
5	BOD incubator GMP model	Osworld	1	200 Liters	QC/BOD/02
5	BOD incubator GMP model	Osworld	1	42 Liters	QC/BOD/03
6	Oven (Gravity Convection)	Osworld	1	215 Liters	QC/OVN/01
7	Vacuum Oven GMP Model	Osworld	1	35x35x50	QC/OVN/02
8	Muffle Furnace - GMP Model	Osworld	1	10x5x5	QC/MFL/01
9	UV-Vis Spectrophotometer	Shimadzu	1	UV 1800	QC/UVS/01
10	Tablet Hardness tester	Veego	1		QC/THT/01
11	Potentiometer - Automatic. Digital	Veego	1		QC/PTM/01
12	HPLC-Isocratic, Prominance	Shimadzu	1		QC/HPC/01
13	Sonicator	-	-		QC/SON/01
14	Refractometer	Arico	1	R-8	QC/RFM/01
15	Polarimeter	Advance	1	PA2	QC/PLM/01
16	pH Meter	Eutech	1	ECPHTUTOR	QC/PHM/01
17	IR Balance	Advance	1	M-3A	QC/IRB/01
18	Vacuum Dessicator with Pump(Leak test aparatus)	Servewell	2		QC/LTA/01
19	Disintegration Test Aparatus	Electrolab	2	ED-2AL	QC/DTA/01
20	Tap Density Tester	Electrolab	1	ETD1020	QC/TDT/01
21	Friability Tester	Electrolab	1	EF-2	QC/FRT/01
22	Stability chamber	Thermolab	3	1000 Litres	QC/STC/01
23	Photostability chamber	Thermolab	1	250 Litres	QC/PTC/01
24	Dissolution test apparatus USP	Electrolab	1	8 Liters	QC/DST/01
25	Bursting Strength Tester	-	1	-	QC/BST/01
	UTILITIES & HVAC SYSTEM				
1	Air Compressor - 100CFM	Kirloskar Pneumatics,Pune	1	100CFM	UT/ACP/01
2	Purified water treatment System	Apex Ecotech Pvt Ltd,Pune	1	2m3/Hr	UT/PWS/01
3	Purified water distribution system	Fabcon Technologies Pvt td,Bangalore	1		UT/PWD/01
4	Thermax Boiler 600Kg	Themax,Pune	1	600Kg	UT/BLR/01
5	Kirloskar Green Diesel Generator	Kirloskar,Bangalore	1	320KVA	UT/DGS/01
6	Effluent Treatment Plant	Green Point,Bangalore	1	10KLD	UT/ETP/01
7	Air Cooled Scroll Chiller	Blue Star	1	80TR	UT/SCH/01
8	AHU	Ethos, Ahmedabad	13	Class 1 lakh	-
9	AHU	Ethos, Ahmedabad	01	Class 10000	-

3.10 PREVENTIVE MAINTENANCE.

We have a planned preventive maintenance programme handled by a team of experienced technicians headed by a qualified Engineer.

Preventive maintenance schedule is drawn which includes the checklist of the items to be attended at regular frequency and carried out accordingly.

In case external agency help required for an equipment, they will carry out the preventive maintenance and the records are maintained.

3.11 QUALIFICATION, CALIBRATION AND RECORDING SYSTEM

Following are the major qualification activity carried out in the site. These qualifications are carried out during commissioning or if there is a major change in the equipment / system

a. Qualification of production equipments

b. Qualification of area

a. Qualification of equipment includes

I. Design qualification (DQ)

ii Installation qualification (IQ)

iii Operational qualification (OQ)

iv Performance qualification (PQ)

Detailed protocol for the above is made for all major equipment used in production. Equipments are cleared for regular after the above qualification

b. Qualification of area includes the following

i. Air changes check

ii. Temperature humidity monitoring

iii. Microbial monitoring of area using settle plate test

iv. Particle count.

Initially above-mentioned parameters checked before clearing the area for regular production. Based on the results, monitoring frequencies are fixed for the above checks and carried out as per the schedule.

Calibration

All critical monitoring equipments like temperature; pressure indicator and controllers are calibrated and maintained by a external agency. Calibration & Validation should be done as per the Master Validation Protocol.

Calibrated instruments are labelled properly

If any instrument found out of calibration, it handled using a documented procedure.

3.12 Sanitation:

Pest control measures are carried out outside the premises by an external agency.

Fumigation of operational area are carried out and the records are maintained

4.0

Premises and Documentation

Documented SOPs are available for each activity. Copies are available with QA Dept. & concerned departments. Employees are detailed about SOPs concerning their area of work. All SOPs are reviewed periodically and the quality operations head is authorized to update them.

4.0.2MASTER FORMULA RECORD (MFR):

Every formula of production has an approved MFR which gives details like quantity of RM / PM for standard Batch size, process details, precautions, in-process checks, reconciliation at various stages of production. Yield,packing details etc. The authorised copy is retained securely. All MFR are reviewed periodically & any change carried out is documented & authorised.

4.0.3 BATCH MANUFACTURING RECORD (BMR):

BMR formats are generated, entries recorded and completed BMRs are retained as per requirement by QA Department.

4.1 MICROBIAL CONTROL OF AIR AND WATER.

Environmental Monitoring: Sterile agar media plates are exposed at Different locations. Environmental Monitoring in production area is carried out and is exposed for period as given in the SOP. If microbial count is above the action limit, fumigation of the area is carried out as per SOP.

Potable water is tested for microbiological purity as per SOP. Purified water is also tested microbiologically as per SOP.

5.0

Production

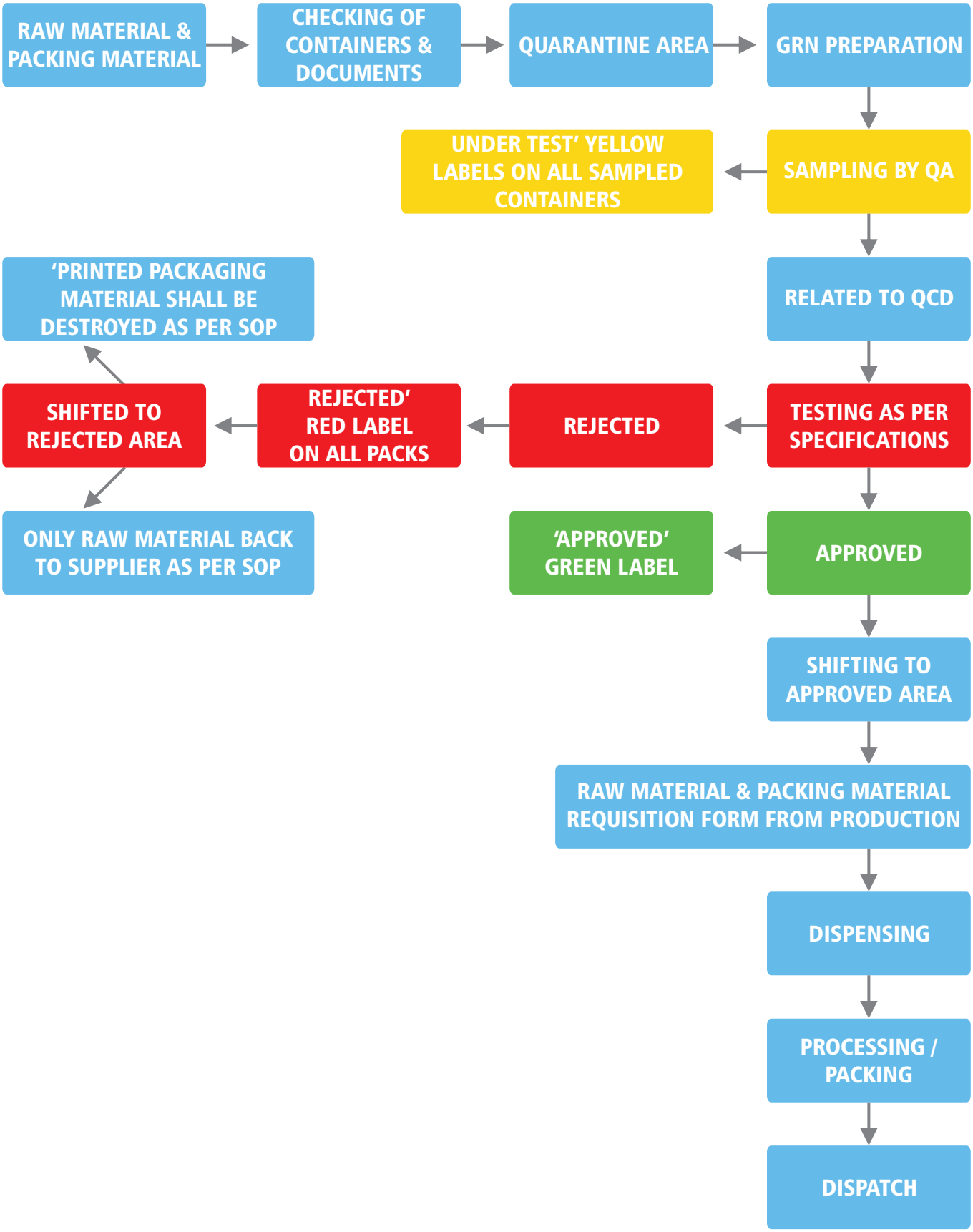
HANDLING OF MATERIALS: (Raw Materials, Packing Materials & Finished products)

- Detailed specification, method of analysis, Testing Methods & source of supply are generated.
- Materials are procured according to these specifications; Copies of this Specification are available with Q.C.
- Stores department receives all raw & packing materials from approved vendors. On receipt of materials, identification, condition, integrity of container etc is confirmed by stores.
- Store then prepares Goods Receipt Note (GRN). On receipt of GRN copy, QC personnel inspect consignment & draw sample for analysis as per SOP & designate them as "UNDER TEST" on the containers from which sample is drawn as per defined sampling plan.
- When material confirms to specifications, it is approved for production. "APPROVED" are then affixed on the containers. If the material does not meet the specifications they are labeled as "REJECTED" & are stored in an area earmarked for the same. Rejected materials are returned to the vendors or disposed off as per SOP.
- Once the production department receives the production plan, BMR is generated.

The details of Batch No., Mfg Date, Exp. Date, BMR Sr. No. are entered on BMR & register. QA Manager verifies this BMR.

- Active & Excipients are dispensed under Dispensing Booth in presence of QA personnel on FIFO or FIFE basis, whichever is early
- Approved raw materials (Q.C Passed) are dispensed & divided in lots in the dispensing booth and sifted in the sifting area.

RAW MATERIAL AND PACKING MATERIAL FLOW CHART



5.2 MANUFACTURING

- The Production supervisor rechecks the weight of dispensed material in production department.
- Manufacturing process is done strictly as per procedure given in BMR.
- The BMR moves from section to section & all relevant entries are recorded as per the progress.

5.3 IN- PROCESS QUALITY EVALUATION:

- QA personnel make surprise checks to ensure that all activities are carried out as per SOP.
- QC tests the composite samples before they are taken for further processing.
- The batches are analyzed as per specification.

5.4 FILLING & PACKING:

- Product changeover on the machine & its area is done as per SOP.
- QA gives line clearance before starting of filling & packing operation.
- Production chemist carries out the operations as per the BMR
- Production & QA chemist as per SOP carries out all the in process checks required during filling & packing.
- QC personnel draw sample from finished packs for testing & analyses the Sample as per Finished Product Specification.
- QA ensures that BMRs are complete in all respects.
- On receiving clearance from QA, the finished product ready for dispatch is sent to BSR from packing.

5.5HANDLING OF REJECTED MATERIAL:

5.5.1RAW MATERIAL

- If the material does not comply with the specification, a rejection report is Prepared.
- A copy each is given to stores & Purchase Depts.
- The containers of the material are then affixed with the label " REJECTED"
- The containers are then kept in an area earmarked for the same.
- Rejected materials are then disposed according to SOP.

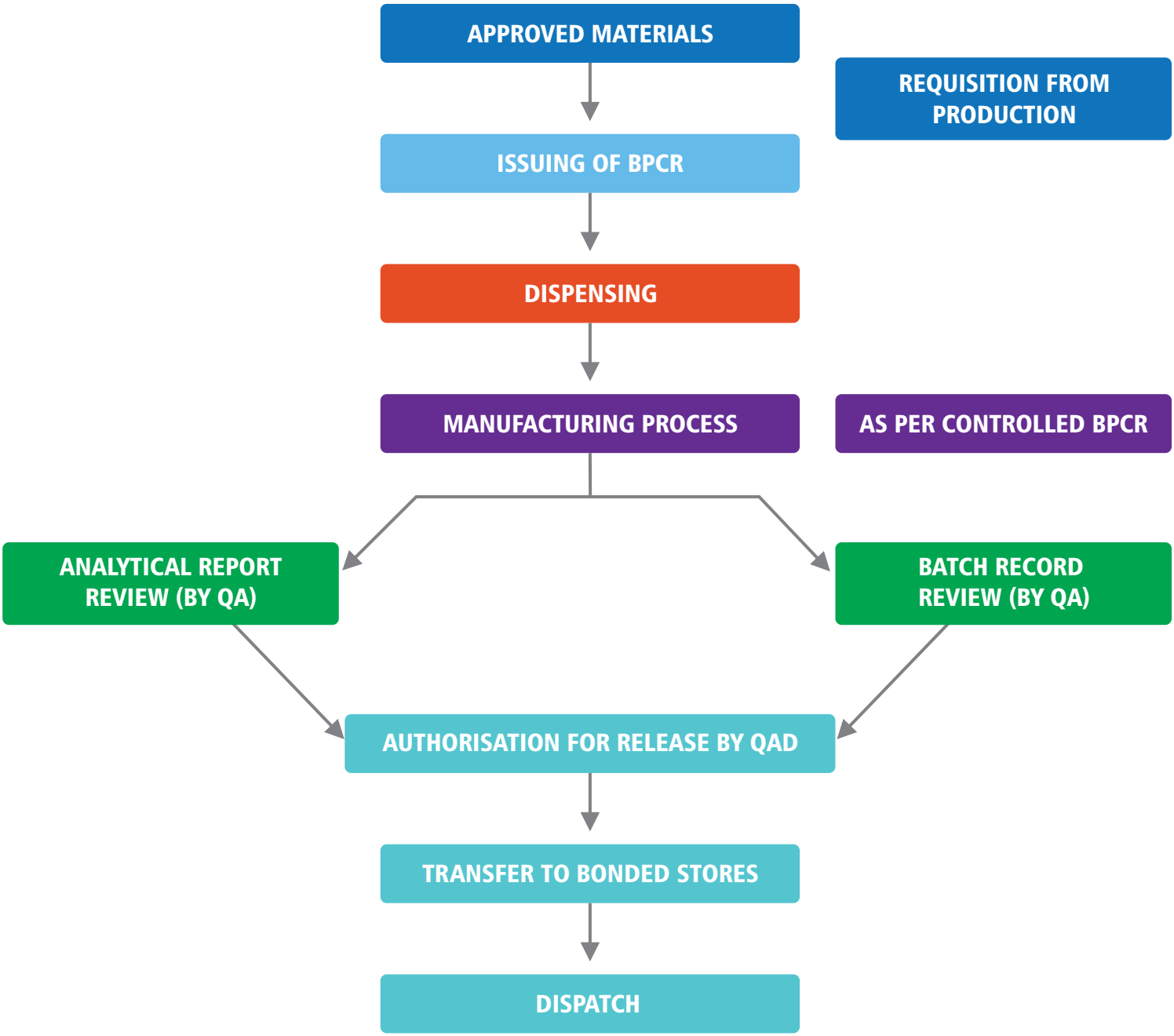
5.5.2 PACKING MATERIAL:

- Rejected printed packing material is totally shredded in company premises as per SOP

5.5.3 IN-PROCESS MATERIAL:

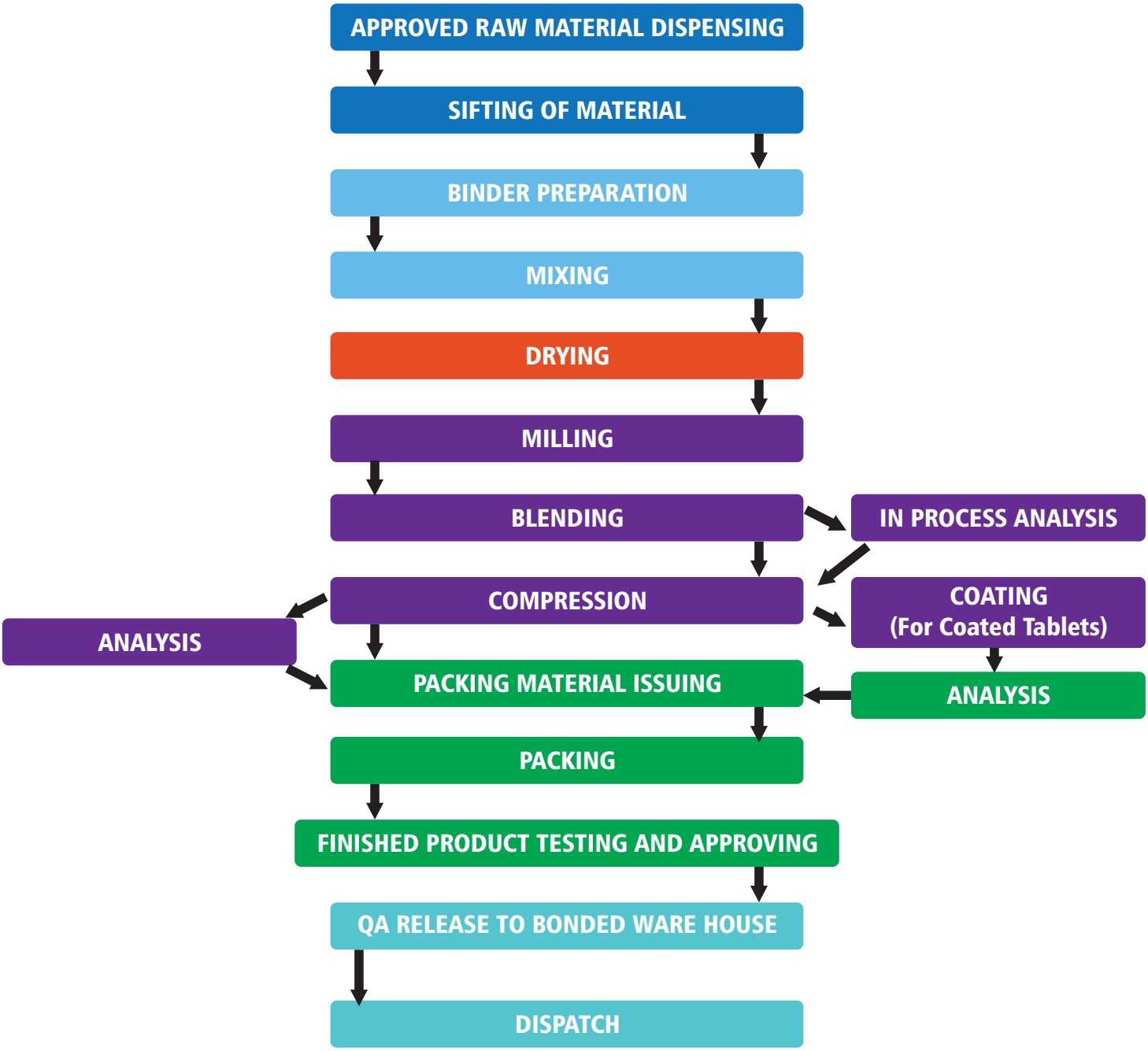
- In Process tested & damaged finished product, if any, is destroyed as per SOP in Presence of QA.

GENERAL PRODUCTION FLOW CHART

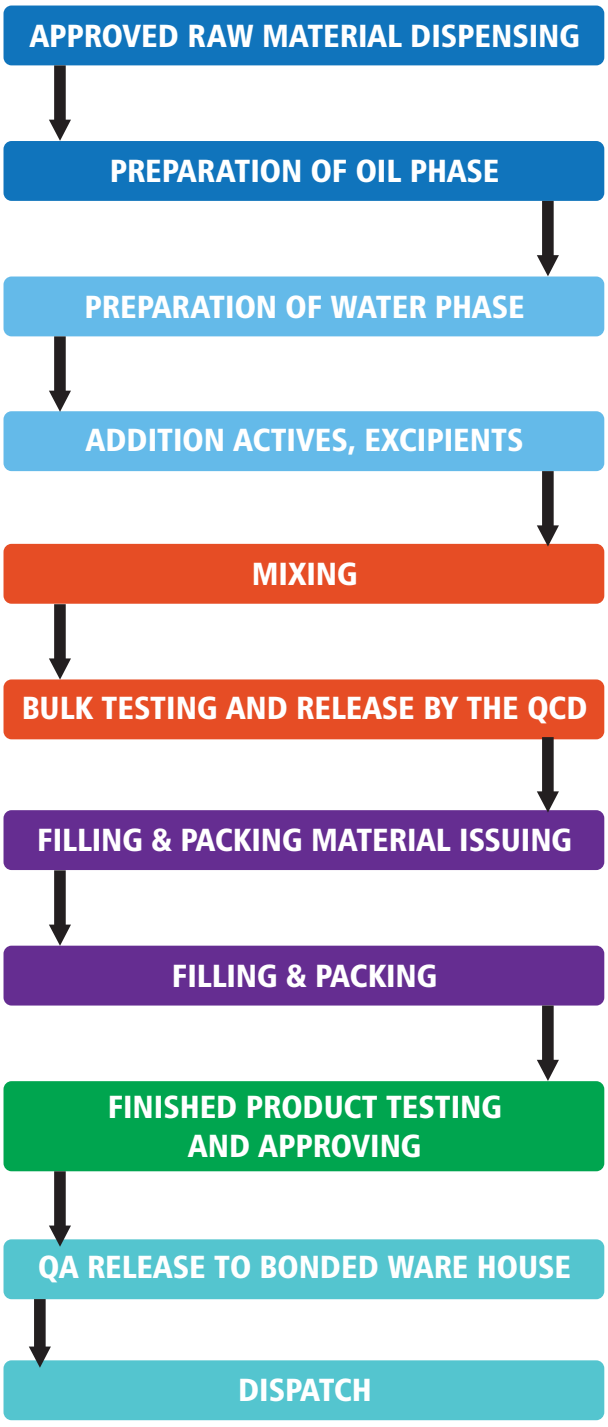


5.7 Flow Charts of manufacturing process

FLOW DIAGRAM OF PROCESS- TABLETS



FLOW DIAGRAM OF PROCESS -EXTERNAL PREPARATIONS



5.8 Cleaning and product change over

All equipment and the area is cleaned thoroughly during product changeover as per SOP. Cleaning method of all production equipments / Area are validated. Appropriate status labelling system is followed to indicate the status of cleaning.

During product change over, QA gives line clearance for all process for continuing production.

5.9 Rejection and reprocess

In coming materials: Incoming materials if rejected, it will be labelled properly and stored in a separate area under lock and key. Supplier will be informed about the rejection and to take necessary action

Semi finished product / finished product: Rejection / Reprocess of the same is carried out as per the written instruction from the QC/QA Manager. If the product is to be destroyed, it will be carried out in the presence of QA personnel after observing all legal formalities.

Written authorisation from the management for such rejection process is sought and after the permission the materials are rejected as per the procedures laid down.

