
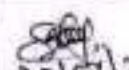



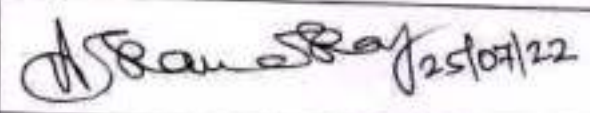
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<p align="center">This Site Master File is accepted by the Management of  <b>Wellous Pharma Private Limited</b>  R.S.No.333-2A &amp; 2B2 Navamal Marutur Village,  Kandamangalam Block,  Villupuram District, Tamil Nadu - 605 102</p>	
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<b>Approved By</b> V. Barath Bhushan  (Head QA)	 25/07/22
<b>Authorized By</b> A. Karunakaran  (Managing Director)	 25/07/22



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## 1.0 GENERAL INFORMATION ON THE MANUFACTURER

### 1.1. Contact information on the manufacturer

#### 1.1.1 Manufacturing Site Address

Wellous Pharma Private Limited,  
R.S.No.333-2A & 2B2 Navamal Marutur Village,  
Kandamangalam Block,  
Villupuram District, Tamil Nadu - 605 102.  
Phone No. 9047007606

#### 1.1.2 Registered Office Address

Wellous Pharma Private Limited,  
Flat No. C-14, Third Floor, Ramaniam Marvel Phase 1,  
Block No. 234, 1<sup>st</sup> Main Road,  
Sri Sathya Sai Nagar,  
Velachery, Chennai - 600042.  
Mobile No. 9047005701.

#### 1.1.3 Contact Information of the Manufacturer

##### Contact Details (24 hours)

Mr. A. Karunakaran,  
Managing Director,  
E-mail karunakarana@wellous.in  
Mobile No +91 - 9442993737/ +91 - 9047005701.

### 1.2 Authorized Pharmaceutical Manufacturing activities of the Site

WPPL is licensed to manufacture Oral Solid Dosage forms Includes Tablets, Hard gelatin Capsules, Oral powders Includes Sachets & Dry powder and Topical formulation Includes Ointment, Cream & Gel.

Category	Manufacturing license
Manufacturing License for products coming under Schedule C & C(1)	Form 28 bearing No TN00004922
Manufacturing License for products not coming under Schedule C & C(1)	Form 25 bearing NoTN00004921

This manufacturing license is issued by The Director of Drugs Control, Chennai, Tamil Nadu as per the provisions of 'Drugs & Cosmetics Act 1940' and the rules made there under.

**Refer Appendix-1 for Manufacturing License and Appendix-2 for List of Dosage forms.**

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**1.3 Any Other Manufacturing Activities Carried Out on the Site**

WPPL is licensed to manufacture Oral Solid Dosage forms includes Tablets, Hard gelatin Capsules Oral powders includes Sachets & Dry powder for Food products issued by Government of India, Food Safety and Standards Authority of India bearing the License number 12417031000815.

**2.0 QUALITY MANAGEMENT SYSTEM OF THE MANUFACTURER**

**2.1 Brief description of the QMS**

The Quality Management System (QMS) is implemented throughout the product lifecycle. The QMS involves the commitment and active participation of senior management, operational management and personnel at all levels within the different departments, in decision – making relating to building the quality into the medicinal products throughout its life cycle.

At WPPL these standards have been incorporated in the form of Quality Policy and Standard Operating Procedures. These standards are reviewed periodically and revised whenever required through an official change control process to meet current requirements. Quality objectives should be clearly elaborated as a part of the strategic framework process and appropriate recognition should be given for outstanding achievements in relation to quality performance.

**Key Responsibilities of Quality Assurance functions are stated below**

Quality Assurance at WPPL is a distinct organization body that functions and reports to Managing Director and is independent of all other plant functions. Head of Quality division is technically qualified with remarkable experience in the responsible area.

WPPL has adopted a policy of operating the pharmaceutical manufacturing under control of Quality Management System. The quality assurance department is fully authorized to take appropriate decision on quality matters. The goal of Quality Assurance activities is to prevent quality issues through effective organization, planning and/or early detection and prevention.