6.0

Validation

With a view to ensure that all instruments are appropriately calibrated, All the processing is reproductive & all the equipment's perform consistently as per the desired parameters, validation data is generated & recorded . The process shall be validated if the data describing its critical attributes meets all the predetermined parameters.

Some of the Critical parameters are:

- Sampling of components
- Analytical Testing
- Process Equipments
- Equipment cleaning & calibration
- In- process control
- Packaging Parameters
- Environmental Conditions
- Equipment is validated at the time of installation (Installation, Operational and Performance Qualification) at the time of change in parameter (Change in design, process, batch size etc.)

  Such equipment is revalidated at a predetermined frequency even. When there is a change to ensure that the process is fully under control at all times.

7.0

Distribution Complaints & Product Recall

7.0.1 ARRANGEMENT & RECORDING SYSTEM FOR DISTRIBUTION:

All the finished goods are transferred to Bonded Stores Room (BSR) after receiving approval from Quality assurance in Charge. BSR always kept under lock and key. The packed shippers received from the packing department bear the product labels. Stock is confirmed as per stock register & dispatches are made as per plan.

7.1.2 COMPLAINTS:

The complaints received from market or FDA are directed to the QA Manager .Generation of details of complaint corrective action is taken to avoid recurrence of complaint. The report is made in a Standard form & the reply is forwarded to complaint. The report of complaint is recorded in complaint file which is reviewed by QA in Charge, Production In Charge.

7.1.3 PRODUCT RECALLS:

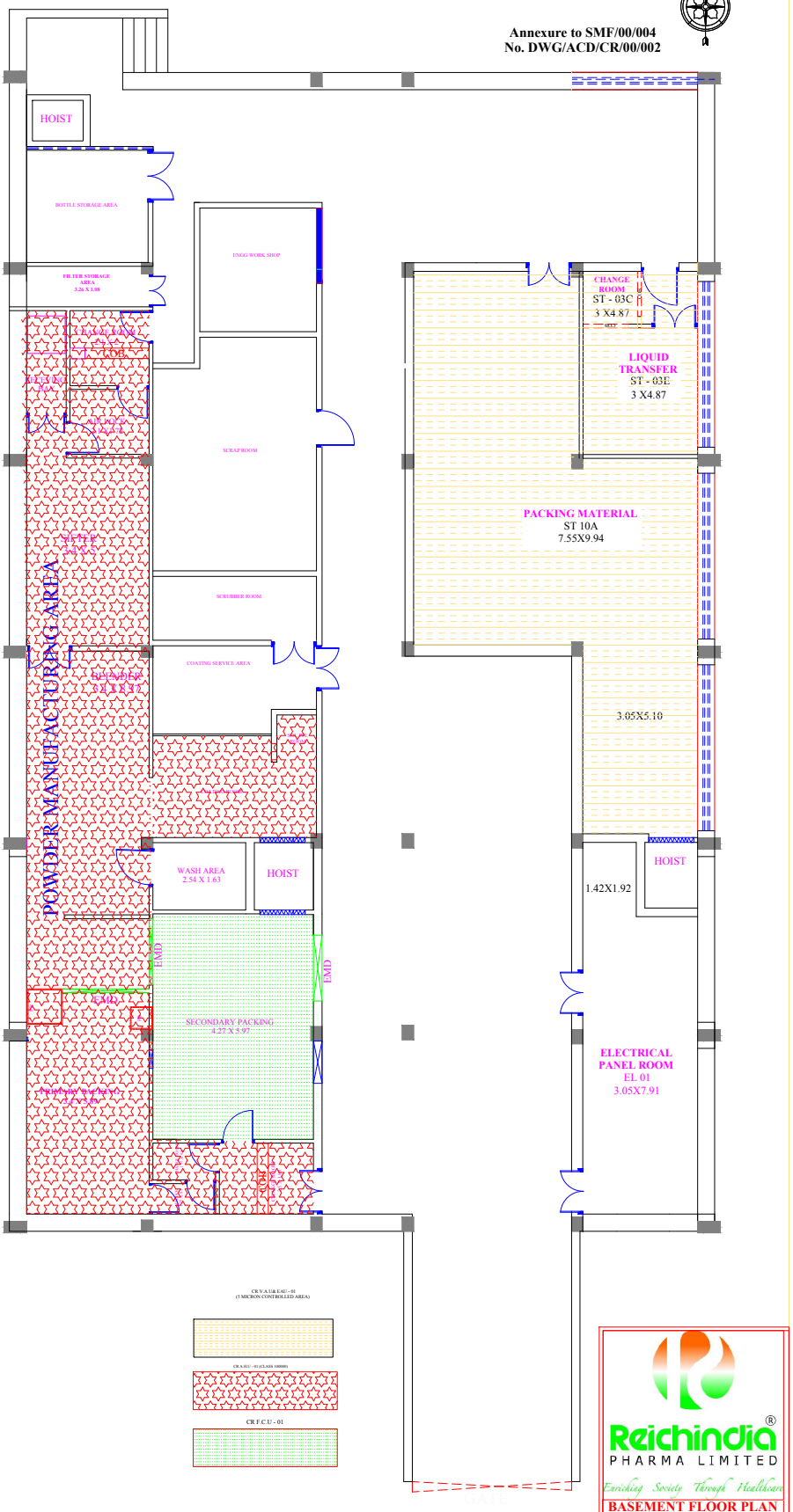
The QA Manager initiates the product recall through the product recall team .Product Recall is initiated when the product is proved to be defective on the basis of quality, purity or expiry. Letters are sent to all the concerned distributors & stockiest asking them to stop sale & withdraw the batch.

The entry received back is stored in separate area after making entries in record book & are labelled as “RETURNED GOODS ‘’ or “REJECTED GOODS” Action is taken on returned goods. The QA Manager informs the Regulatory Authority. The stock is destroyed in presence of QA.

Area Classification

Drawings

REICHINDIA PHARMA LIMITED

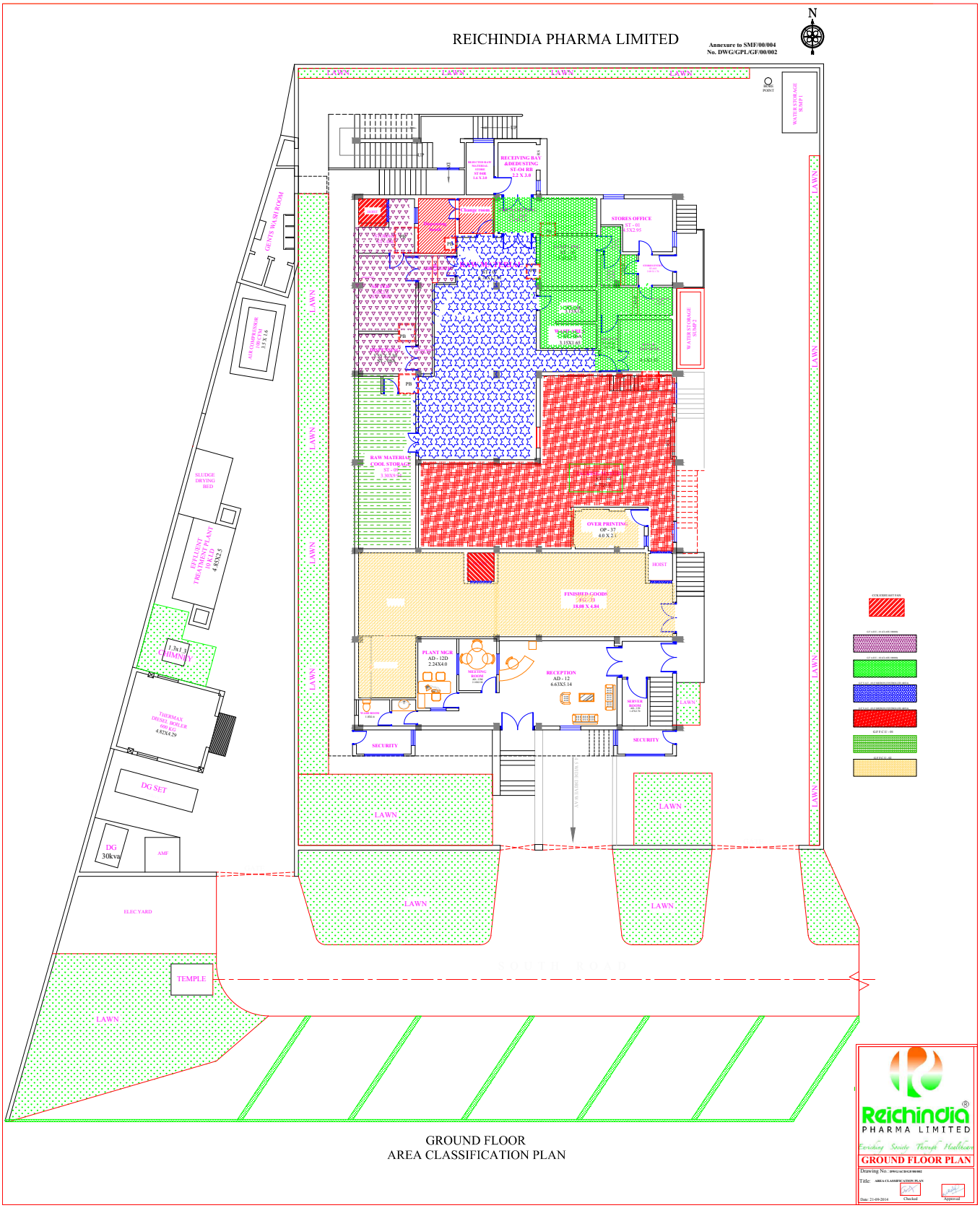


BASEMENT FLOOR
AREA CLASSIFICATIONPLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare
BASEMENT FLOOR PLAN
Drawing No.: DWG/ACD/CR/00/002
Title: AREA CLASSIFICATION PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/GF/00/002



GROUND FLOOR
AREA CLASSIFICATION PLAN

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GROUND FLOOR PLAN
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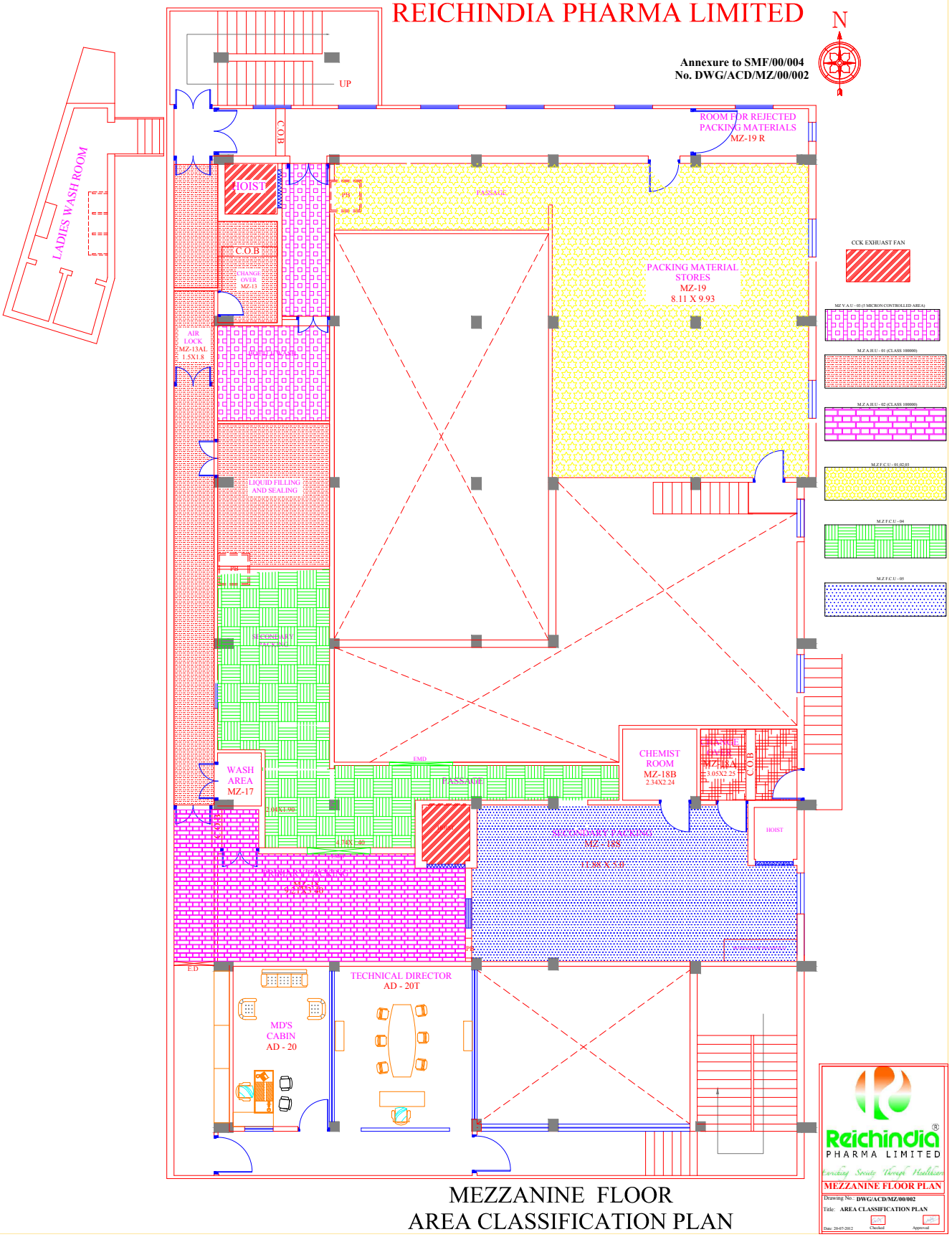

MEZZANINE FLOOR
AREA CLASSIFICATION PLAN

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MEZZANINE FLOOR PLAN
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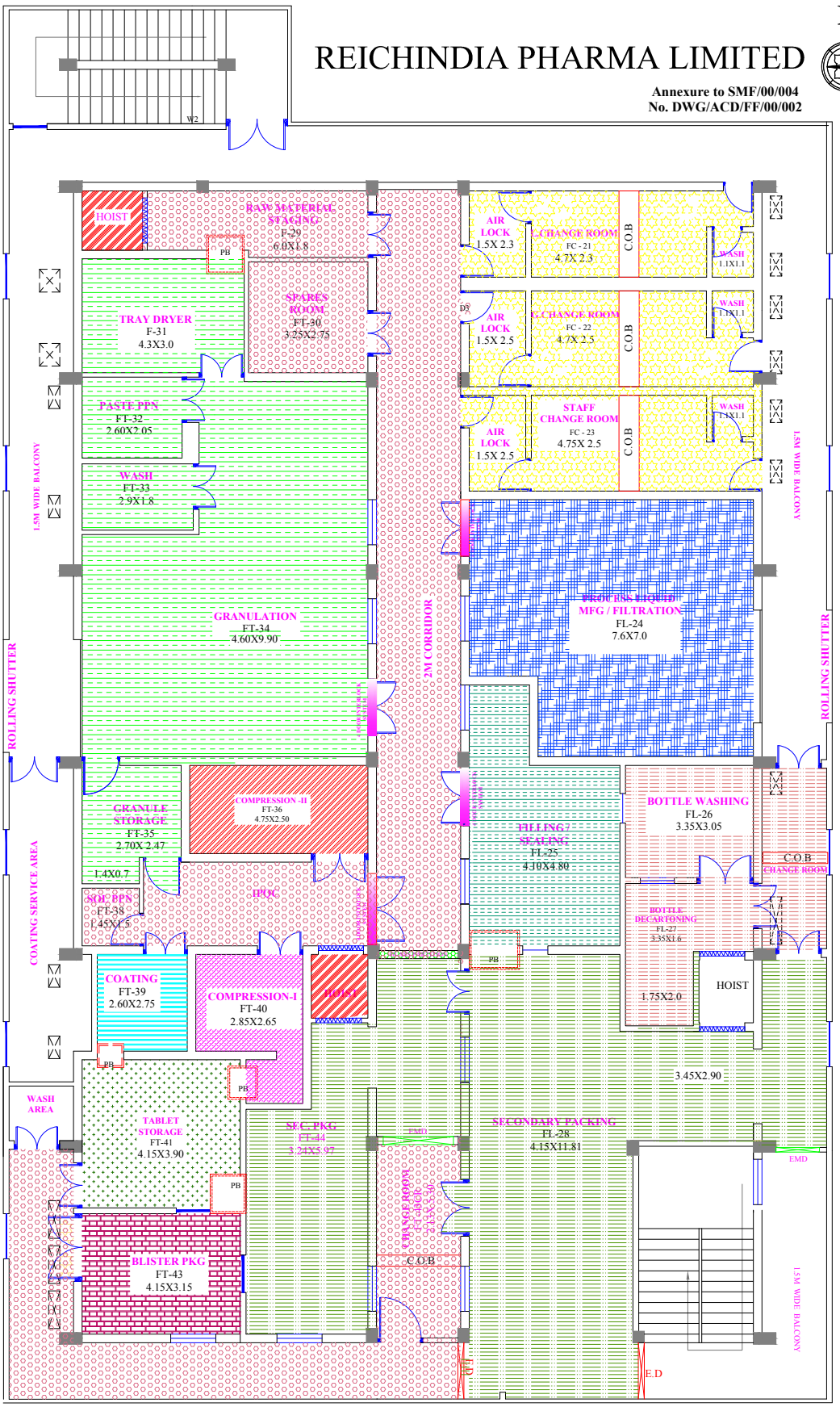

FIRST FLOOR
AREA CLASSIFICATION PLAN

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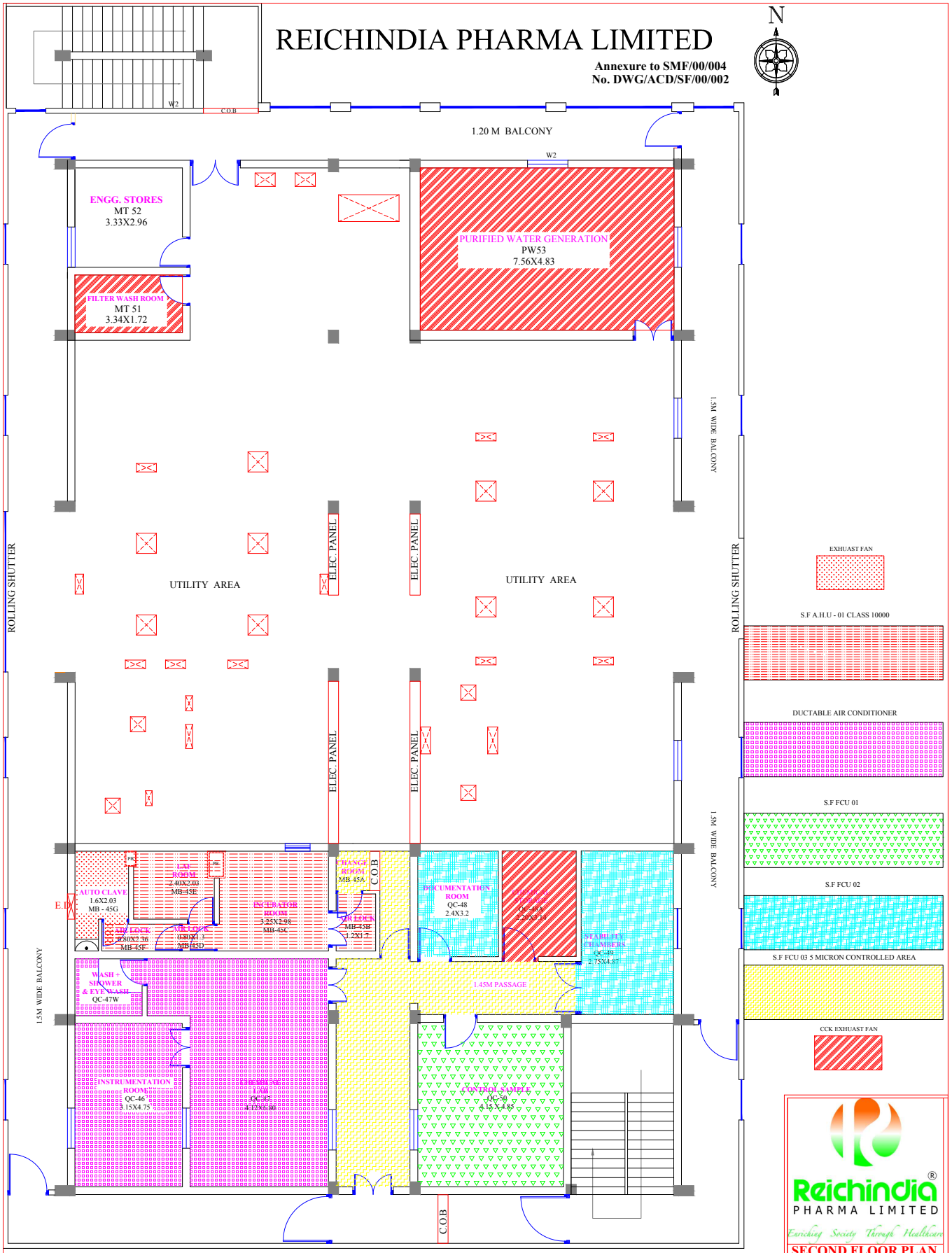

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SECOND FLOOR PLAN

Drawing No.: DWG/ACD/SF/00/002
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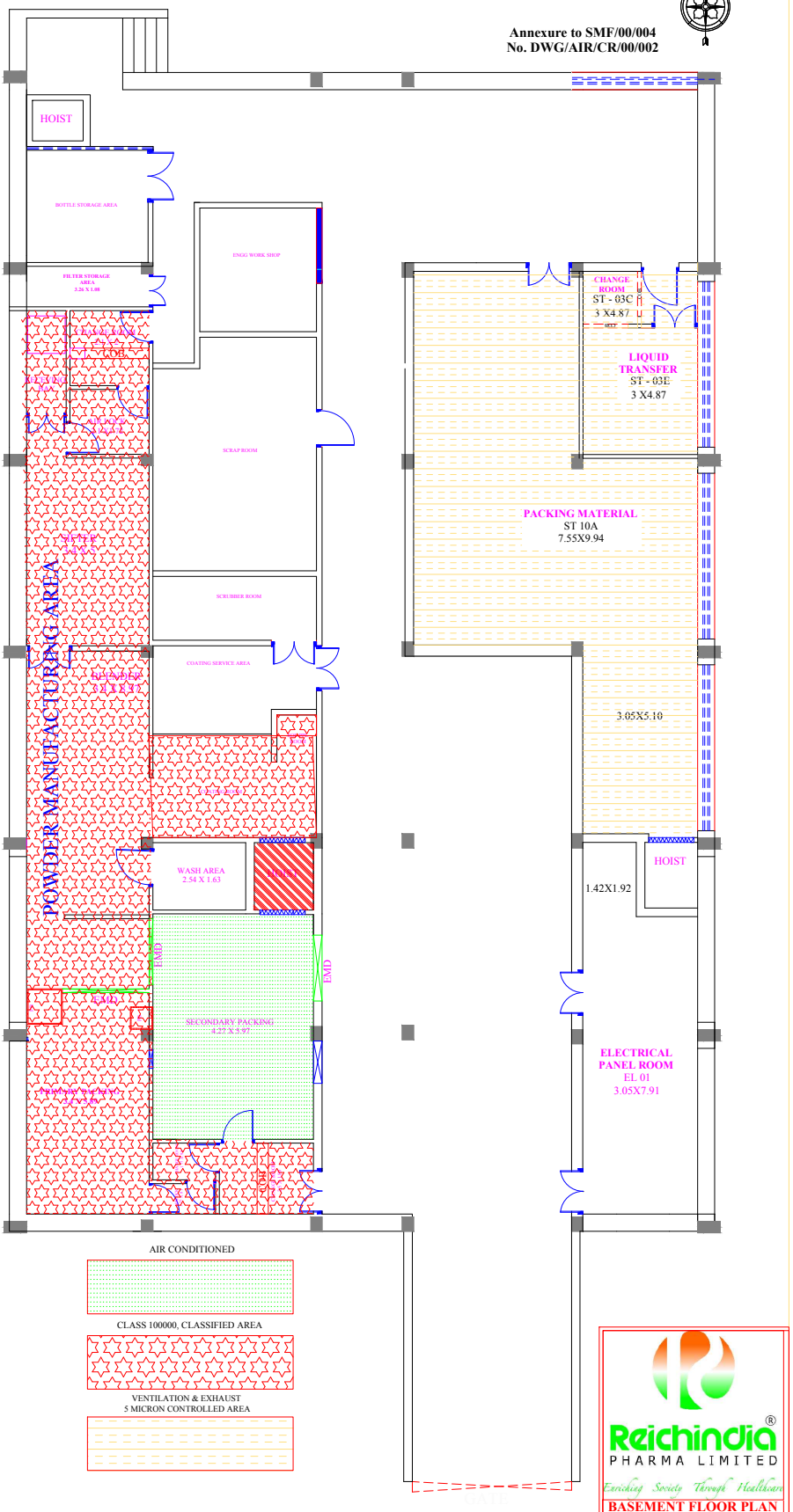
SECOND FLOOR
AREA CLASSIFICATION PLAN