- Ensure compliance of GMP requirements.
- Ensure effective functioning of the Quality Management System
- Approve and verify implementation of defined systems, standards and procedures.
- Document and data control system.
- Supplier/Vendor qualification system.
- Handling of regulatory inspections at the site.

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- Validation of manufacturing process and analytical procedures.
- Approval or rejection of all process & specifications related to the strength, identity, purity, quality of the finished drug product.
- All necessary controls on intermediate products and finished goods.
- Ensure compliance of GMP through Internal Quality Audit (Self Inspections).
- Handling of out of specification results, deviations, market complaints, and product recall.
- Ensure the implementation of Corrective and preventive action (CAPA).
- Change control system.
- Review batch manufacturing and testing records & Release of finished drug products complying with specified quality standards.
- To approve or reject any request to rework or reprocess.

#### **Accreditation and Certification**

GMP certificate issued by Director of Drugs control, Tamil Nadu, **Refer Appendix -3**

#### **2.2 Release of Finished Products for Sales**

The Quality Assurance department checks the Batch manufacturing, Packaging records and Certificate of Analysis along with all data relevant to the quality of the product, before meant for sales and distribution. Batch release is done by QA Head/Designee.

#### **2.3 Management of Suppliers and Contractors**

Raw and Packaging Materials procured only from approved vendors. Vendors are assessed through questionnaires. Vendors qualified as per the laid down SOP. Prior to commercial purchase from suppliers, samples are obtained and analysed against the specification.

Every container/pack evaluated physically and chemically identified whereby ensure no falsified materials released for processing.

This facility uses outside expertise for pest and rodent control, calibrations and annual maintenance for some equipment / utilities / QC instruments. Some analytical services at the following external approved analytical laboratories are utilized during any break down or maintenance of any laboratory equipment and to handle any overflow of work. Their services are also utilized for special test.

**Refer Appendix-04 for list of contract laboratories and Service providers**


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## 2.4 Quality risk management

This guidance provides principles and examples of tools for quality risk management that can be applied to different aspects of pharmaceutical quality. These aspects include development, manufacturing, distribution, inspection, and submission/review processes throughout the lifecycle of drug products.

Two primary principles of quality risk management are

- The evaluation of the risk to quality should be based on scientific knowledge and ultimately link to the protection of the patient; and
- The level of effort, formality, and documentation of the quality risk management process should be commensurate with the level of risk.

### General quality risk management process

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the drug product across the product lifecycle. The emphasis on each component of the framework might differ from case to case but a robust process will incorporate consideration of all the elements at a level of detail that is commensurate with the specific risk.

## 2.5 Product quality reviews

Product Quality Review reports are prepared for all the products manufactured in the facility during previous calendar year as defined in the respective procedure. QA Head along with cross functional Heads evaluate the consistency of the results as intended.

## 3.0 PERSONNEL

### Organization Chart

The complete Organogram of the factory is enclosed as **Appendix 5**

### Key Personnel, Qualification, Experience & Responsibilities

- Mr.A.karunakaran, Managing Director, B. Pharm, having 31 years of experience in Pharmaceutical Industry.
- Mr.V.Barath Bhushan, Director, Regulatory Affairs, B.Sc., PGDBA, having 34 years of experience in Pharmaceutical Industry.
- Mr.T.G.Venkatesan, Director, Planning and Purchase, B. Pharm, having 31 years of experience in Pharmaceutical Industry.
- Mr.S.P. Ruku Mangathan, Admin Head, BA, having 17 years of experience in Pharmaceutical Industry.

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### **Training program**

The HR department organizes Induction training to all the new employees to acquaint with the company's policies, practices, GMP & Hygiene as per relevant SOP and maintain the records of such Induction training. Training needs are identified as per job description which shall be approved by respective Department Heads. All the employees receive training as per Annual refresher training schedule.

The training is imparted to groups identified from various levels by in-house faculty as well as by external experts wherever required. The training program includes Induction, Job Specific SOPs training, Refresher training and external seminars/conferences. The following training aids are used for effective in-house training program.

The effectiveness of the training is evaluated through post-training questionnaires.

Retraining needs are identified on the basis of Questionnaire evaluation, recurrence of Non-conformances, and Failure Investigations. The training records of all personnel are maintained by respective Department.


### **Health Requirements for Personnel**

- All personnel engaged in manufacturing ensure free from contagious diseases.
- All the employees are medically examined at the time of recruitment through registered Physician and records of Medical examination are maintained and periodic re-examinations are conducted once in a year. HR department is responsible for health check-ups of employees.
- Employees working at visual inspection area are subjected to additional colour blindness test.
- Employees are instructed to inform immediate supervisor about any sickness.
- Employees need to produce a Medical Fitness Certificate before resuming work after illness.

### **Personnel Hygiene requirements Including Clothing**

- Every person engaged in manufacturing activities has to comply with requirements of personal cleanliness and hygiene conditions.
- Separate change room facilities have been provided for male / female employees and visitors. Adequate space has been provided for changing and resting purposes.
- Gowning and de-gowning instructions in the form of SOPs and Photos are displayed in each change rooms. Laundry is outsourced. **Refer Appendix-04**



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#### 4.0 PREMISES AND EQUIPMENT

##### 4.1 Premises

The plant is spread over 3.6 acres and the build-up area is 30000 square feet in two floors. Manufacturing facility is surrounded on the East by road, west by vacant land, north by vacant land and south by vacant land.

Ground floor consists of Ware house (RM, PM & FG), Manufacturing and Packaging activities for Tablets, Hard gelatin capsules and oral powders. First floor consists of Ware house (FG), Manufacturing and Packaging activities for Ointments, Quality Control Unit, Service floor for AHU and Admin Office.

Utility Building consists of DG room, Air compressor room and water treatment plant in the ground floor.

Plant is built up of suitable size facilitate to ease of cleaning, maintenance & operations. Building is built with adequate space and facilities to prevent processing mix-up & cross contamination. Anti-Termite treatment was done during the construction of building and special attention was given to keep proper segregation of materials, equipment and men / material movement. All constructions were done as per the approved design and the details, given by expert civil engineers & architects. Finishes of each building were carried out taking into account of specific process requirements.

- Buildings were constructed of Reinforced cement concrete structures with smooth finish & paints.
- Flooring in Ware house area includes Raw materials, Packing materials and finished Goods and clean container storage area, Production, QA office and secondary packaging area is made up of polished Kota stones .The corners are with epoxy coving as per requirement.
- Complete epoxy flooring is provided in sampling, dispensing, manufacturing and primary packaging areas & microbiology section in Quality control department.
- Wherever required Epoxy Covings are provided. The walkable false ceilings in manufacturing and primary packaging areas are made up of clean room panels. False ceiling in Ware house area includes Raw materials and Finished Goods and Secondary packaging area is made of Gypsum board
- The brick walls in the manufacturing and primary packing areas are painted with poly urethane paint.

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- All the walls in the manufacturing area are made up of Clean room panels, doors and double glass visual panel were provided in required places.
- Stainless steel-clean room panel provided in all washing areas, GMP drain traps are provided in manufacturing area.
- Switches located in the manufacturing areas and corridors are concealed. In all areas clean room light fixtures are provided. Separate service floors are provided for utilities.
- Adequate slopes are provided towards drainage system. Toilets do not communicate directly either with production or with storage area.

#### **Manufacturing Areas**

- The layout of premises is such that production areas are connected in a logical order as per the sequence of operation and cleanliness level.
- Men & Material Movements are separate.
- Men entry via Airlocks and material entry through hatch boxes are provided separately to manufacturing cubicles.