Air Classifications

Drawings

REICHINDIA PHARMA LIMITED



BASEMENT FLOOR AIR CLASSIFICATION PLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare
BASEMENT FLOOR PLAN
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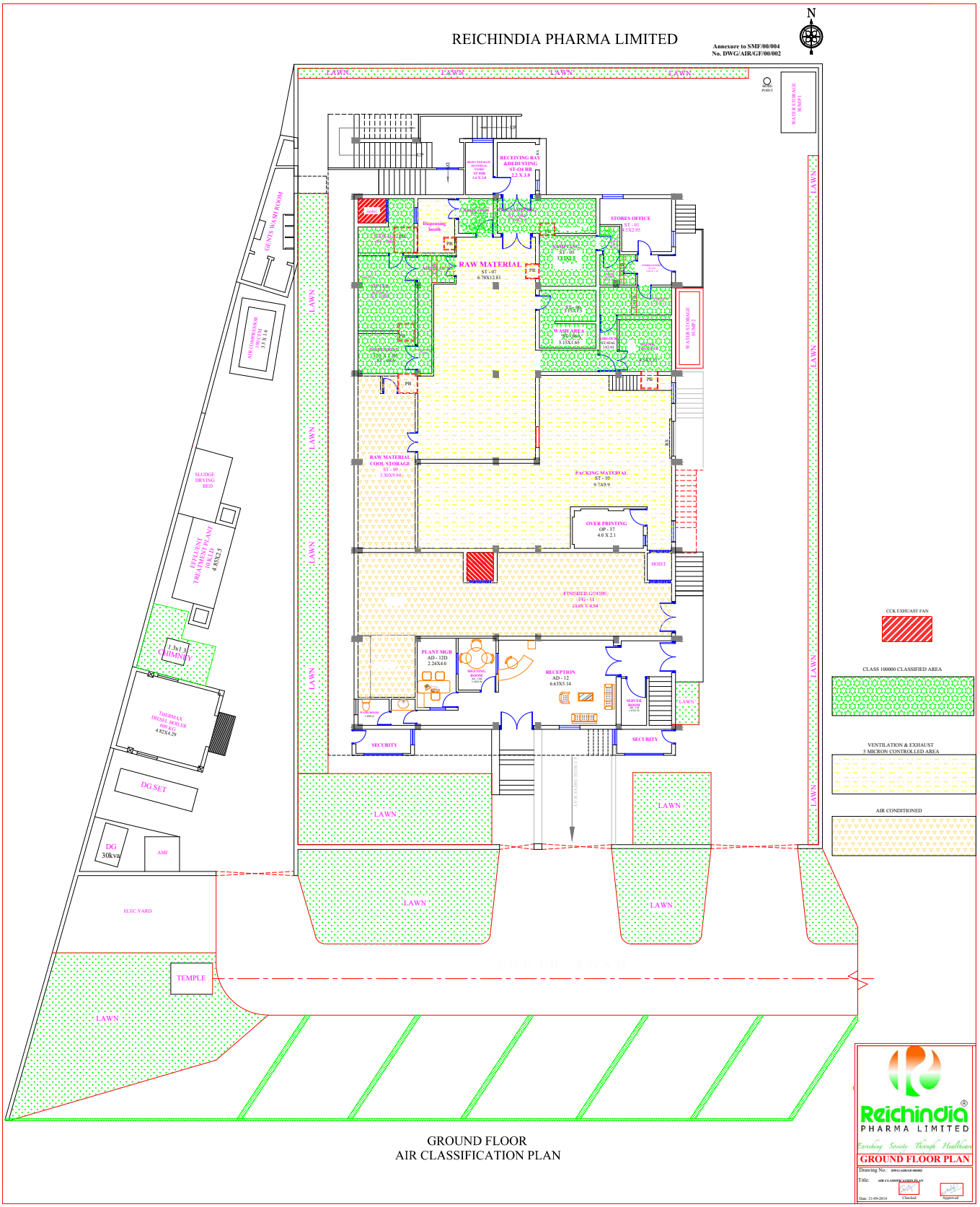

GROUND FLOOR
AIR CLASSIFICATION PLAN

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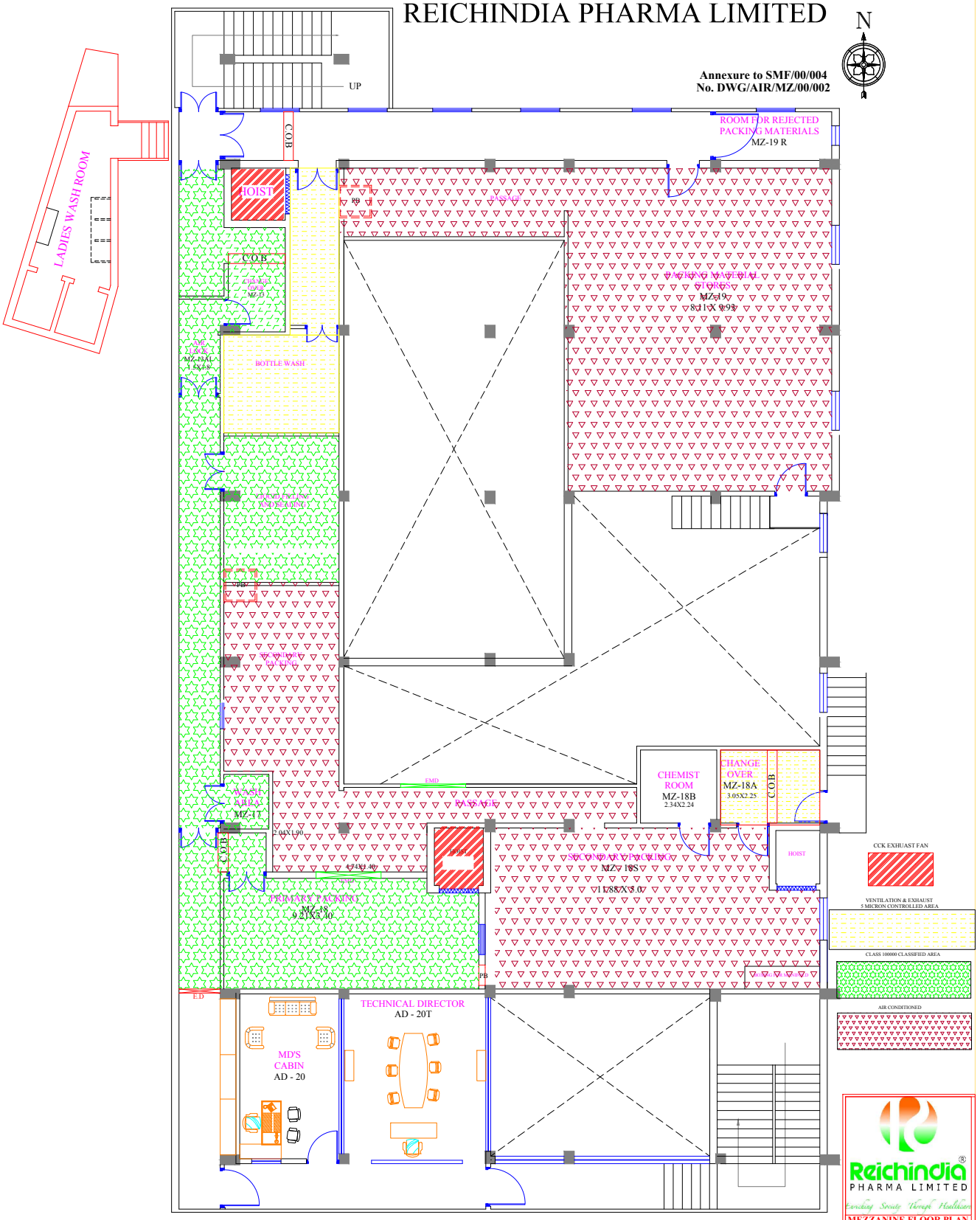
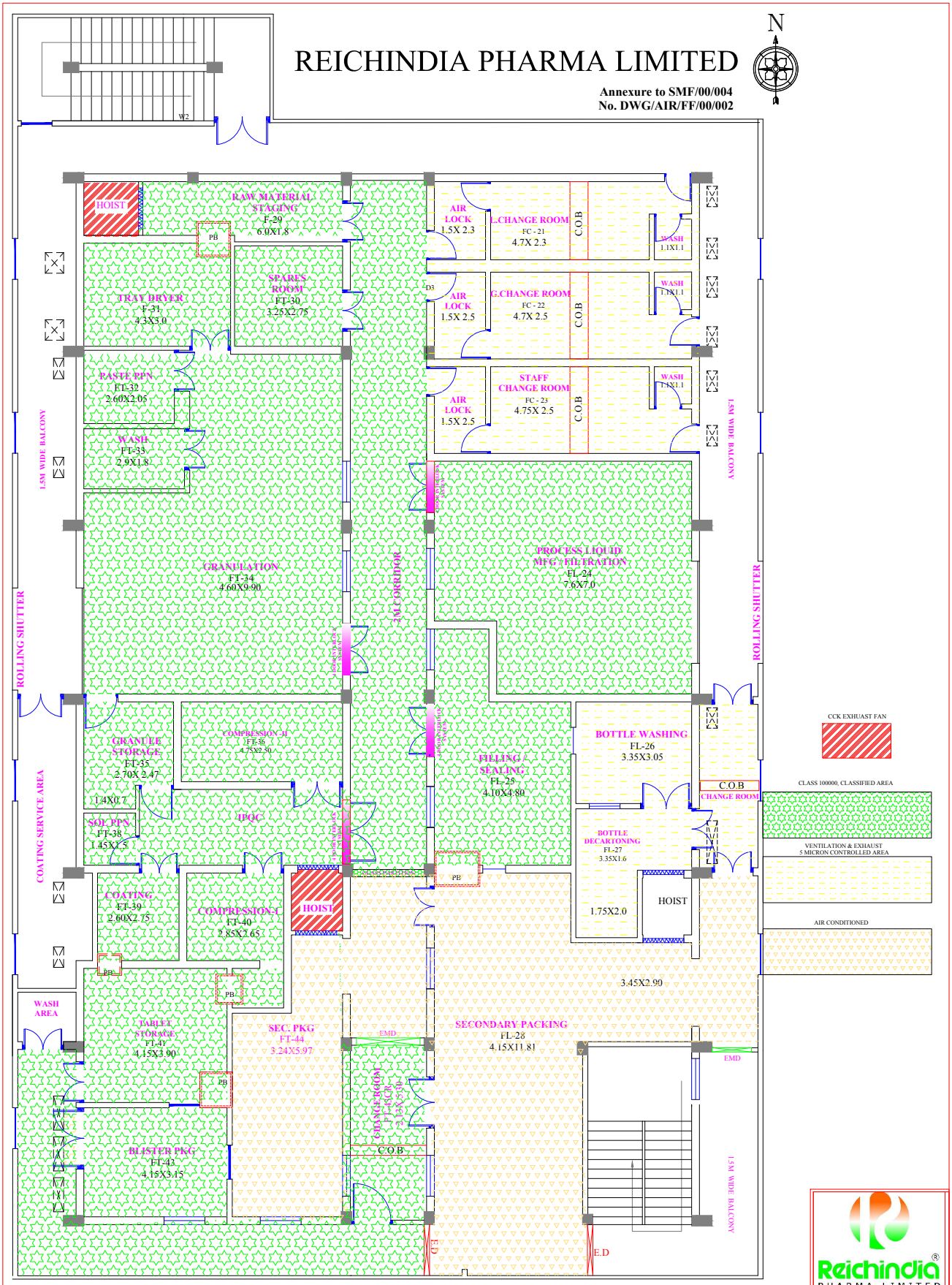


MEZZANINE FLOOR
AIR CLASSIFICATION PLAN

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/AIR/FF/00/002



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AIR CLASSIFICATION PLAN

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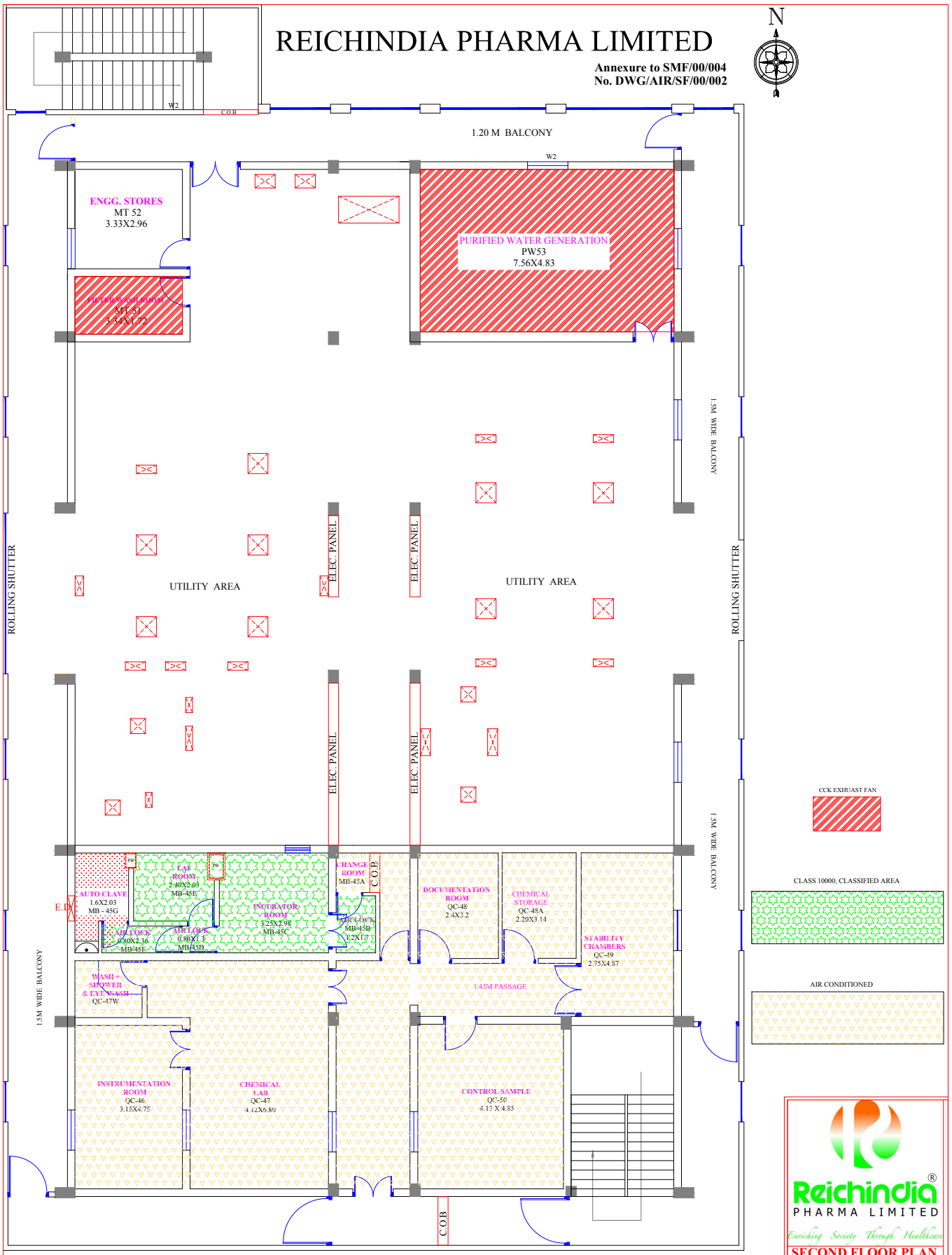

SECOND FLOOR
AIR CLASSIFICATION PLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

SECOND FLOOR PLAN

Drawing No.: **DWG/AIR/SF/00/002**
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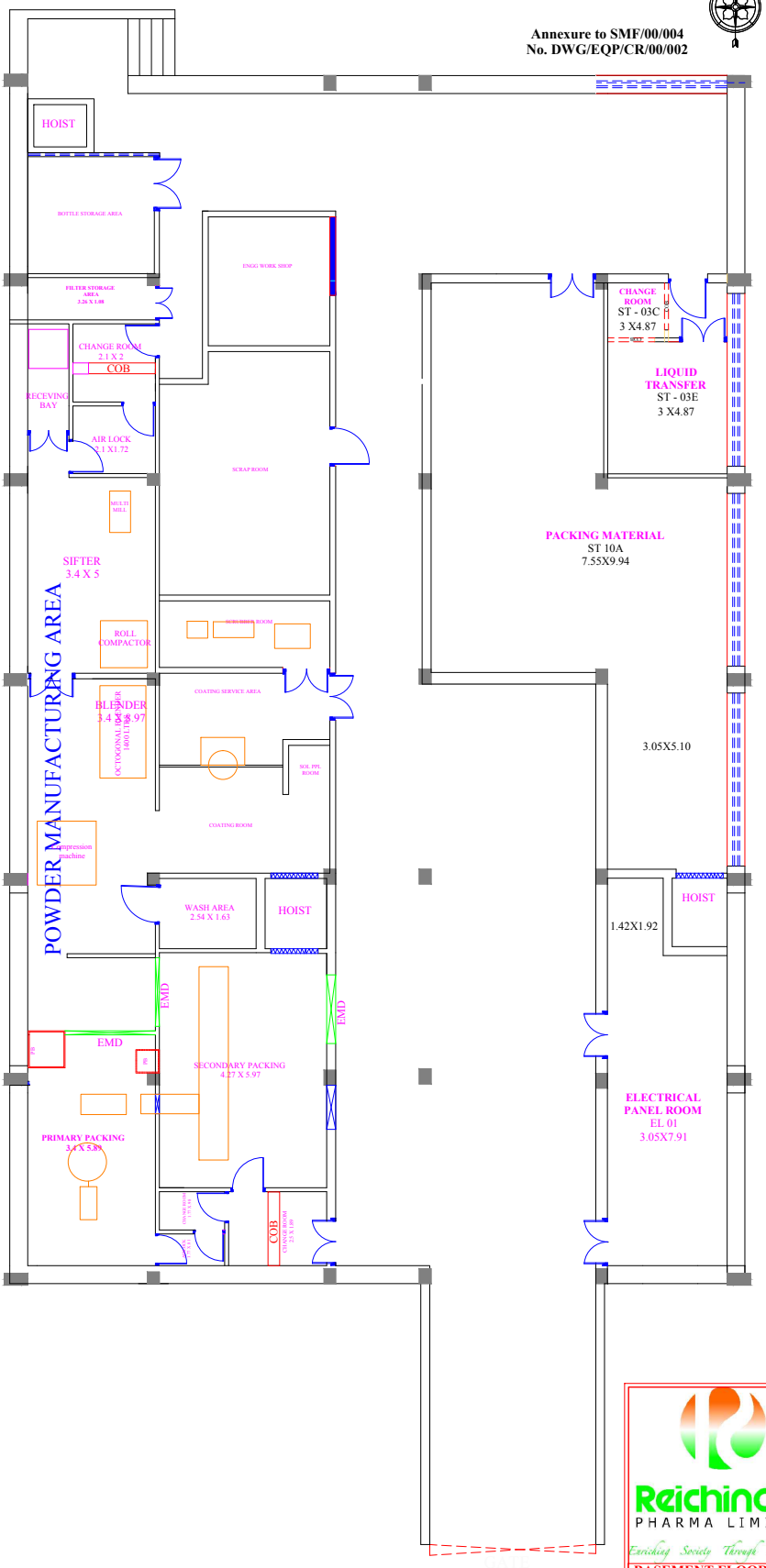
Date: 20-07-2012 Checked Approved

Equipment Plan

Drawings

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/CR/00/002



BASEMENT FLOOR MAJOR EQUIPMENT PLAN

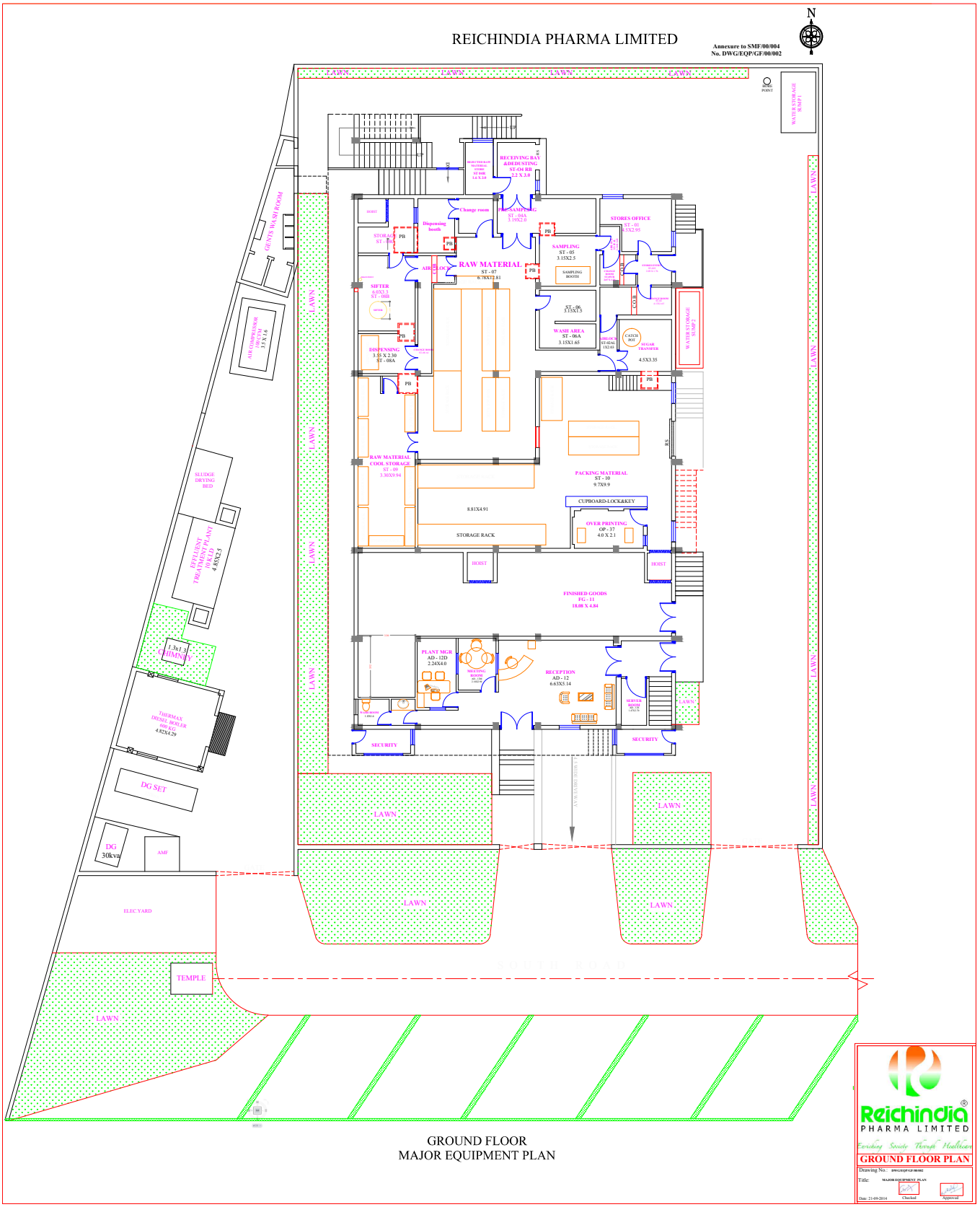
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

BASEMENT FLOOR PLAN

Drawing No.: DWG/EQP/CR/00/002
Title: MAJOR EQUIPMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/GF/00/002

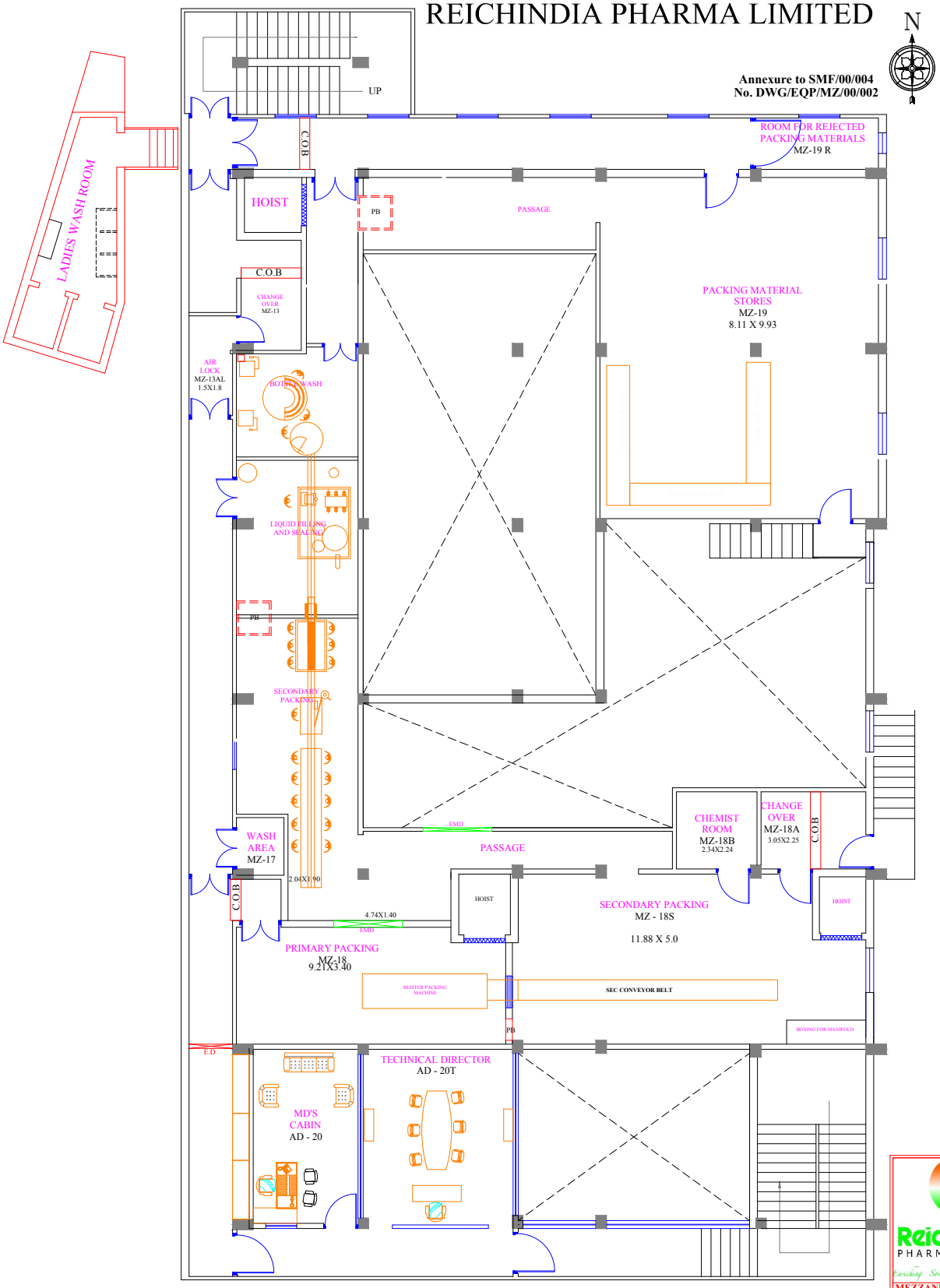


GROUND FLOOR
MAJOR EQUIPMENT PLAN

Reichindia PHARMA LIMITED
Enriching Lives Through Healthcare
GROUND FLOOR PLAN
Drawing No.:
Title: MAJOR EQUIPMENT PLAN
Date: 21-09-2014 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/MZ/00/002

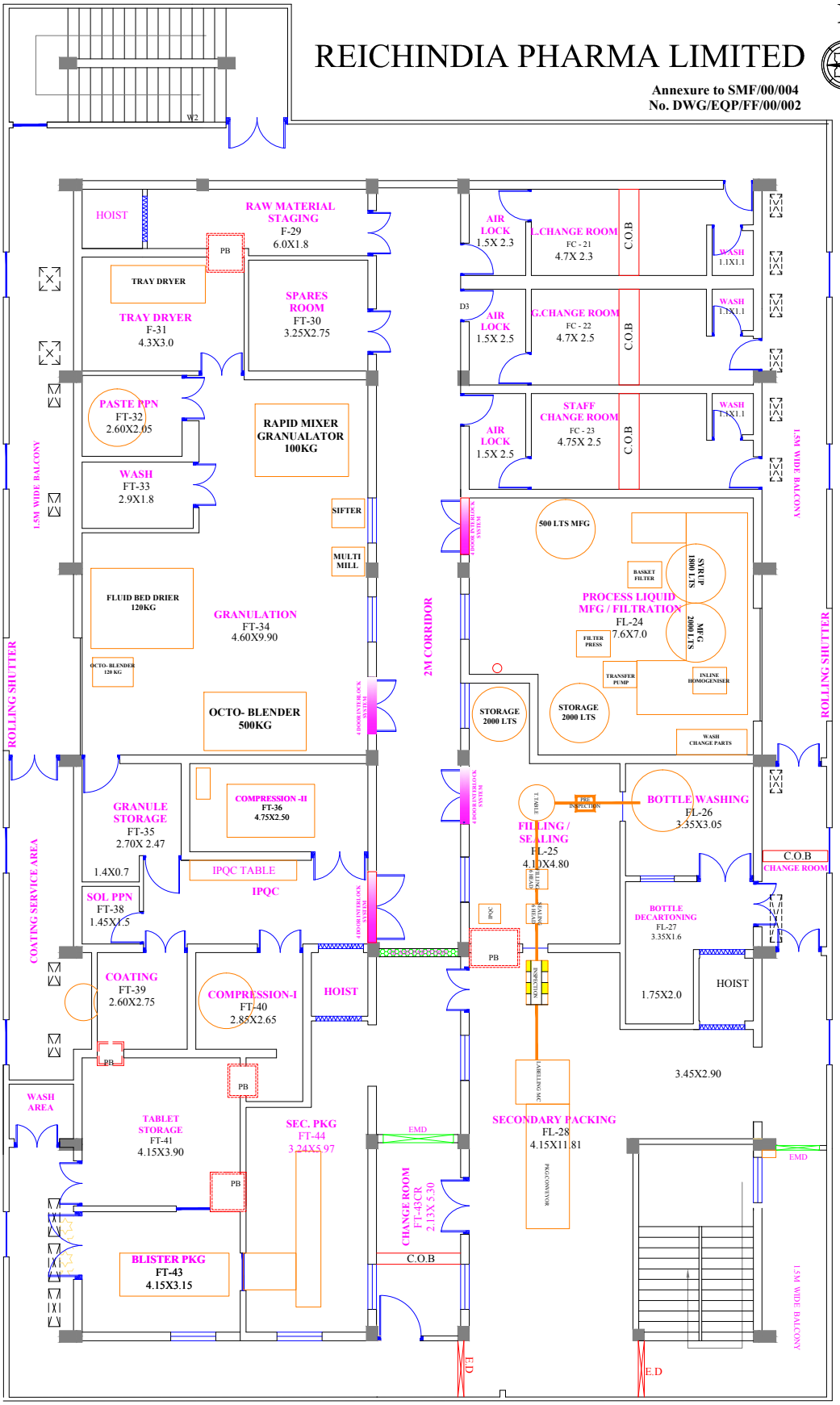


MEZZANINE FLOOR
MAJOR EQUIPMENT PLAN

Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
MEZZANINE FLOOR PLAN
Drawing No.: DWG/EQP/MZ/00/002
Title: MAJOR EQUIPMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/FF/00/002

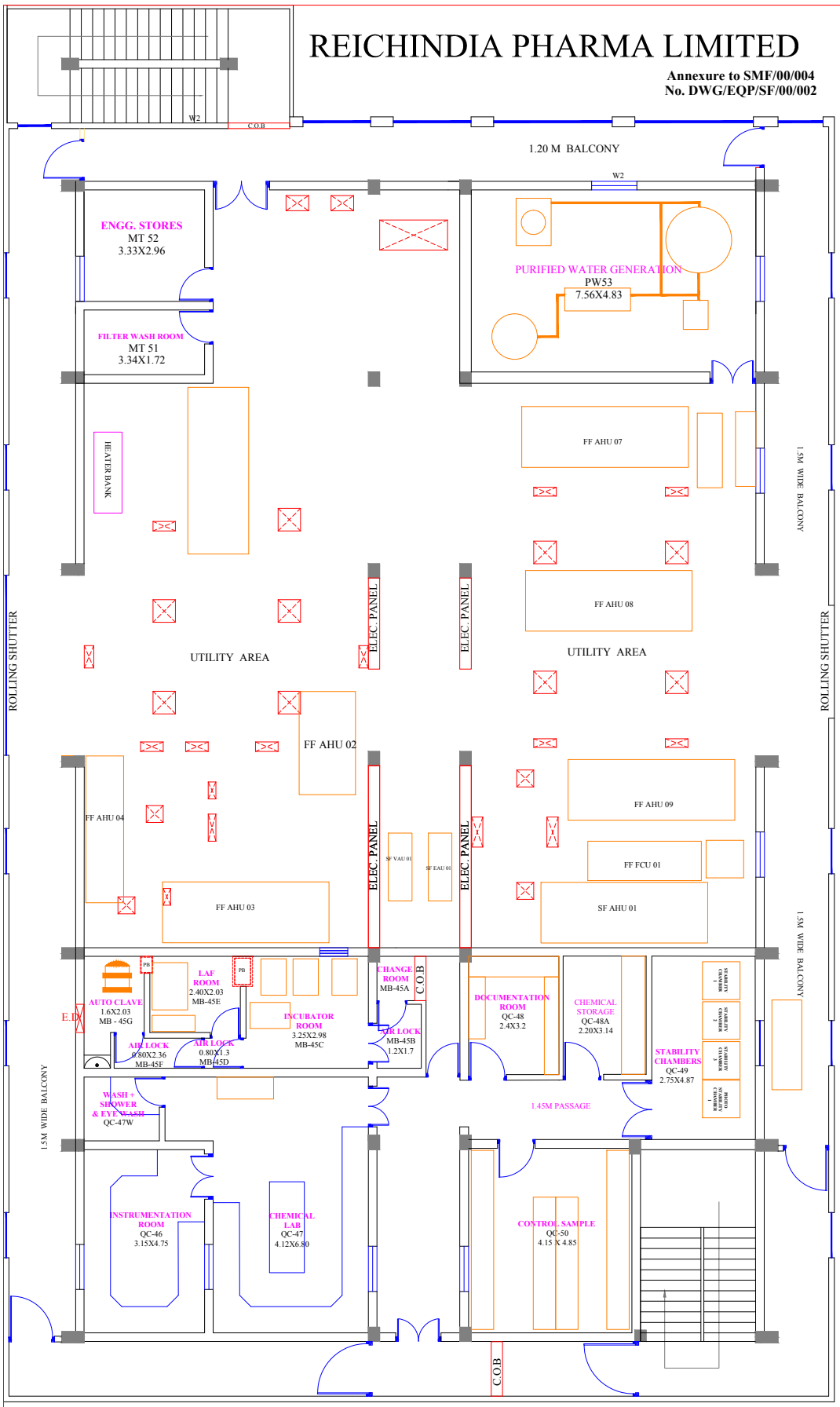


FIRST FLOOR
MAJOR EQUIPMENT PLAN

Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
FIRST FLOOR PLAN
Drawing No.: DWG/EQP/FF/00/002
Title: MAJOR EQUIPMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/SF/00/002



SECOND FLOOR
MAJOR EQUIPMENT PLAN

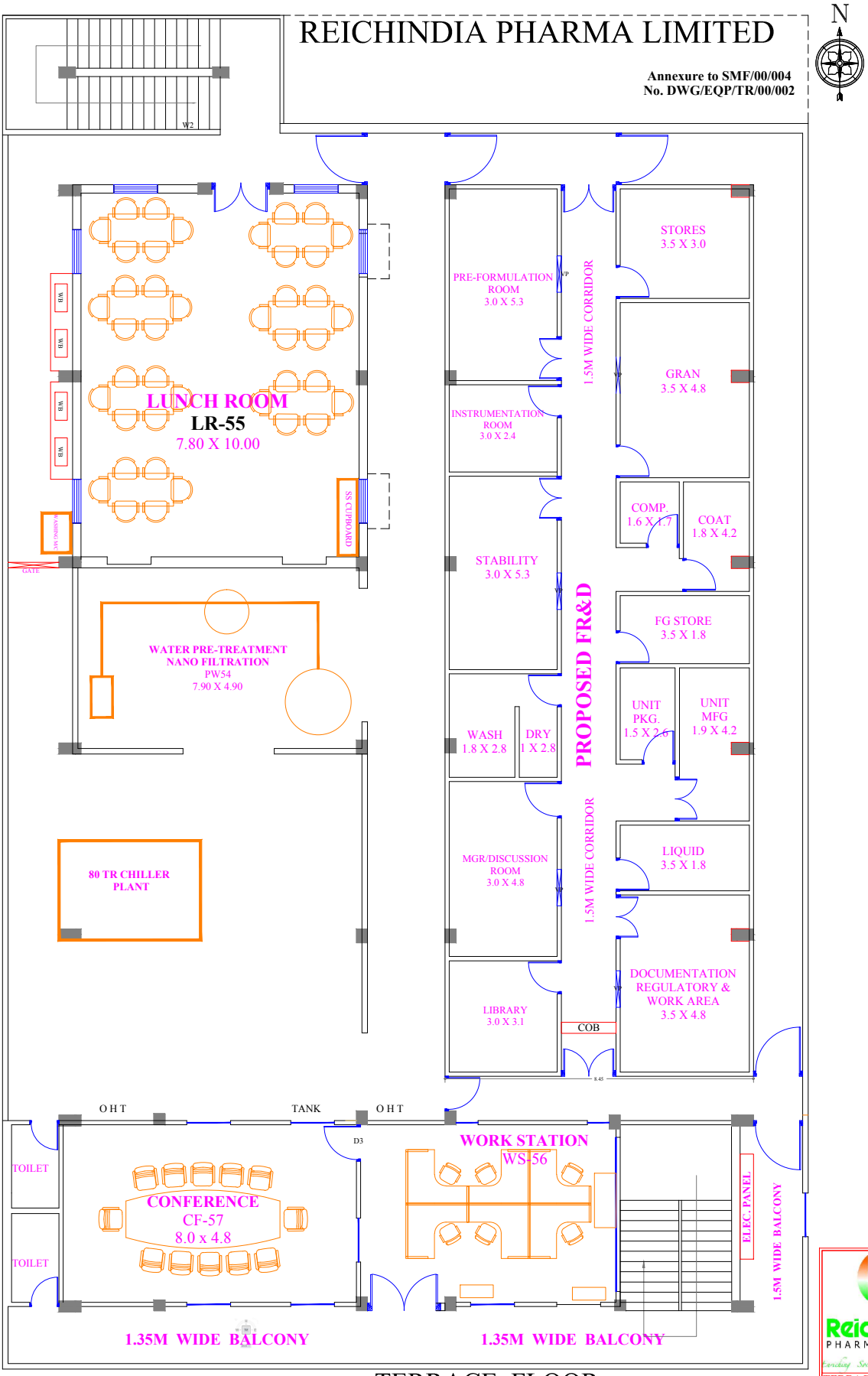
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

SECOND FLOOR PLAN

Drawing No.: **DWG/EQP/SF/00/002**
Title: **MAJOR EQUIPMENT PLAN**
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/EQP/TR/00/002

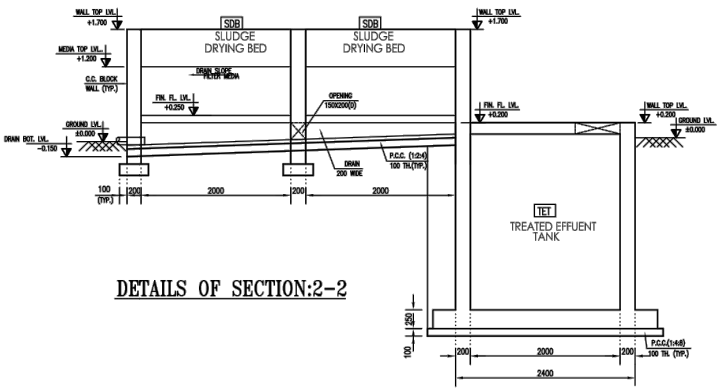


TERRACE FLOOR
MAJOR EQUIPMENT PLAN

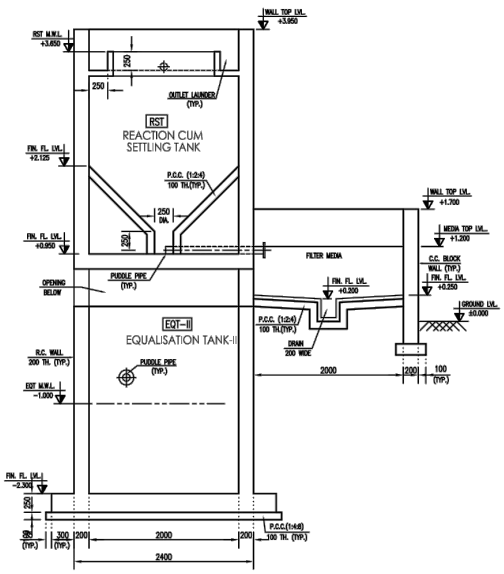
Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
TERRACE FLOOR PLAN
Drawing No.: DWG/EQP/TR/00/002
Title: MAJOR EQUIPMENT PLAN
Date: 20-07-2012 Checked Approved

ETP-Effluent Treatment Plant

Drawings



DETAILS OF SECTION:2-2



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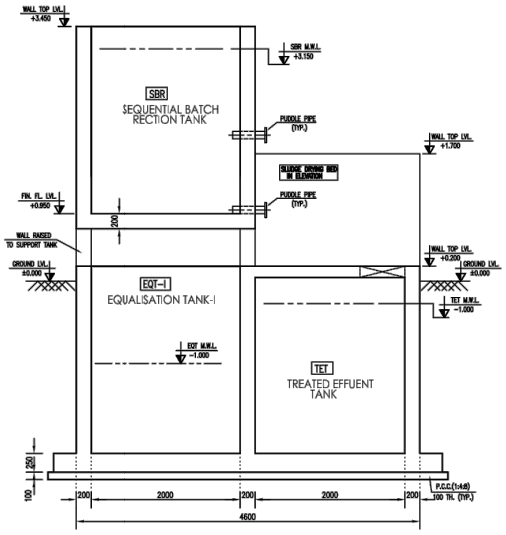

DETAILS OF SECTION:4-4

NOTES:

1. ALL DIMENSIONS ARE IN MILLIMETERS. AND LEVELS IN METERS.
2. DO NOT SCALE THE DRAWING, FOLLOW FIGURED DIMENSIONS ONLY.
3. FINISHED GROUND LEVEL IS TAKEN AS ±0000 FOR E.T.P.
4. THE SAFE BEARING CAPACITY OF SOIL IS TAKEN AS 150 kN/sq.m. FOR FOOTINGS BEARING CAPACITY OF SOIL IS TAKEN AS 150 kN/sq.m. AT A DEPTH OF 1500 FROM FINISHED GROUND LEVEL.
5. P.C.C. (1:3:6)/M7.5 SHALL BE PROVIDED FOR COLUMN FOOTING/ FLOOR BED BELOW TANK BOTTOM RAFT, EQUIPMENT FOUNDATION AS BED CONCRETE.
6. GRADE OF CONCRETE M25 DESIGN MIX FOR ALL LIQUID RETAINING STRUCTURES RAFTS, WALLS & LAUNDERS & OTHER STRL. MEMBERS.
7. REINFORCEMENT STEEL SHALL BE Fe 415 / HYSD BARS / TOR-40 CONFORMING TO IS 1786 FOR ALL STRUCTURES.
8. STRUCTURAL STEEL FOR HANDRAIL, INSERT PLATES ETC. SHALL BE M.S. CONFIRMING TO IS 2280.
10. ALL TANKS FLOOR SHALL BE PROVIDED 50 THK. I.P.S FLOORING.
11. ALL TANKS OUTSIDE SHALL BE PROVIDED WITH CEMENT PLASTING IN CM (1:4) WITH ROUGH FINISH.
12. SLUDGE DRYING BED WALL SHALL BE OF SOLID CEMENT BLOCK MASONRY IN CM (1:6).
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15. ALL TANKS EXCEPT SECONDARY SETTLING TANK FLOOR, SHALL BE LEVELLED AND SECONDARY SETTLING TANK FLOOR SHALL BE SLOPED AS SHOWN IN DRAWING.
16. ALL TANKS FLOORING SHALL BE OF 100 THK. IPS.
17. SLUDGE DRYING BED FLOORING SHALL BE 100 THK. IPS OVER 100 TH. P.C.C. BED.
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21. ALL TANKS SHALL BE HYDRO TESTED BEFORE BACK FILLING/ERECTION OF EQUIPMENT
22. IN CASE ANY DISCREPANCY IN THIS DRAWING NO CONSTRUCTION SHALL BE CARRIED OUT TILL WRITTEN CLARIFICATION IS OBTAINED.