#### **Storage Area**

- In the RM, PM and FG stores, separate areas are allocated for physical segregation of material under quarantine, released materials (Approved) and rejected materials.
- Separate areas for sampling and dispensing provided with sampling and dispensing booths & dispensed raw materials are stored separately in day stores.
- Movements of materials from unclassified area to classified areas are done through dynamic pass boxes.
- Storage areas are always kept in clean and dry conditions with required storage conditions and they are monitored and recorded.
- Quarantine /under test areas clearly marked with Yellow color & approved areas are marked with green color.
- Rejected, recalled and returned material or products stored in dedicated storage area.
- All printed packaging materials are kept under lock and key and the areas are accessible only to the authorized personnel.
- Heavy duty racks are provided for storing all raw, packing and intermediate materials.

#### **4.1.1 Brief Description of HVAC Systems**

- Adequate number of Air Handling units is provided to supply clean air to processing areas.

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- Designed the AHU in such a way that 90 % of the air is re-circulated and 10 % fresh air is taken from the atmosphere (after filtration).
- Air changes in the manufacturing area are designed to meet ISO class 8.
- Temperature and RH is maintained throughout the facility wherever required.
- Differential pressure is maintained in the process area to restrict the contamination in respective processing area with appropriate cascade air locks.
- Four types of filters are used in the air handling units. 10 $\mu$ , 3 $\mu$  and 0.3 $\mu$  (HEPA filter - 99.97% efficiency) in supply and 20 $\mu$  filter for Return are available. Dispensing, Manufacturing and Packaging area are maintained as per (International Organization for Standardization) ISO Class 8.
- Processing area is provided with terminal HEPA filters and Clean room corridors and Storage areas are provided with plenum HEPA filters.
- Besides the above, the AHU used in Powder filling section is fitted with dehumidifying unit capable of providing low RH levels.
- The return air pick up in all areas is at the bottom level through Inbuilt return Air-raisers.

The Pre-filters and intermediate filters are dismantled in accordance with an SOP and the integrity of the filters is checked by visual inspection. Yearly once HEPA filters are checked for filter integrity to ensure that there are no leaks. SOP for AHU handling is available for operation and monitoring the control parameters on daily basis to ensure the system is working as intended.

***Refer Appendix 6 for Lay out, AHU zone, Pressure zone, Men and Material flow, and manufacturing process flow chart for each dosage forms.***

#### **4.1.2 Brief Description of Water System**

Raw water sourced from Under Ground Sump. The water is pre-treated by chlorination and passed through a sand filter followed by Activated carbon filter (ACF). The ACF filtered water is dosed with anti scalant dosing agent and pumped through a 5 micron Filter assembly before fed into the RO system for fine filtration and further pumped using a high pressure pump through Reverse Osmosis membranes which generates potable water.

The RO water is then pumped through the Cation, Anion and Mixed bed and the same is further passed through an Ultra Violet (UV) ray and taken to the Purified water Storage Tank which caters purified water to meets IP/BP specification.

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Purified water is stored in SS316L designed to produce 1000 liter of purified water per hour. Distribution of the Purified water achieved through continuous circulating loop system to avoid stagnation. Distribution supply lines are made of SS316L which has 3 user points.

Purified water is circulated at ambient temperature. The Purified water circulation system equipped with hot water sanitation facility. UVlamp burning hours monitored regularly as per the respective procedure. Pressure difference across the filters are noted to check the integrity of filters.

***Schematic drawing of water system in Appendix 7***

#### **4.1.3 Utilities**

##### **Compressed Air**

Compressed air which comes in contact with the product or product containing equipment is generated using Air compressor where the compressed air is tested periodically for oil free, moisture free and microbial test as that of the intended procedure.

##### **Nitrogen**

Manufacturing facility is equipped with nitrogen lines in necessary areas such as Pouch filling section and the same is filtered through 0.2 micron filters.

#### **4.2 Equipment**

All the manufacturing equipment are designed, qualified and maintained to suit its intended purpose. The manufacturing equipment is designed as per GMP requirement with ease of cleaning and maintenance. All the product contact parts are made up of SS 316 or of suitably qualified material, which are non-reactive, non-corrosive and non-toxic. Certain equipment facilitated with CIP.

**4.2.1** The Major Equipment and Instruments used in the Production and Quality Control department is listed as **Appendix 8**.