THESE NOTES TO BE READ WITH ALL OTHER DRAWINGS.

LIST OF CIVIL UNITS

MARK	DESCRIPTION	QTY	CAPACITY/SIZE	MOC
BSC-1&2	BARSCREEN CHAMBER-1 & 2	01	1200X1200X1000 TD.	B.M.
EQT-1&2	EQUALISATION TANK-1 & 2	01	2000X2000X2500 TD	R.C.C.
RCT	REACTION CUM SETTLING TANK	01	2000.X2000X2500 TD	R.C.C.
SBR	SEQUENTIAL BATCH REACTION TANK	01	2000X2000x3000 TD	R.C.C.
TET	TREATED EFFLUENT TANK	01	2000.X2000X2500 TD	R.C.C.
SDB	SLUDGE DRYING BED	02	1500X1500X1700 TD	B.M.

LIST OF ELECTRO-MECHANICAL EQUIPMENTS

MARK	DESCRIPTION	QTY	CAPACITY/SIZE	QTY
RSP	RAW SEWAGE PUMP[SUBMERSIBLE]	02		C.I.
REP	RAW EFFLUENT PUMP[SUBMERSIBLE]	02		C.I.
TAB	AIR BLOWER	02		C.I.
FFP	FILER FEED PUMP	02		C.I.
DMF	DUAL MEDIA FILTER	01		M.S.E.P.
GP	GARDEN PUMP	02		C.I.

N O T E S .

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REV.No	DATE	DESCRIPTION	BY	VERIFIED
4				
3				
2				
1				

REVISION

ETP / STP PLAN

Drawing No.: **DWG/UT/ETP/00/002**

Title: **ETP STP PLAN PLAN**

Date: 20-07-2012 Checked Approved

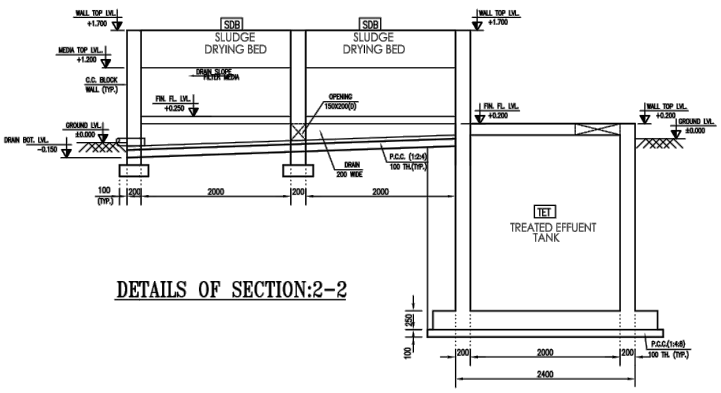
Reichindia® PHARMA LIMITED

Enriching Society Through Healthcare

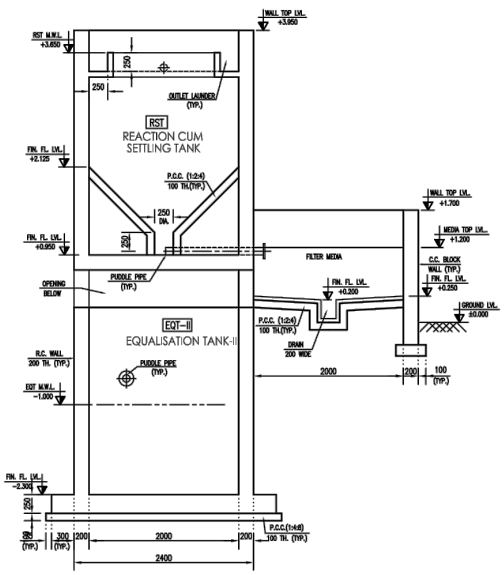
Revision No. : 03
Doc No. : SMF/004
Page No. : 75 of 110

Effective Date : 17/01/2017
Next Review Date : 16/01/2019

Reichindia® PHARMA LIMITED



DETAILS OF SECTION:2-2



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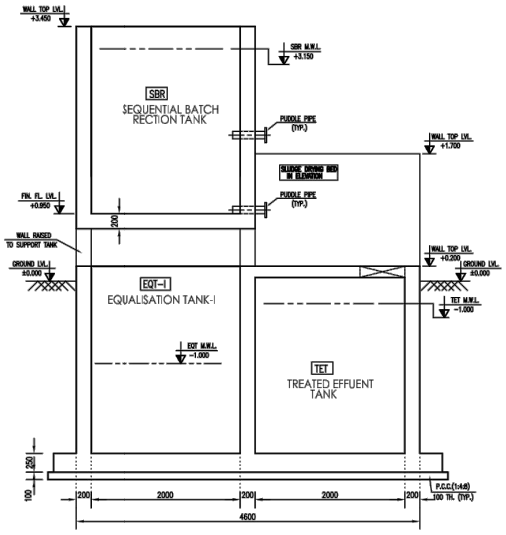

DETAILS OF SECTION:4-4

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FFP	FILER FEED PUMP	02		C.I.
DMF	DUAL MEDIA FILTER	01		M.S.E.P.
GP	GARDEN PUMP	02		C.I.

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REV.No	DATE	DESCRIPTION	BY	VERIFIED
4				
3				
2				
1				

REVISION

ETP / STP PLAN

Drawing No.: **DWG/UT/ETP/00/002**

Title: **ETP / STP PLAN PLAN**

Date: 20-07-2012 Checked Approved

Reichindia® PHARMA LIMITED

Enriching Society Through Healthcare

Revision No. : 03
Doc No. : SMF/004
Page No. : 76 of 110

Effective Date : 17/01/2017
Next Review Date : 16/01/2019

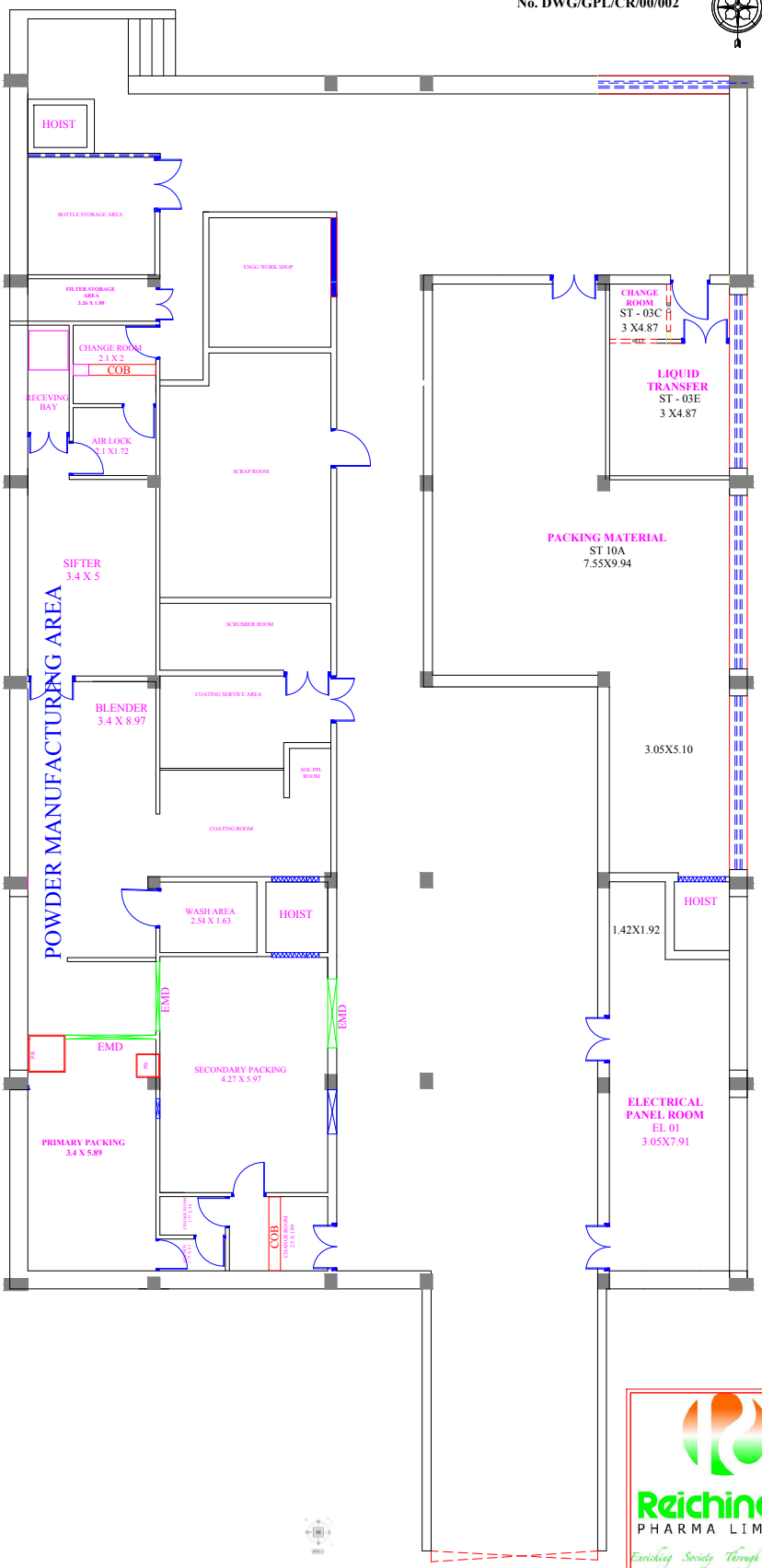
Reichindia® PHARMA LIMITED

General Floor Plan

Drawings

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/CR/00/002



BASEMENT FLOOR GENERALPLAN

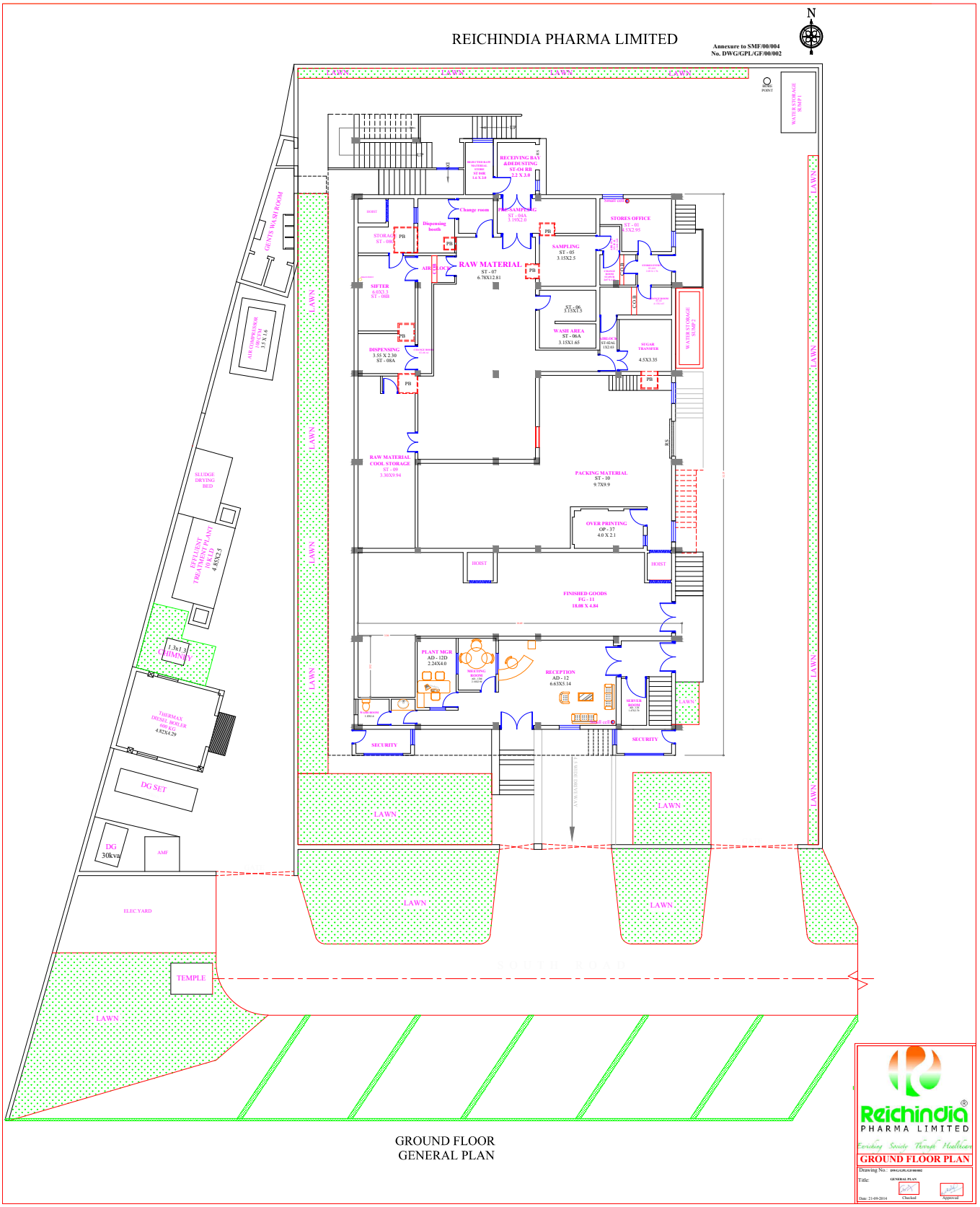
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

BASEMENT FLOOR PLAN

Drawing No.: DWG/GPL/CR/00/002
Title: GENERAL PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/GF/00/002

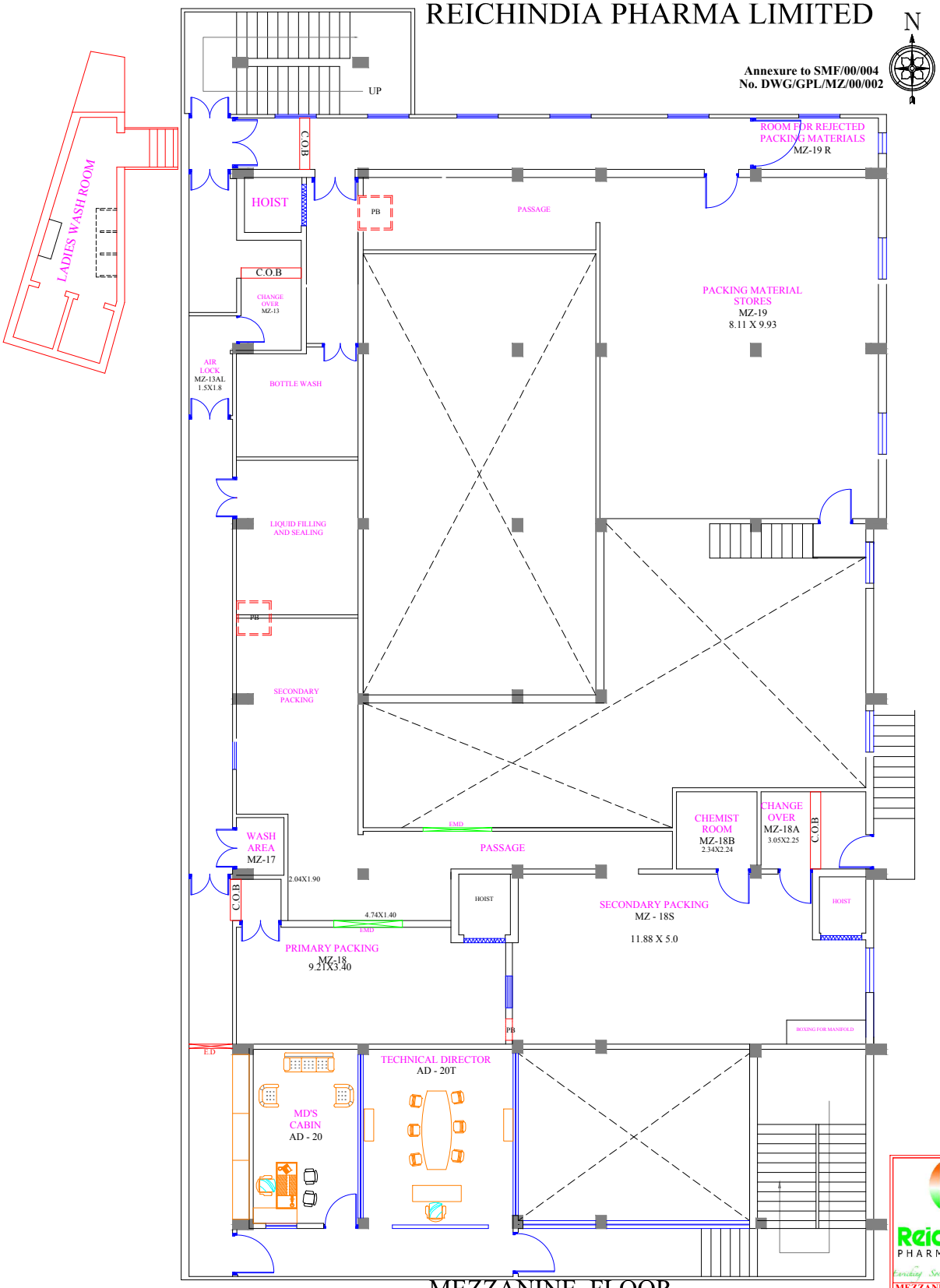


GROUND FLOOR
GENERAL PLAN

Reichindia PHARMA LIMITED
Enriching Stride Through Healthcare
GROUND FLOOR PLAN
Drawing No.: DWG/GPL/GF/00/002
Title: GENERAL PLAN
Date: 21-09-2014 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/MZ/00/002

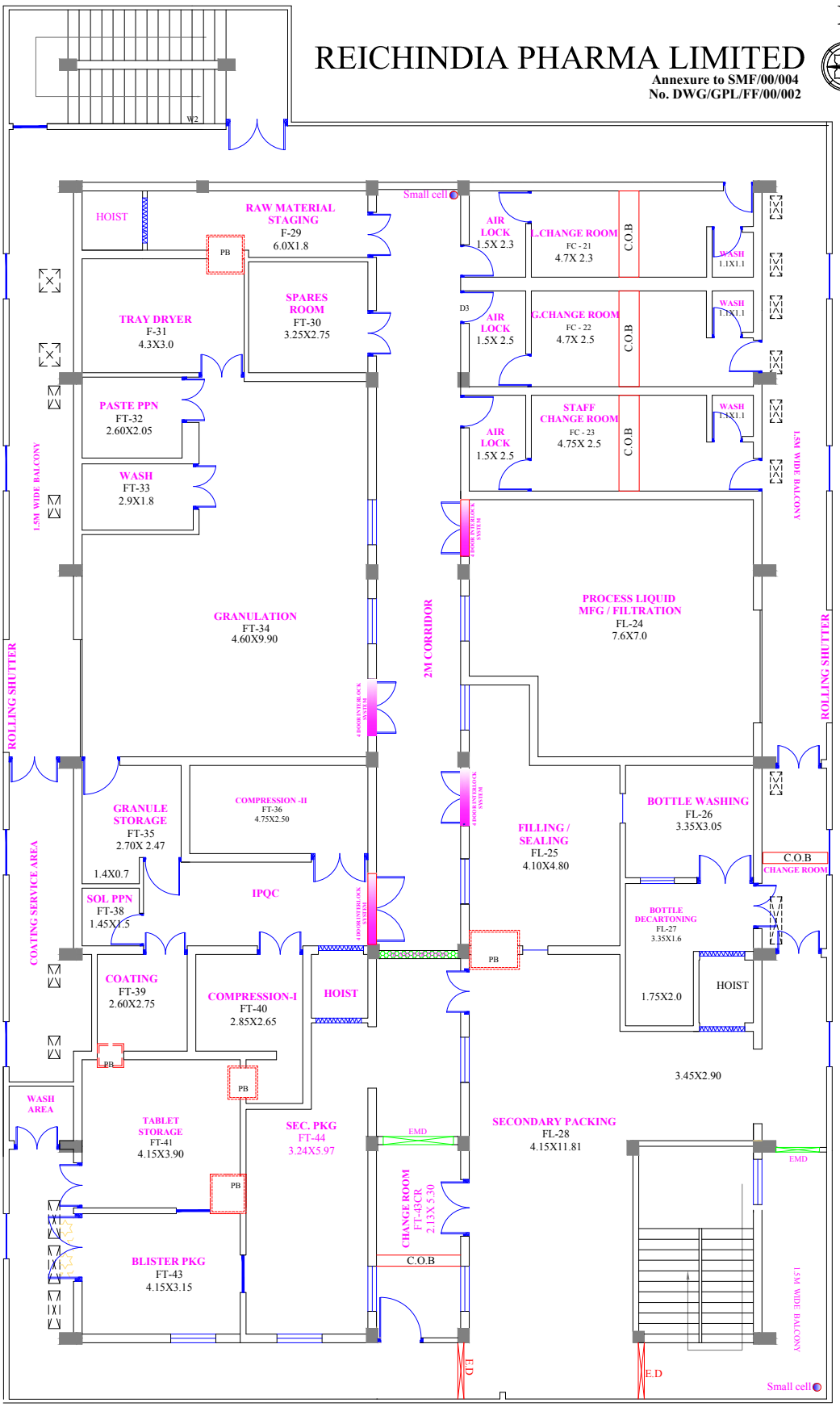


MEZZANINE FLOOR
GENERAL PLAN

Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
MEZZANINE FLOOR PLAN
Drawing No.: DWG/GPL/MZ/00/002
Title: GENERAL PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/FF/00/002

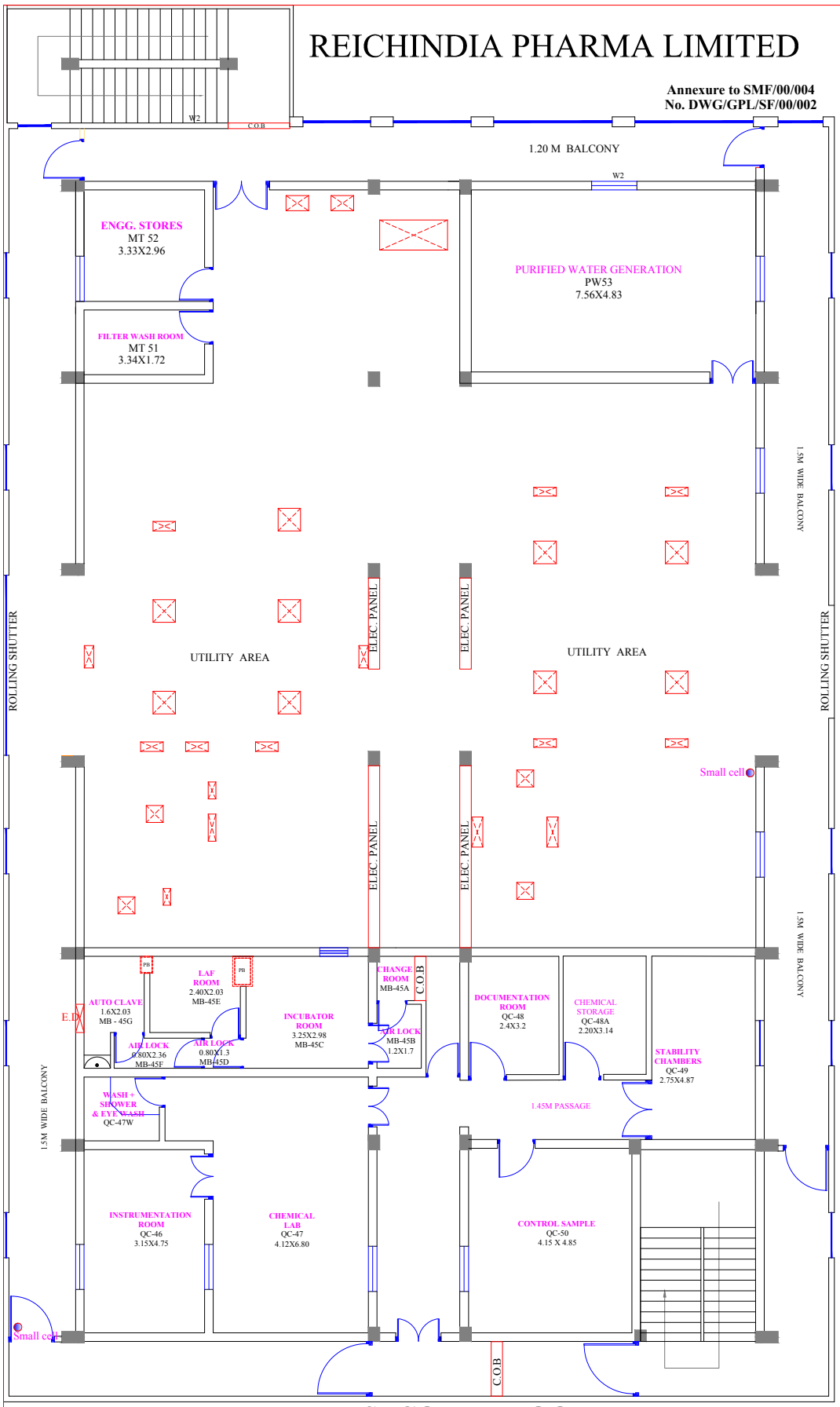


FIRST FLOOR GENERAL PLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare
FIRST FLOOR PLAN
Drawing No.: DWG/GPL/FF/00/002
Title: GENERAL PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/SF/00/002



SECOND FLOOR GENERAL PLAN

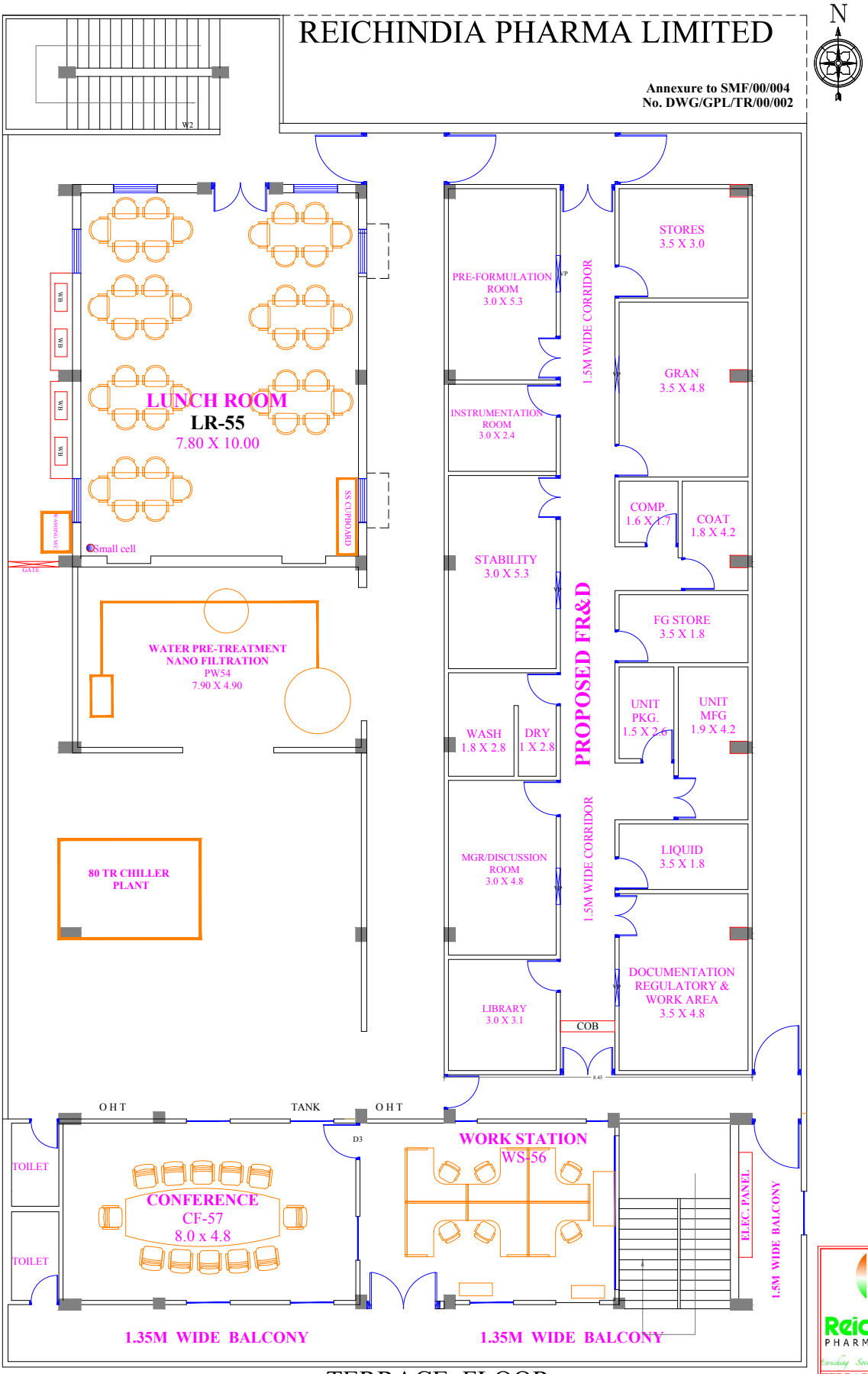
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

SECOND FLOOR PLAN

Drawing No.: DWG/GPL/SF/00/002
Title: GENERAL PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/GPL/TR/00/002



TERRACE FLOOR
GENERAL PLAN

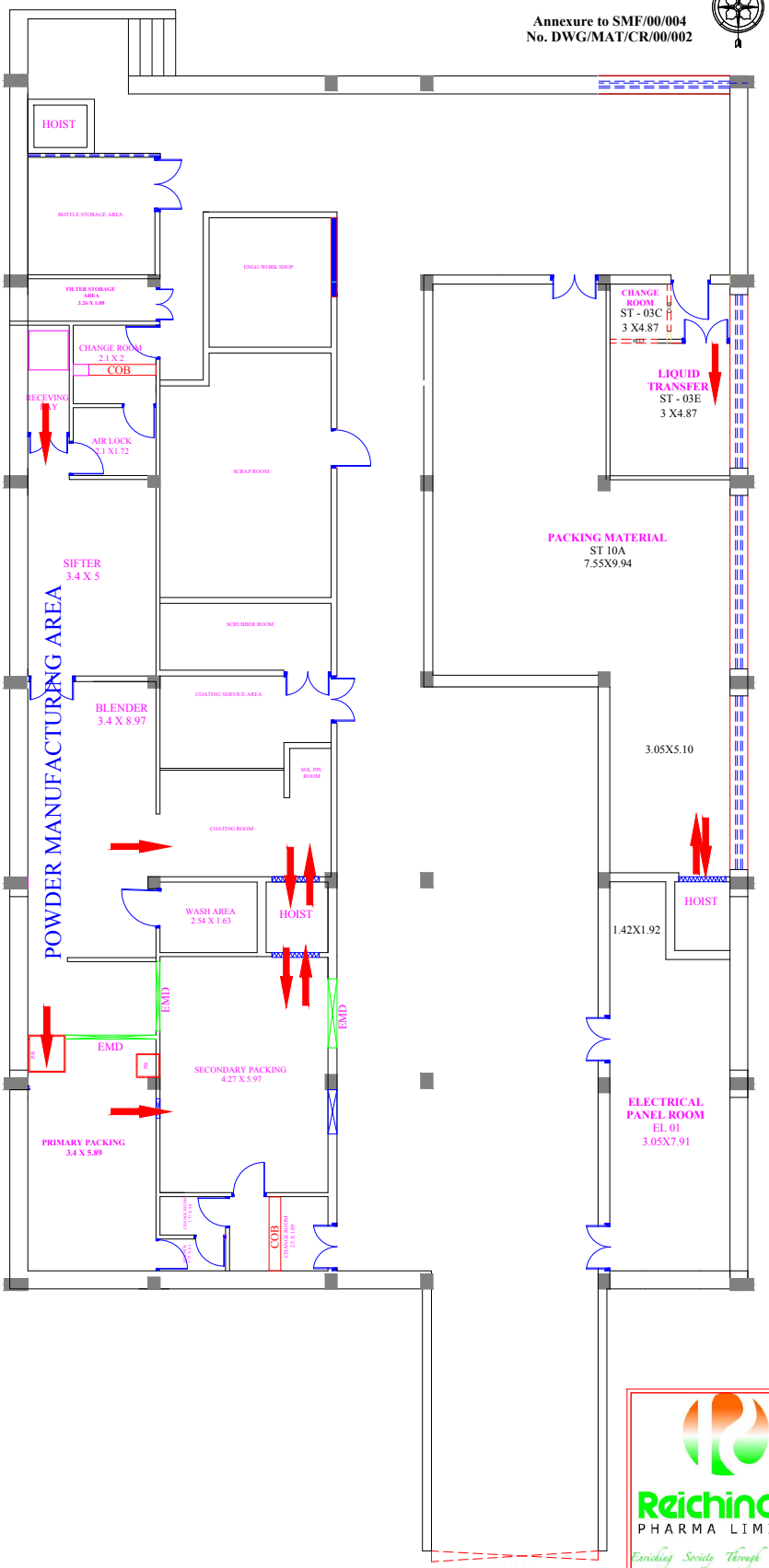
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare
TERRACE FLOOR PLAN
Drawing No.: DWG/GPL/TR/00/002
Title: GENERAL PLAN
Date: 20-07-2012 Checked Approved

Material Movement

Drawings

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MAT/CR/00/002



BASEMENT FLOOR MATERIAL MOVEMENT PLAN

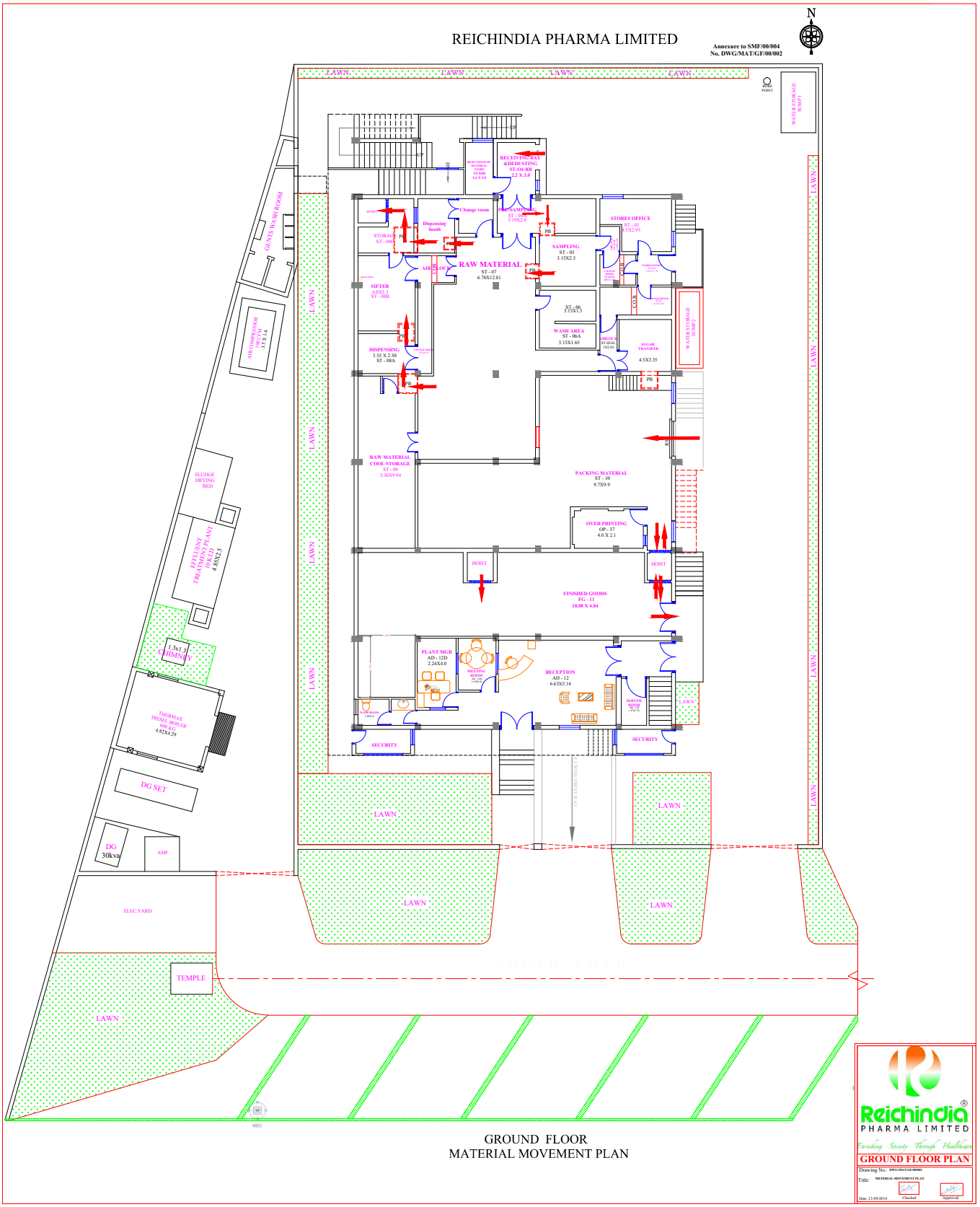
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

BASEMENT FLOOR PLAN

Drawing No.: DWG/MAT/CR/00/002
Title: METERIAL MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MAT/GF/00/002

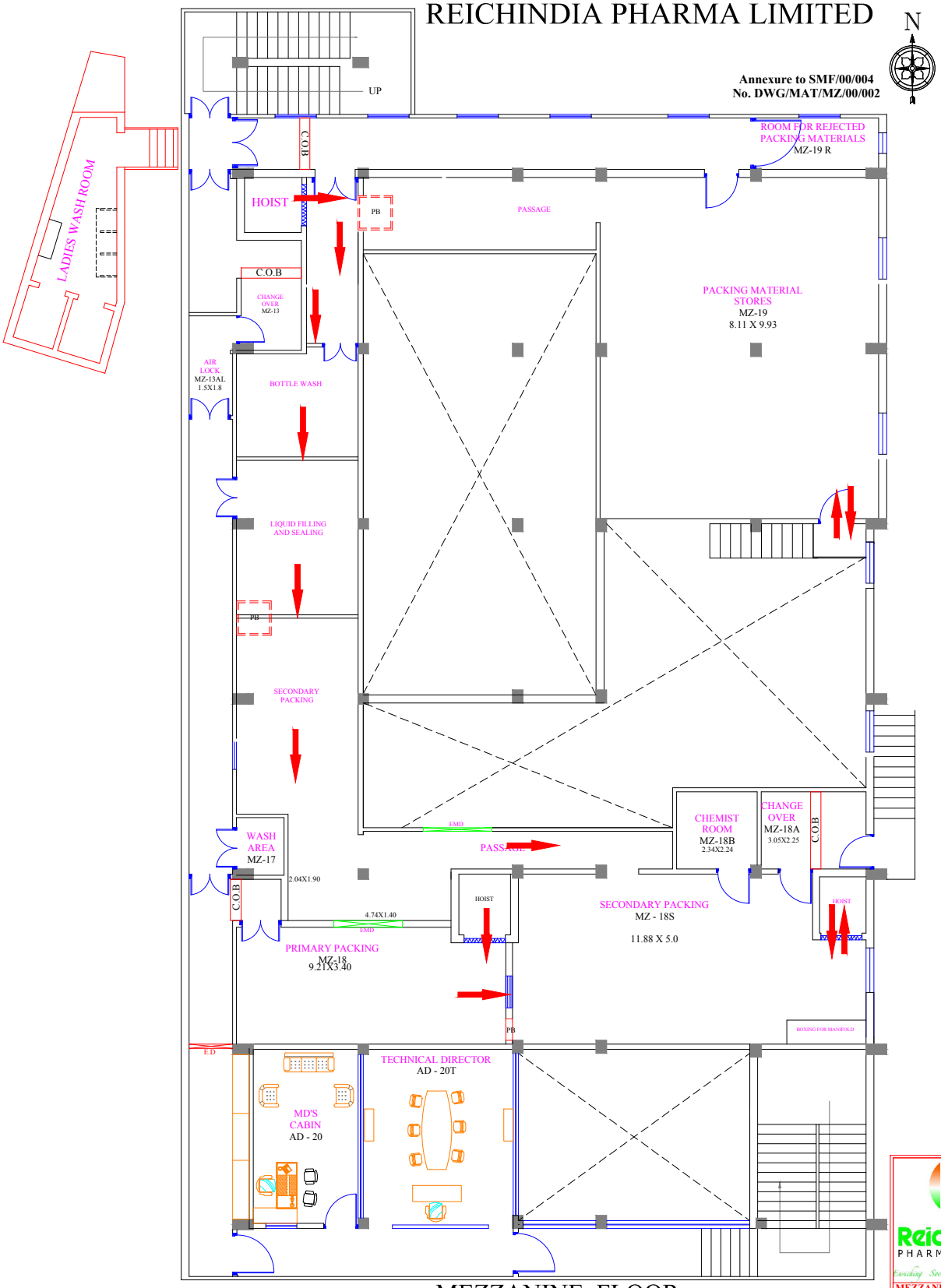


GROUND FLOOR
MATERIAL MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Stride Through Healthcare
GROUND FLOOR PLAN
Drawing No.: DWG/MAT/GF/00/002
Title: MATERIAL MOVEMENT PLAN
Date: 21-09-2014 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MAT/MZ/00/002

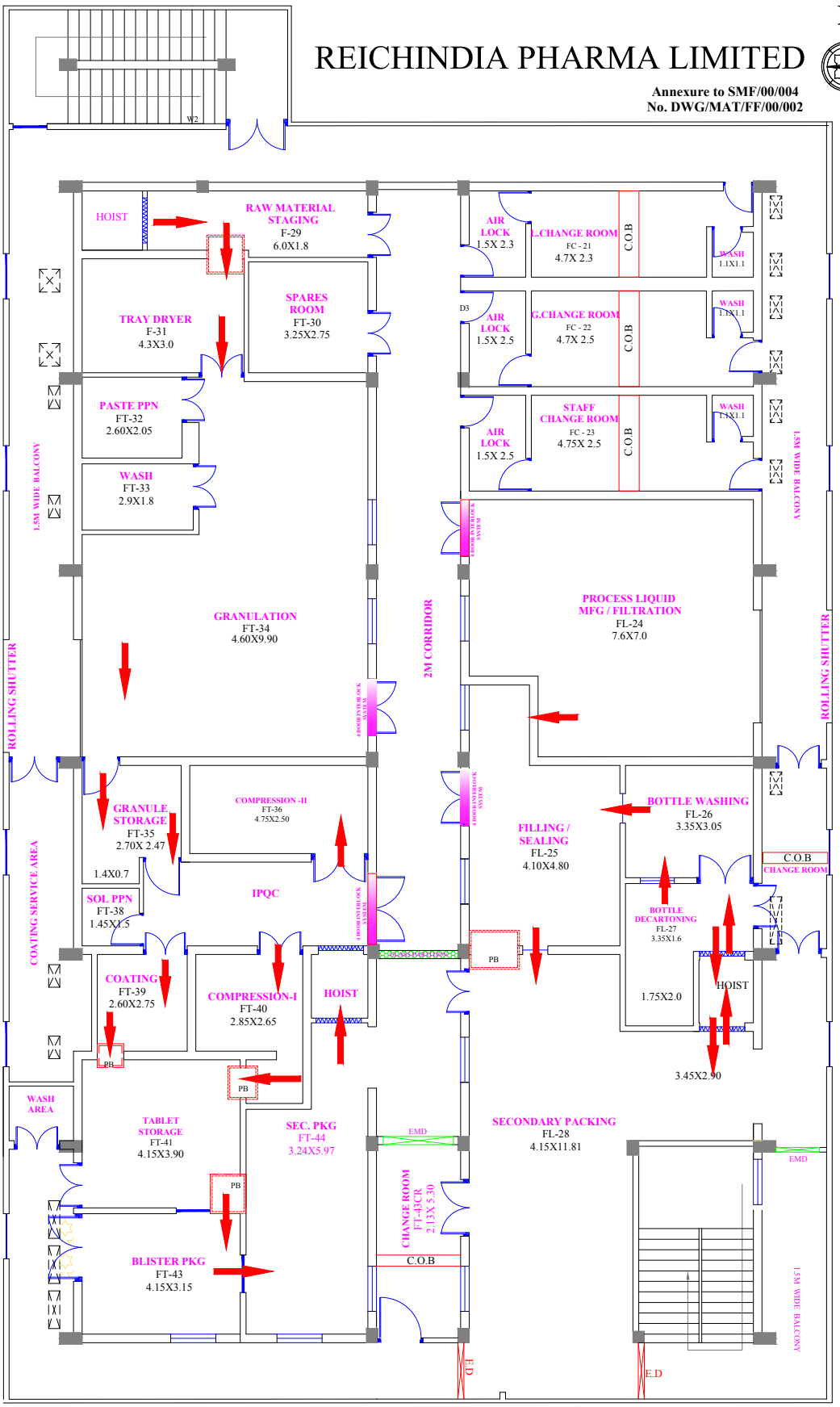


MEZZANINE FLOOR
MATERIAL MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Secrets Through Healthcare
MEZZANINE FLOOR PLAN
Drawing No: DWG/MAT/MZ/00/002
Title: METERIAL MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MAT/FF/00/002