##### **4.2.2 Cleaning and sanitation procedures for Manufacturing areas and Equipment**

Each area in production undergoes cleaning as per the standard operating procedures. The SOPs clearly specify the type of detergents to be used and the sanitizing agents with their concentration and frequency. SOP also addresses the changing of disinfectants at defined frequency.

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All the equipment undergoes cleaning as per the cleaning procedures. The cleaning procedures are validated as per the cleaning validation protocol. The cleaning of equipment is evaluated based on the Rinse /Swab analysis which includes Chemical and Microbial testing.

#### 4.2.3 Planned preventive maintenance program

All the utility equipment and process related equipment are taken into consideration for maintenance program as per respective SOP. The engineering department is responsible for carrying out maintenance and servicing the equipment. Wherever external agency for contractual or maintenance work is required, written procedures are available to carry out the same.

The annual plan for preventive maintenance of all equipment prepared and authorized at the beginning of the calendar year. Such annual plan gives the proposed date of preventive maintenance as per defined frequency. A detailed procedure for preventive maintenance available which indicates the frequency of checks, detail of preventive measure taken appropriately documented.

In case of any equipment breakdown, user department intimate Engineering through Equipment breakdown form. In turn, Engineering assessed for In-House or Authorised outsource servicing. Adequate records maintained.

#### 5.0 DOCUMENTATION

The Documentation system of manufacturing and Quality control are very comprehensive and well controlled in accordance to the standard operating procedures to avoid any ambiguity and uncertainty.

The level of Documentation includes

- Company Quality Policy
- Quality Manual
- Site Master File
- Validation Master Plan
- SOPs, MOAs, Specifications, BMRs and BPRs
- Validation/Qualification Protocols and Reports
- QMS documents
- Stability data
- Records and Raw data


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All the master documents are stored and controlled by QA. The controlled/displayed copies of SOPs, Specifications and STPs are distributed to the respective departments by QA through distribution list. The superseded copies of the documents are retrieved at the time of issuance of new version. The retrieved copies are destroyed and master copy is made superseded and archived.

A written procedure available to store various documents in the record and archival room with defined period of time

## 6.0 PRODUCTION

### 6.1 Type of Products

Plant is designed to manufacture oral solid dosage forms includes Tablets, Hard gelatin capsules and oral powders and topical formulation includes Ointment, Cream & Gel.

The products manufactured are meant for the human consumption.

This facility does not manufacture products falling under the following categories  
 $\beta$ -lactam antibiotics, Penicillin group products, Cytotoxic products, wound dressing, surgical dressing, drug substances, other chemicals, cosmetic and toilet preparations, household cleaning products, disinfectants, agricultural, horticultural and pesticide products.

### Toxic, Hazardous, and Sensitizing Materials

There are no toxic, Hazardous and sensitising materials handled at the Site.

### 6.2 Process Validation

The results of process validation establish a consistency in product quality attributes. Three consecutive batches of validation ensure that the manufacturing process consistently produces the product to meet the pre-determined specifications. Change control is followed in case of any changes. If the change calls for revalidation of the process, validation is repeated. A process is considered for validation whenever there is a technology transfer of a product from Formulation Development or from the product owner to the manufacturing site. Process Validation is applicable under the following circumstances

- New product
- An Existing product undergoes change in process, critical equipment, formula & batch size.

Quality Assurance maintains the validation protocol along with the report. If at any stage, the process is found to be unacceptable, then a suitable corrective action is initiated.

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### Release of validation batches

Development batches are not released for sale. Validation batches are analysed as per the approved specifications and they are released for sale if they comply with the release specifications and review of the manufacturing and testing documents is satisfactory.

### Policy for Reprocessing or Rework

As per organization policy, Reprocess / Rework are carried out as per the laid down SOP. Reprocess/Rework if carried out which is intimated to the client/Regulatory agency where applicable. Based on the approval, Quality Assurance design and authorize the protocol for execution.

## 6.3 Material Management and Warehousing

### Arrangements for the handling of starting and packaging materials

- All the materials are verified on receipt and a unique non-repetitive code number is assigned to each consignment called 'Control Number'. This number is displayed on the labels affixed on the containers.
- The materials are stored at appropriate storage conditions as per SOP.
- There are dedicated places/ storage areas provided for Receipt, Quarantine, Under Test, Approved and Rejected materials.
- Raw materials and Packing materials are sampled from each batch of each consignment as per approved sampling procedures.
- The status of the materials during storage is clearly identified by affixing labels as 'QUARANTINE label', 'UNDER TEST' and 'APPROVED' or 'REJECTED' as appropriate.
- Only approved materials and which are within the retest date are issued for processing. The materials are weighed by dispensing chemist and checked by In process Quality Assurance. The dispensed materials of a batch are identified by Analytical Report Number.
- Receipt, issue, use, destruction of materials is maintained which is reconciled at specified intervals.
- Environmental conditions of the facility are designed, maintained and monitored to meet the requirements of process & storage.


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#### **Arrangements for the handling of Bulk and Finished Product**

- Manufacturing is carried out strictly in accordance with the instructions given in the batch manufacturing record (BMR).
- All the activities of production namely dispensing, manufacturing, packaging, In-process control and Quality control are handled by qualified personnel of the respective departments and all the master documents are approved by Head - Quality Assurance.
- Independent In-process checks are carried out by Quality Assurance in the course of manufacture and results are recorded in the BMR.
- Line clearance is carried out before any change over.
- Bulk products are issued for packing after reports received from quality control and approved by Quality assurance.
- All the materials required for packaging are verified on receipt for correct identity and approval status. Line clearance is checked by the Packing supervisor and counterchecked by Quality Assurance. In-process checks are carried out in the course of packing and results are recorded in the BPR. Independent In-process checks are carried out by Quality Assurance.
- Finished goods are quarantined till release by QA. Before final release, QA verifies batch records, In-process records and QC reports. Authorized person of QA gives the batch release.

#### **Arrangements for the handling of Rejected material and Product**

- Raw material and Finished product facilitated with dedicated Rejected storage area under control of Quality Assurance.
- Based on the evaluation done by QA, the rejected material is either destroyed or returned to the supplier/Manufacturer.
- The "REJECTED" finished drug products and printed packaging materials are destroyed under the supervision of QA personnel and records are maintained

### **7.0 QUALITY CONTROL**

#### **Description of Quality Control System and Activities**

- Quality Control has authority & responsibility to approve or reject active pharmaceutical ingredients, excipients, and packaging materials, intermediate and finished products.

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- Adequate laboratory facilities (chemical, instrumentation and microbiology) are provided for the testing of active pharmaceutical ingredients, excipients, and packaging component materials, intermediate and finished products.

#### **Functions of Quality Control**

- Sampling of raw materials and packing materials as per SOP.
- Preparation of specifications and testing methods for Raw materials, packing materials, Intermediates, Finished products.
- Analytical method validation/verification for finished products.
- Testing of Raw materials, Packing materials, Intermediates and Finished products to comply as per the Specifications and maintenance of relevant work sheets.
- Issue of Certificate of Analysis.
- Testing of stability study samples and validation samples.
- To establish, verify and implement all quality control procedures.
- To maintain Reference samples for Raw materials and finished products.
- Evaluation, storage and maintenance of Reference Standards.
- Storage and maintenance of Retention samples.
- Participation in the investigation of complaints of product quality.
- Environmental monitoring of the facility.
- Quality review of the products.

### **8.0 DISTRIBUTION, COMPLAINTS, PRODUCT DEFECTS AND RECALL**

#### **8.1 Description of Storage and Distribution Practices**

Secured Finished warehouse is available where entry is controlled for only authorized persons. Warehouse is responsible for the entry, storage and dispatch of the packed goods. Products which are sensitive to temperature are transported through refrigerated vehicle. Materials are stored on pallets. The finished products are distributed by Road or Sea or Air as per the customer requirement with appropriate safety measures.

#### **Records of Distribution**

Records of Distribution of product are maintained which facilitates the traceability of the product which includes customer details and quantity sold to each customer.