FIRST FLOOR
MATERIAL MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
FIRST FLOOR PLAN
Drawing No.: DWG/MAT/FF/00/002
Title: METERIAL MOVEMENT PLAN
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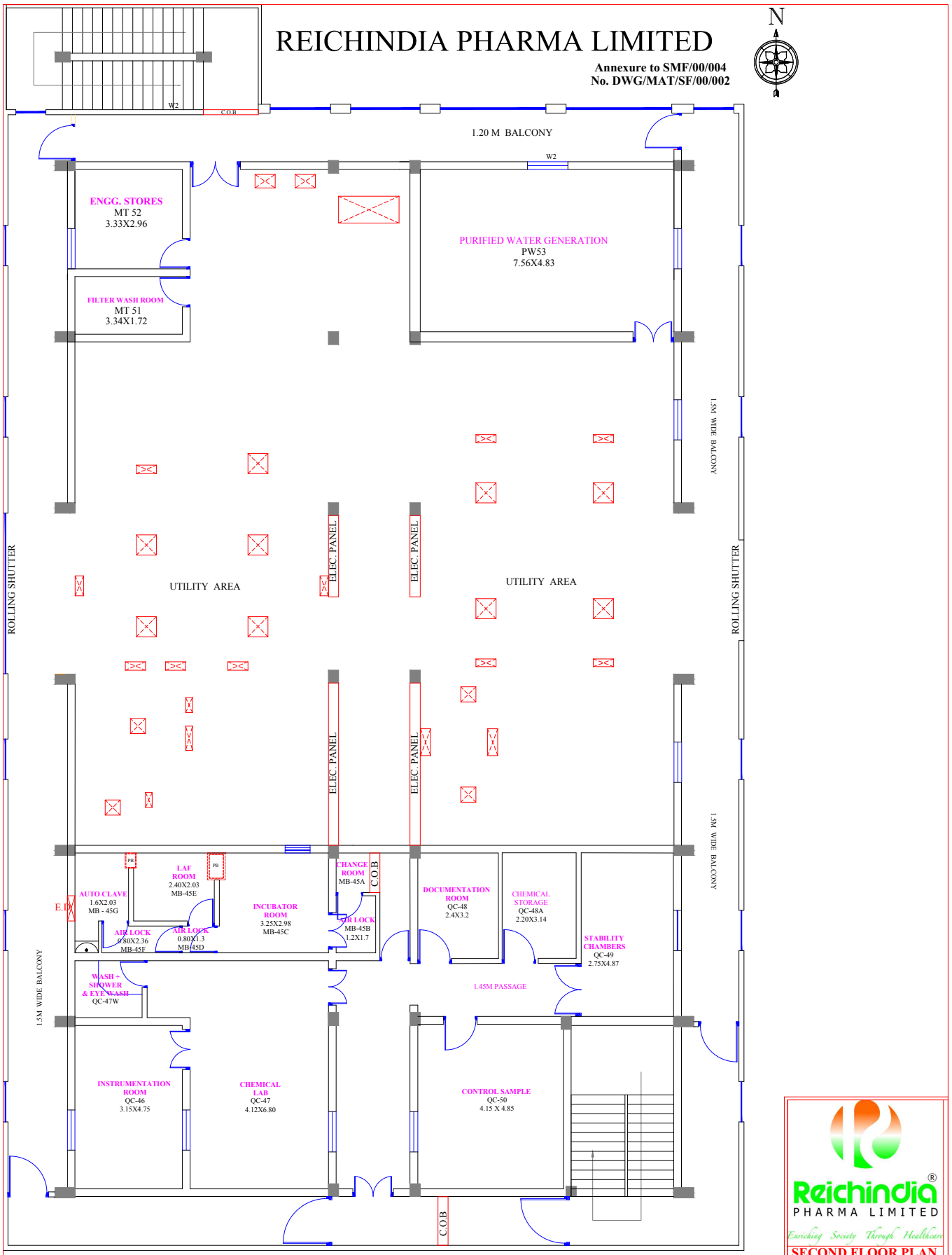
Annexure to SMF/00/004
No. DWG/MAT/SF/00/002



SECOND FLOOR
MATERIAL MOVEMENT PLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

SECOND FLOOR PLAN

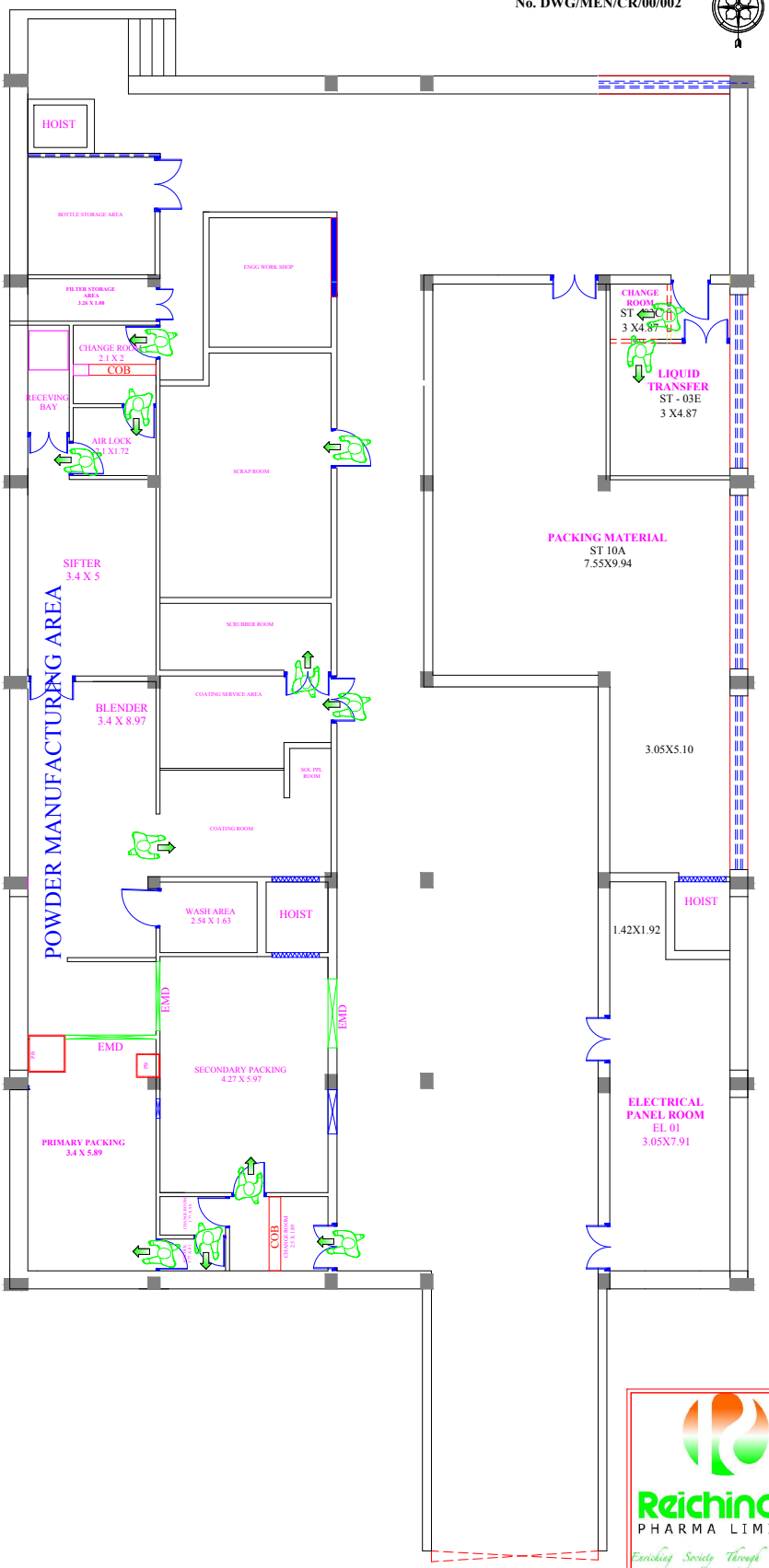
Drawing No.: **DWG/MAT/SF/00/002**
Title: **METERIAL MOVEMENT PLAN**
Date: 20-07-2012 Checked Approved

Men Movement

Drawings

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/CR/00/002



BASEMENT FLOOR
MEN MOVEMENT PLAN

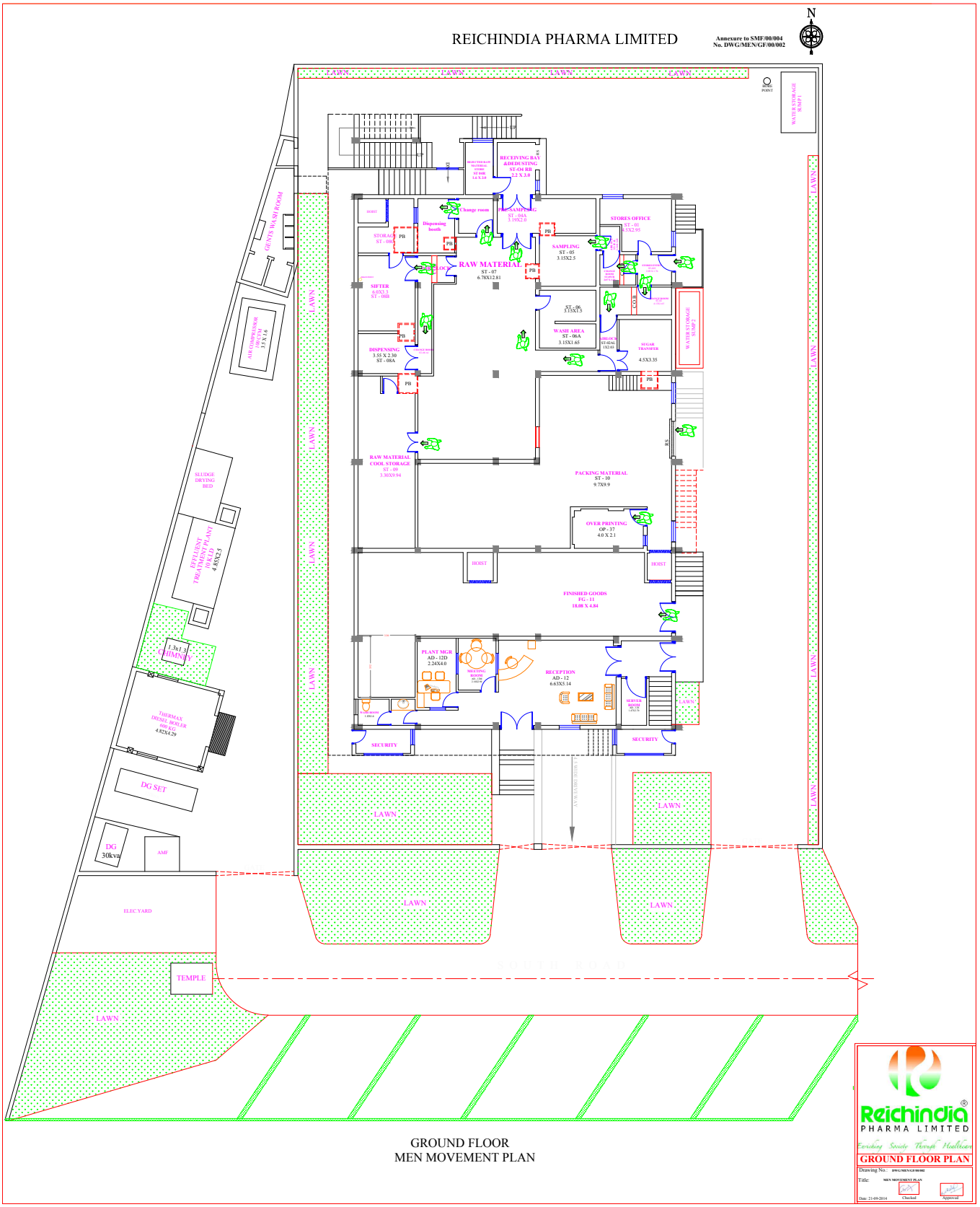
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

BASEMENT FLOOR PLAN

Drawing No.: DWG/MEN/CR/00/002
Title: MEN MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/GF/00/002

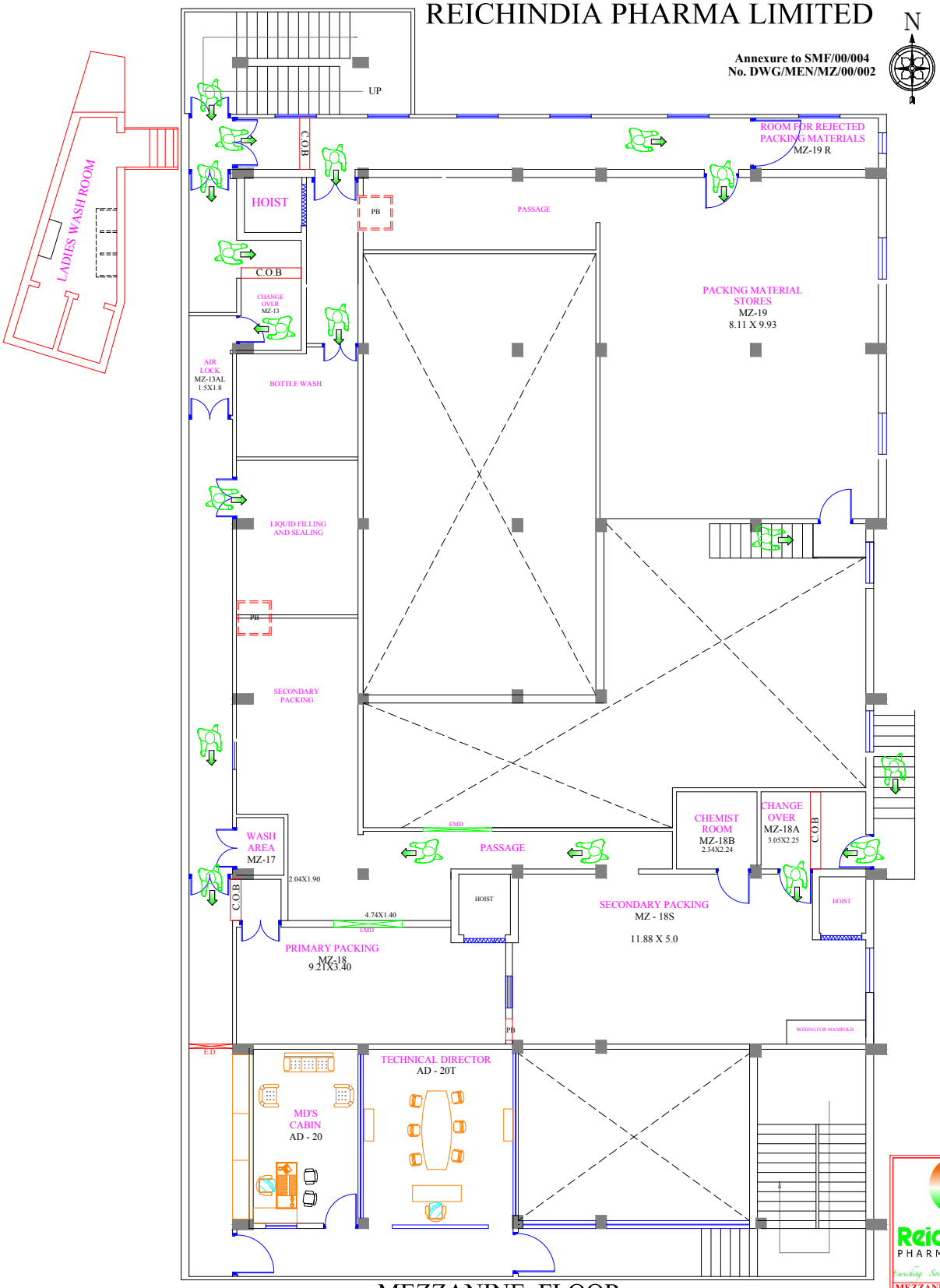


GROUND FLOOR
MEN MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Stride Through Healthcare
GROUND FLOOR PLAN
Drawing No.: DWG/MEN/GF/00/002
Title: MEN MOVEMENT PLAN
Date: 21-09-2014 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/MZ/00/002

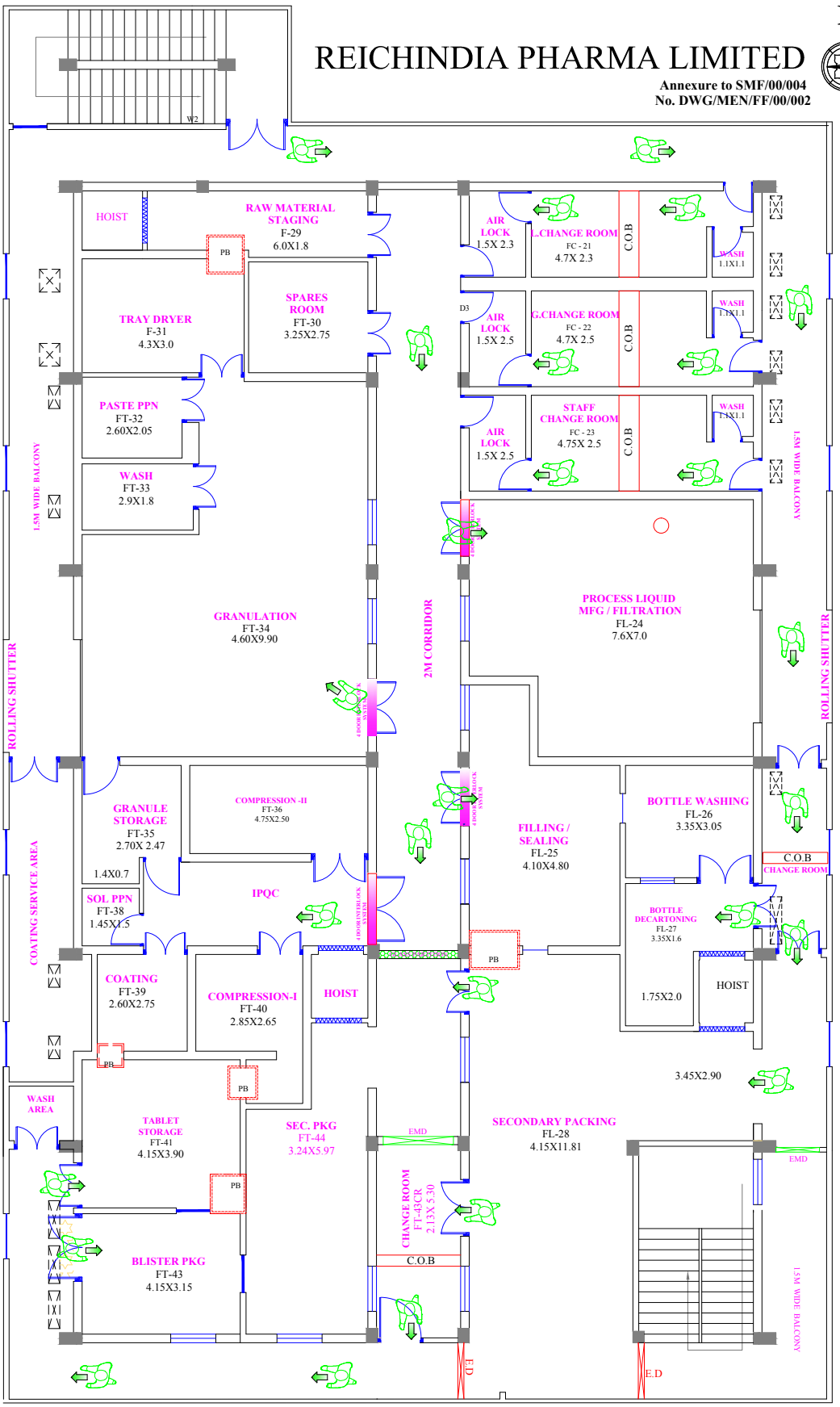


MEZZANINE FLOOR
MEN MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Secrets Through Healthcare
MEZZANINE FLOOR PLAN
Drawing No.:
Title: DWG/MEN/MZ/00/002 MEN MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/FF/00/002

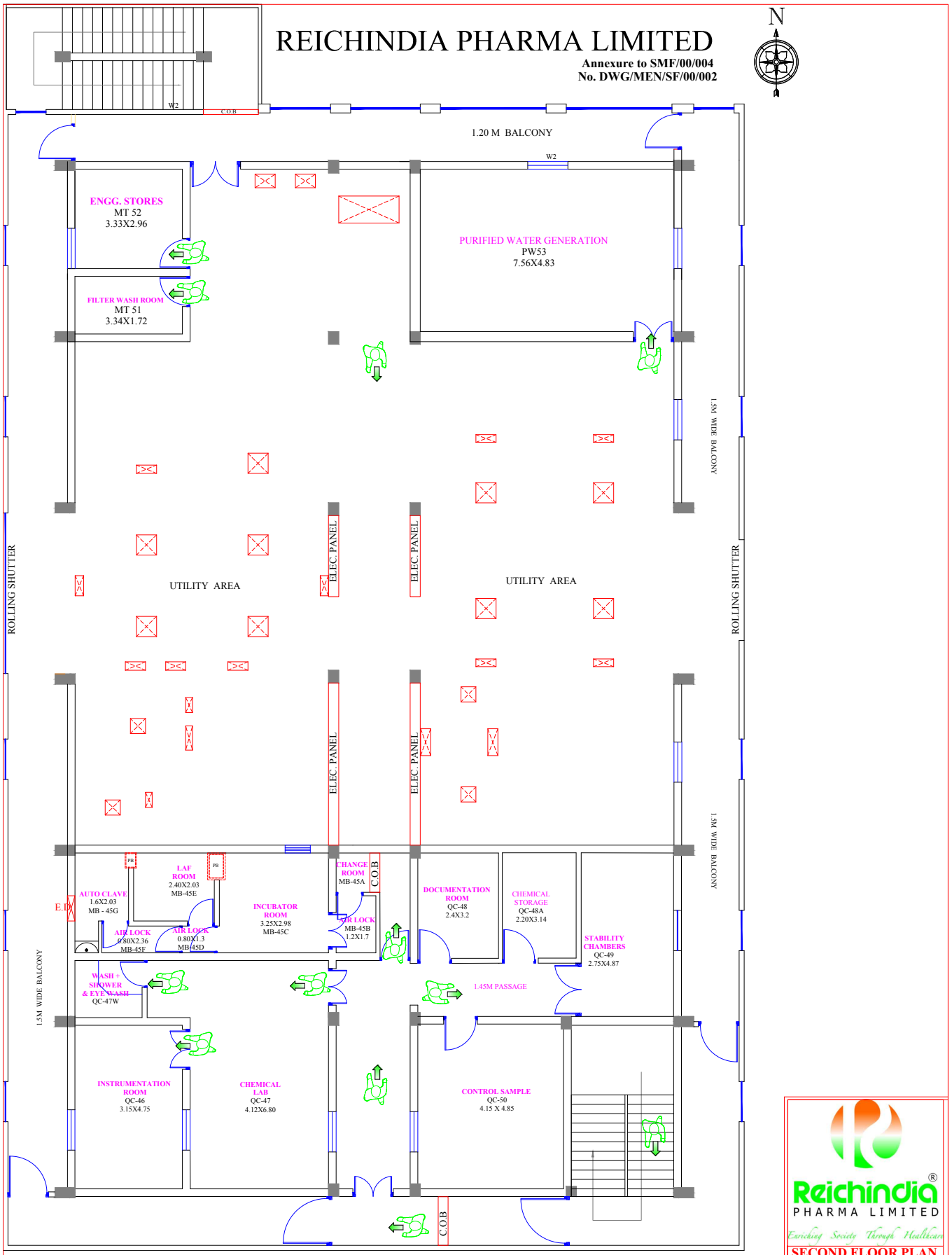


FIRST FLOOR
MEN MOVEMENT PLAN

Reichindia PHARMA LIMITED
Enriching Society Through Healthcare
FIRST FLOOR PLAN
Drawing No.: DWG/MEN/FF/00/002
Title: MEN MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/SF/00/002