#### **8.2 Complaints, Products defects and recalls**

A well-defined procedure for the handling of Market complaint is available, which defines responsibility for logging and investigation. QA personnel are responsible for logging and classifying the market complaint. The QA Head along with cross functional heads is responsible for investigating complaints as per laid down procedures.

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The reports are prepared which constitute the details of compliant, investigation report, action plan and response to the compliant. The report is reviewed by cross functional heads and approved by QA Head.

**Product Recalls**

Products are recalled and documented in accordance with the written Quality Assurance procedure. The Head Quality Assurance is responsible for co-ordination of the product recall. When the recalled product is received at the factory, Warehouse Department identifies and stored separately in a secure area while awaiting a decision. The investigation teams headed by Quality Assurance carry out investigation and report the corrective action plan. Corrective action taken is recorded.

**9.0 SELF INSPECTION**

The Self-inspection program for effective quality management is designed, documented and followed up for corrective and preventive actions. The self-audits are carried out with comprehensive checklist by giving pre information to the respective department. All the departments are audited periodically as per the predetermined schedule. The self-inspection team consists of representative from various departments other than the department being audited. The observations are notified to the auditee department to initiate corrective and preventive actions which shall be monitored by Audit team & Quality Assurance. The records are maintained for the same.

**10.0 LIST OF APPENDIX**

- 10.1 Manufacturing License – Appendix 1
- 10.2 List of dosage forms – Appendix 2
- 10.3 GMP Certificate– Appendix 3
- 10.4 List of contract laboratories and service providers- Appendix 4
- 10.5 Organogram- Appendix 5
- 10.6 Lay out, AHU zone, Pressure zone, Men and Material flow and manufacturing process flow chart for each dosage forms-Appendix 6
- 10.7 Schematic drawing of water system- Appendix 7
- 10.8 List of major production and laboratory equipment- Appendix 8

**11.0 ABBREVIATIONS**

- 11.1 QA - Quality Assurance
- 11.2 GMP - Good Manufacturing Practice
- 11.3 Sq. Ft - Square feet
- 11.4 QC - Quality Control

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11.5	HR	- Human Resource
11.6	M.Pharm	- Master of Pharmacy
11.7	B.Pharm	- Bachelor of Pharmacy
11.8	M.Sc	- Master of Science
11.9	B.Sc	- Bachelor of Science
11.10	SOP	- Standard Operating Procedures
11.11	SS	- Stainless Steel
11.12	PW	- Purified Water
11.13	AHU	- Air Handling Unit
11.14	UV	- Ultra Violet
11.15	IP	- Indian Pharmacopoeia
11.16	BP	- British Pharmacopoeia
11.17	CAPA	- Corrective and Preventive Actions
11.18	No.	- Number
11.19	SMF	- Site Master File
11.20	HEPA	- High efficiency Particulate Air
11.21	WPPL	- Wellous Pharma Private Limited
11.22	RO	- Reverse Osmosis
11.23	HVAC	- Heat Ventilation and Air Conditioning
11.24	RM	- Raw Material
11.25	PM	- Packing Material
11.26	FG	- Finished Goods
11.27	%	- Percentage
11.28	μ	- Micron
11.29	BMR	- Batch Manufacturing Record
11.30	BPR	- Batch Packaging Record
11.31	MOA	- Method of Analysis
11.32	DGM	- Deputy General Manager
11.33	GM	- General Manager