SECOND FLOOR
MEN MOVEMENT PLAN

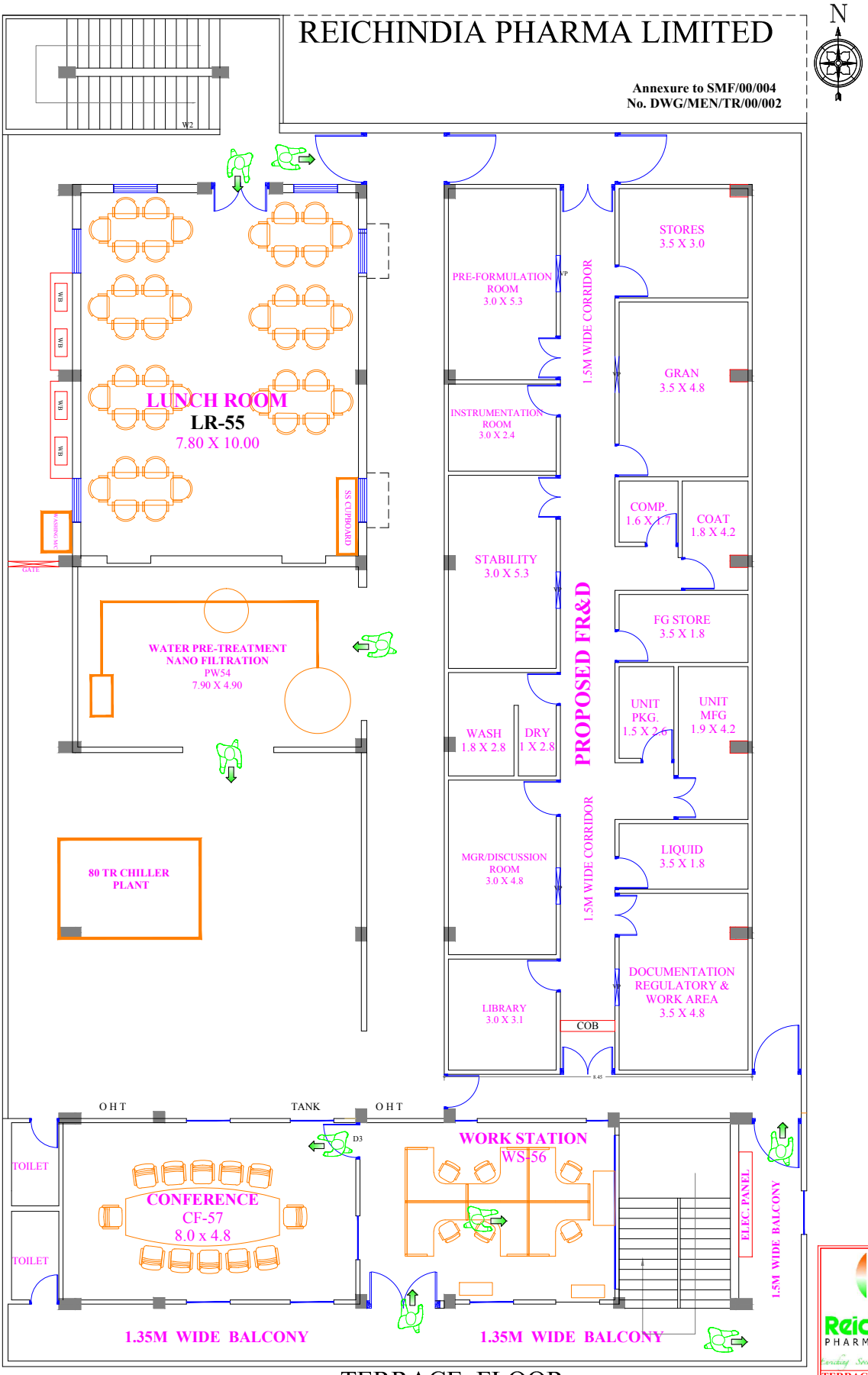
Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare

SECOND FLOOR PLAN

Drawing No.: DWG/MEN/SF/00/002
Title: MEN MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

REICHINDIA PHARMA LIMITED

Annexure to SMF/00/004
No. DWG/MEN/TR/00/002

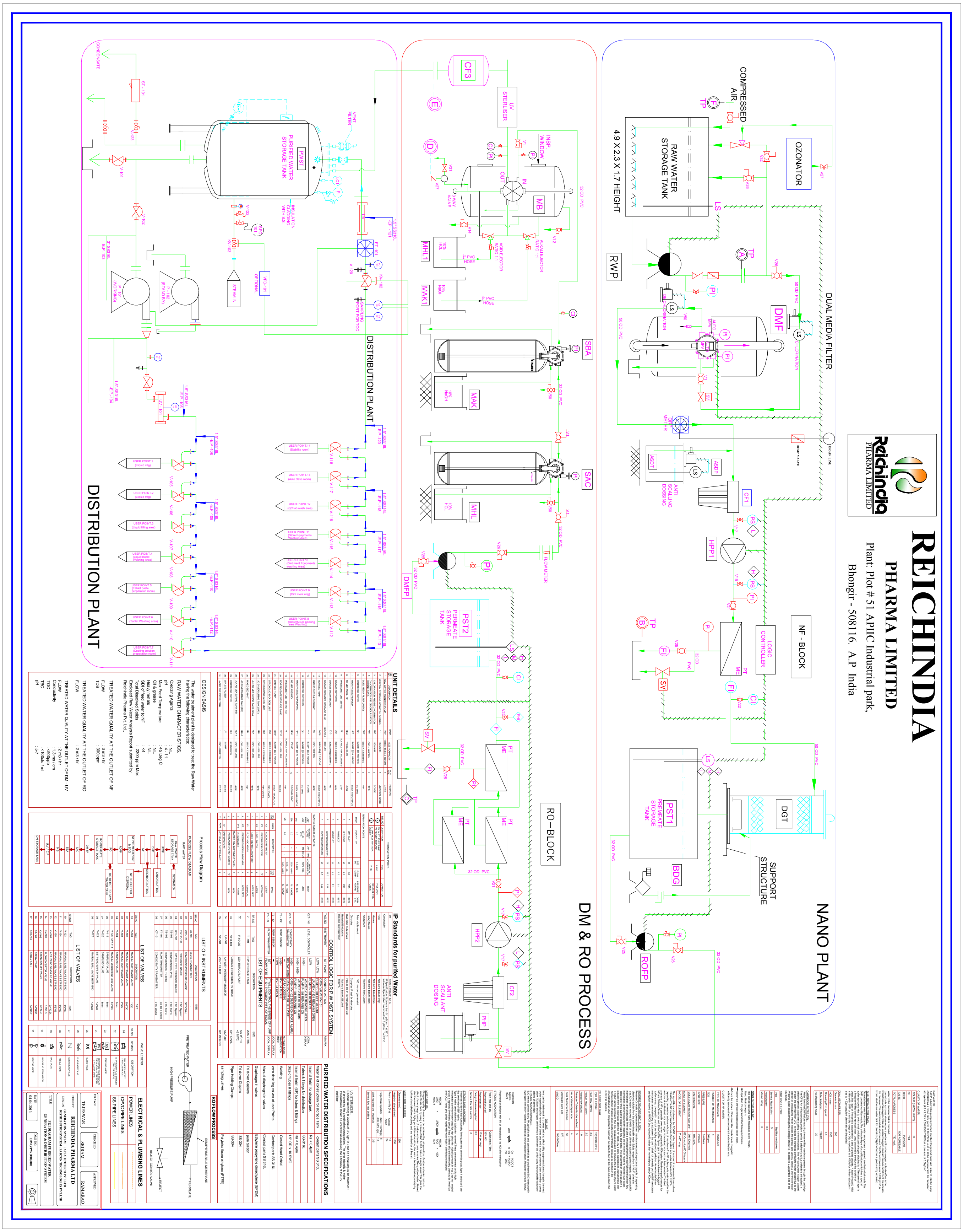


TERRACE FLOOR
MEN MOVEMENT PLAN

Reichindia® PHARMA LIMITED
Enriching Society Through Healthcare
TERRACE FLOOR PLAN
Drawing No.: DWG/MEN/TR/00/001
Title: MEN MOVEMENT PLAN
Date: 20-07-2012 Checked Approved

Purified Water System

Drawings


REICHINDIA
PHARMA LIMITED
Plant: Plot # 51 APIIC Industrial park,
Bhongir - 508116. A.P India
NANO PLANT
DM & RO PROCESS
DISTRIBUTION PLANT
DUAL MEDIA FILTER
OZONATOR
RAW WATER STORAGE TANK
NF - BLOCK
RO - BLOCK
UNIT DETAILS
DESIGN BASIS
LIST OF INSTRUMENTS
LIST OF VALVES
LIST OF EQUIPMENTS
ELECTRICAL & PLUMBING LINES
PURIFIED WATER DISTRIBUTION SPECIFICATIONS

Qualifications & Experience of Key Personnel

REICHINDIA PHARMA LIMITED

Hyderabad

SITE MASTER FILE

Document No	**: SMF/004**
Revision No.	**: 03**
Effective Date	**: 17/01/2017**
Dated	**: 16/01/2019**

ANNEXURES

Plot No.51, TSIIC Industrial Park,

Hyderabad-Warangal Highway, Bhongir –508 116

Phone: 09866911449

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*Annexure to*SMF/003 No.002

QUALIFICATIONS & EXPERIENCE OF KEY PERSONNEL.

Production :

S. No.	Name	Qualification	Dept	Designation	Total Exp.
1.	Mr. N.Siva Reddy	B.Pharm.	Production	Plant Manager	22 Years
2.	Mr. V.Narasimha	B. Sc, DPPM	Production	Manager -Production	28 Years
3.	Mr.R.Kishore Reddy	B. Sc.,	Production	Asst. Manager-Production	14 Years
4.	Mr. K.Nagaraju Reddy	M.Pharm,	Production	Executive- Production	3 Years
5.	Mr.N.Mahender Reddy	M.Pharm,	Production	Executive- Production	3 Years
6.	Mr.Vijayasimha M.T.	B.Com,	Stores	Asst. Manager Stores	22 Years

Quality Operations:

1.	Mr. K.V.Rama Rao	M. Sc. (Organic Chemistry)	Quality Control & Assurance	Manager-Quality Operations	22 Years
2.	Mr.P.Saimon	M.Sc Microbiology	Quality Control	Asst.Manager-Quality Control	14 Years
3.	Ms.G.Deepthi	M.Sc Microbiology	Quality Control	Sr.Executive Quality Control	6 Years
4.	Ms.B.Sushmitha	Graduate-Biotech	Quality Assurance	Sr.Executive Quality Assurance	3 Years

Engineering Services :

S.No	Name	Qualification	Dept	Designation	Total Exp.
1.	Mr. B.TejeswaraRao	Diploma In Air Conditioning	Engineering.	Manager-Engineering Services	13 Years
2.	Mr.Ch.Sateesh Kumar	Diploma In Electrical	Engineering.	Executive-Electrical	09 Years
3.	Mr.Ramanna	Diploma In EEE	Engineering.	Executive-Electrical	6 Years

Administration:

S.No	Name	Qualification	Dept	Designation	Total Exp.
1.	Mr. A.Kiran Kumar	M.B.A	Admin	Manager-Admin	22 Years
2	Mr.S.P.M Nazeer Hussain	M.B.A	Accounts	Sr.Executive	05 Years
2.	Mr. Srihari	B. Com	Accounts	Executive	04 Years
3.	Mr. A.Vishnuvardan	B.Com	Accounts	Executive	09 Years
4.	Mr. R. Surender	M.A	Regulatory	Manager Liaison	10 Years

*Annexure to **SMF/004 No. 004***

H.V.A.C SYSTEM DETAILS OF CRITICAL AREA

S.No	Area	Area Classification (un manned condition)	Temp. & RH% condition	Designed air changes/ Hour
	Ground floor			
1.	Stores	100000	--------	25
2.	Change Room	100000	-------	25
3.	Stores office	100000	--------	25
4.	Air lock	100000	-------	25
5	Sugar storage/Transfer	100000	--------	25
6	Equipment wash area	100000	-------	25
7	Sampling	100000	--------	25
8	Staging	100000	--------	25
9	De-dusting	100000	--------	25
10	Rejects stores	Controlled Area 5micron	--------	25
11	Raw material	Controlled Area 5micron	--------	25
12	Storage	100000	NMT 25^0C,RH NMT 55%	25
13	Sifter	100000	NMT 25^0C,RH NMT 55%	25
14	Dispensing	100000	NMT 25^0C,RH NMT 55%	25
15	Cool storage	--------	NMT 25^0C	25
16	Packing	--------	--------	25
17	Over printing	--------	--------	25
18	Finished Goods	--------	NMT 25^0C	25
19	Office	--------	NMT 25^0C	25

	MEZZANINE FLOOR			
20	Administration	--------	NMT 25^0C	25
21	Secondary packing Block-1	Controlled Area 5micron	NMT 25^0C	25
22	Secondary packing	Controlled Area 5micron	NMT 25^0C	25
23	Primary packing	Controlled Area 5micron	NMT 25^0C	25
24	Change over	100000	NMT 25^0C,RH NMT 55%	25
25	Corridor-1	100000	NMT 25^0C,RH NMT 55%	25
26	airlock	100000	NMT 25^0C,RH NMT 55%	25
27	Corridor-2	100000	NMT 25^0C,RH NMT 55%	25
28	Staging	100000	NMT 25^0C,RH NMT 55%	25
29	Primary filling	100000	NMT 25^0C,RH NMT 55%	25
30	Wash	100000	NMT 25^0C,RH NMT 55%	25
31	Powder primary packing	100000	NMT 25^0C,RH NMT 55%	25
	FIRST FLOOR			
32	Granulation	100000	NMT 25^0C,RH NMT 55%	35
33	Granules	100000	NMT 25^0C,RH NMT 55%	35
34	Wash area	100000	NMT 25^0C,RH NMT 55%	25
35	Paste	100000	NMT 25^0C,RH NMT 55%	25
36	Drying	100000	NMT 25^0C,RH NMT 55%	30
37	Compression-I	100000	NMT 25^0C,RH NMT 55%	30
38	Coating	100000	NMT 25^0C,RH NMT 55%	35
39	Compression-II	100000	NMT 25^0C,RH NMT 55%	30
40	Bulk packing	100000	NMT 25^0C,RH NMT 55%	30
41	Blister packing	100000	NMT 25^0C,RH NMT 55%	30
42	Wash	100000	NMT 25^0C,RH NMT 55%	30

43	2m corridor-1	100000	NMT 25^0C,RH NMT 55%	30
44	2m corridor-2	100000	NMT 25^0C,RH NMT 55%	30
45	1.5m corridor	100000	NMT 25^0C,RH NMT 55%	30
46	Secondary packing	100000	NMT 25^0C,RH NMT 55%	30
47	Storage	100000	NMT 25^0C,RH NMT 55%	30
48	RM staging	100000	NMT 25^0C,RH NMT 55%	30
49	Liquid MFG	100000	NMT 25^0C,RH NMT 55%	30
50	Liquid filling sealing	100000	NMT 25^0C,RH NMT 55%	30
51	Ladies change room	Controlled Area 5micron	--------	25
52	Wash	Controlled Area 5micron	--------	25
53	Airlock	Controlled Area 5micron	--------	25
54	Gents change room	Controlled Area 5micron	--------	25
55	Wash	Controlled Area 5micron	--------	25
56	Airlock	Controlled Area 5micron	--------	25
57	Staff change room	Controlled Area 5micron	--------	25
58	Wash	Controlled Area 5micron	--------	25
59	Airlock	Controlled Area 5micron	--------	25
60	Bottle de-cartoning	Controlled Area 5micron	--------	25
61	Bottle wash	Controlled Area 5micron	--------	25
62	1.5m wide corridor	Controlled Area 5micron	--------	25
63	Sec packing	FCU	NMT 25^0C	15
	SECOND FLOOR			
64	Airlock-1	10000	NMT 25^0C,RH NMT 55%	45
65	Incubator	10000	NMT 25^0C,RH NMT 55%	45

66	Airlock-2	10000	NMT 25^0C,RH NMT 55%	45
67	Airlock-3	10000	NMT 25^0C,RH NMT 55%	45
68	LAF	10000	NMT 25^0C,RH NMT 55%	45
69	Chemical Lab	Controlled Area 5micron	--------	25
70	Wash	Controlled Area 5micron	--------	25
71	Chemical storage	--------	--------	25
72	Corridor-1	Controlled Area 5micron	--------	25
73	Corridor-2	Controlled Area 5micron	--------	25
74	Change room	Controlled Area 5micron	--------	25
75	Control sample	FCU	NMT 25^0C	25
76	Stability room	FCU	NMT 25^0C	25
77	Records room	FCU	NMT 25^0C	25
78	Instrumentation	FCU	NMT 25^0C	25

*Annexure to **SMF/004 No.004***

DIFFERENTIAL PRESSURE OF AREA

Sl. No	Area	Abs Pressure	Adjacent area	Abs Pressure	Differential Pressure	Limits
	GROUND FLOOR					
1	Stores office	2	Stores entry	1	1	NLT +0.8
2	Stores entry	1	Changeover	2	1	NLT +0.8
3	Changeover	2	Stores entry	1	1	NLT +0.8
4	Air lock	3	Changeover	2	1	NLT +0.8
5	Sugar Storage/Transfer	2	Air lock	3	1	NLT +0.8
6	Equipment wash area	0.5	Raw material	1	0.5	NLT +0.8
7	Sampling	2	Raw material	1	1	NLT +0.8
8	Pre sampling	0.5	Raw material	1	0.5	NLT +0.8
9	Raw material	1	Quarantine	2	1	NLT +0.8
10	Day Storage	2	Raw material	1	1	NLT +0.8
11	Sifter	2	Raw material	1	1	NLT +0.8
12	Dispensing	2	Raw material	1	1	NLT +0.8
13	Cool storage	2	Raw material	1	1	
14	Packing	NA	NA	NA	NA	
15	Over printing	NA	NA	NA	NA	
16	Finished Goods	2	Ambient	1	1	
	MEZZANINE FLOOR					
17	Administration	NA	NA	NA	NA	NA
18	Secondary packing Block-1	1	Power packing	2	1	NLT +0.8
19	Secondary packing	0.5	Primary filling	1	0.5	NLT +0.8
20	Primary packing	0.5	Staging	1	0.5	NLT +0.8
21	Change over	1	airlock	3	2	NLT +0.8
22	Corridor-1	2	Change over	1	1	NLT +0.8
23	airlock	3	Corridor-2	2	1	NLT +0.8

24	Corridor-2	2	Ambient	1	1	NLT +0.8
25	Staging	1	Primary packing	0.5	0.5	NLT +0.8
26	Primary filling	1	Corridor-2	2	1	NLT +0.8
27	Wash	0.5	Corridor-2	2	1.5	NLT +0.8
28	Powder packing	2	Secondary packing Block-1	1	1	NLT +0.8

FIRST FLOOR

Sl. No	Area	Abs Pressure	Adjacent area	Abs Pressure	Differential Pressure	Limits
30	Granulation	1	Corridor	2	1	NLT +0.8
31	Granules	1	Corridor	2	1	NLT +0.8
32	Wash area	0.5	Granulation	1	0.5	NLT +0.8
33	Paste	0.5	Granulation	1	0.5	NLT +0.8
34	Drying	0.5	Granulation	1	0.5	NLT +0.8
35	Compression-I	1	Corridor	2	1	NLT +0.8
36	Coating	1	Corridor	2	1	NLT +0.8
37	Compression-II	1	Corridor	2	1	NLT +0.8
38	Bulk packing	1	Corridor	2	1	NLT +0.8
39	Blister packing	1	Corridor	2	1	NLT +0.8
40	Wash	0.5	Corridor	2	1.5	NLT +0.8
41	2m corridor-1	2	Airlock	3	1	NLT +0.8
42	2m corridor-2	2	Airlock	3	1	NLT +0.8
43	1.5m corridor	2	Airlock	3	1	NLT +0.8
44	Secondary packing	1	Corridor	2	1	NLT +0.8
45	Storage	1	Corridor	2	1	NLT +0.8

46	RM staging	1	Corridor	2	1	NLT +0.8
47	Liquid MFG	1	Corridor	2	1	NLT +0.8
48	Liquid filling	1	Corridor	2	1	NLT +0.8
49	Ladies change room	2	Ambient	1	1	NLT +0.8
50	Airlock	3	Ladies change room	2	1	NLT +0.8
51	Wash	0.5	Ladies change room	2	1.5	NLT +0.8
52	Gents change room	2	Ambient	1	1	NLT +0.8
53	Wash	0.5	Gents change room	2	1.5	NLT +0.8
54	Airlock	3	Gents change room	2	1	NLT +0.8
55	Staff change room	2	Ambient	1	1	NLT +0.8
56	Wash	0.5	Staff change room	2	1.5	NLT +0.8
57	Airlock	3	Staff change room	2	1	NLT +0.8
58	Bottle de-cartoning	1	1.5m wide corridor	2	1	NLT +0.8
59	Bottle wash	0.5	Bottle de-cartoning	1	0.5	NLT +0.8
60	1.5m wide corridor	2	Ambient	1	1	NLT +0.8

61	**SECOND FLOOR**					
62	Airlock-1	3	Change over	1	1	NLT +0.8
63	Incubator	1.5	Airlock-1	3	1.5	NLT +0.8
64	Airlock-2	2	Incubator	1.5	0.5	NLT +0.8
65	Airlock-3	3	Airlock-2	2	1	NLT +0.8
66	LAF	2	Airlock-3	3	1	NLT +0.8

8.0 Abbreviations :

1) SMF ……Site Master file
2) WHO……World Health Organization
3) CGMP…..Current Good Manufacturing Practice
4) QC…….....Quality Control
5) QA…….Quality Assurance
6) SOP……..Standard Operating Procedure
7) PU…….Poly Urethane
8) HVAC……Heat Ventilation Air
9) UPS …….Un-Interrupted Power Supply
10) TS…….Telangana State
11) TR…….Tonnes of Refrigeration
12) CCK……..Centrifugal Curved Kruger
13) GMP……..Good Manufacturing practice
14) AHU…….....Air Handling Unit
15) DM…….De- Mineralized
16) PCI…….Pest Control of India
17) SS……...Stainless Steel
18) UV……...Ultra Violet
19) PW…….Purified Water
20) HMI……Human Machine Interface
21) CFM……..Cubic Feet Per Minute
22) TDS……..Total Dissolved Solvents
23) BOD…….....Biochemical Oxygen Demand
24) ETP……Effluent Treatment Plant
25) BMR……..Batch Manufacturing Record
26) HEPA…… High Efficiency Particulate Arrestance
27) ROPP……Roll-on Pilfer-Proof
28) BPM……..Bottles Per Minute
29) HP…….Horse Power
30) FBD…….....Fluid Bed Dryer
31) HPLC……High Performance Liquid Chromatography
32) FIFO…….First in First Out
33) IR……...Infra-Red
34) FIFE…….First In First Expiry
35) TSPCB….Telangana State Pollution Control Board