**12.0 REFERENCE**

12.1 Schedule - M

12.2 EU guideline; Site Master File


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### 13.0 REVISION HISTORY

Date of Revision	Version No.	Changes Made	Change Control No.	Effective Date
NII	00	New	NA	28/12/18
22/03/18	01	Copy of manufacturing License included in the Annexure	CC/18/001	26/03/18
22/03/19	02	Refer change control CC/19/009	CC/19/009	22/03/19
01/06/21	03	<ul style="list-style-type: none"> <li>• Procedure for Personnel and Water system revised.</li> <li>• Appendix -2, List of Products revised.</li> <li>• Appendix-8, List of major Production and Quality Control equipment revised.</li> <li>• Periodic review of Appendix 4 , List of Contract Laboratories and Service providers; Appendix 5, Organogram; Appendix 6, Manufacturing process flow chart for dosage forms.</li> </ul>	CC/21/019	01/06/21
25/07/22	04	<ul style="list-style-type: none"> <li>• Procedure for Personnel and Water system revised.</li> <li>• Appendix -2, List of Products revised.</li> <li>• Appendix -3, GMP Certificate.</li> <li>• Appendix -4, List of Contract Laboratories and Service Providers.</li> <li>• Appendix -5, Organogram.</li> <li>• Appendix-8, List of major Production and Quality Control equipment revised.</li> <li>• Periodic review of Appendix 6, Manufacturing process flow chart for dosage forms.</li> </ul>	CC/22/034	25/07/22

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# **Appendix 1**

## **Manufacturing License**

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R.Dis.No. 18081/011/2018 dt. 20.3.18 GRANT

FORM 25  
(See rule 70)

License to manufacture for sale or for distribution of drugs other than those specified in Schedules C, C(1) and X

Number of License TN00004921 and Date of Issue 20.3.2018

1. Directors of M/s. Wellous Pharma Private Limited

is hereby licensed to manufacture the following categories of drugs being drugs other than those specified in Schedules C, C(1) and X to the Drugs and Cosmetics Rules, 1945, on the premises situated at R.S. No. 333-2A & 2B2

Navamal Martur Village, Kandamangalam Block, Villupuram District, Tamilnadu

under the direction and supervision of the following competent technical staff - 605102

a) Competent technical staff (Names):

1. Thiru. T. G. Venkatesan Bpharm - for Manufacturing
2. Thiru. V. Barathbushan Bsc (chem) - for Testing

b) Names of Drugs (each item to be separately specified):

Vide List attached

2. The license authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the license, subject to the conditions applicable to license for sale.
3. The license unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of license and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
4. The license is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.



Signature ..... [Signature]

Designation **Director of Drugs Control**  
Chennai-600 006

Licensing Authority

[Signature]  
20.3.18

[Signature]  
20.3.18



R.Dis.No. 18081/01/1/2017 dt. 20.3.18

FORM 28  
(See rule 76)

Grant

License to manufacture for sale or for distribution of drugs specified in Schedules C and C (1) excluding those specified in Schedule X

Number of License TN00004922 and Date of Issue 20.3.2018

1. Directors of M/s. Kellous Pharma private Limited

Is hereby licensed to manufacture at the premises situated at R.S. No. 399-2A + 2B2 Navamal Martur Village Kandamangalam Block, Villupuram District, Tamil Nadu

the following drugs, being drugs specified in Schedules C and C (1) excluding those specified in Schedule X to the Drugs and Cosmetics Rules, 1945.

Names of Drugs: Vide List attached

2. Names of approved competent technical staff:

1. Thiruv. T. G. Venkatesan B. Pharm - For 1869

2. Thiruv. V. Barathbushan B.Sc (Chem) - For 0 Testing

3. The License authorises the sale by way of wholesale dealing and storage for sale by the licensee of the drugs manufactured under the License subject to the conditions applicable to Licenses for sale.
4. The License unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of License and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach.
5. The License is subject to the conditions stated below and to such other conditions as may be specified in the Rules for the time being in force under the Drugs and Cosmetics Act, 1940.



Signature ..... [Signature] 20/3

Designation Director of Drugs Control  
Chennai-600 008

Licensing Authority

[Signature]  
20.3.18

[Signature]  
20/3/18





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## **Appendix 2**

### **List of dosage forms**

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## Appendix-2



## SITE MASTER FILE

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Revision No. : 04

## LIST OF PRODUCTS

Effective Date: 25/04/22

Review Date : 2 Years

## Tablets

S. No.	Product Name	Composition
1	PARACETAMOL TABLETS BP 500MG (For Export)	Each uncoated tablet contains Paracetamol BP 500mg Excipients qs
2	ACECLOFENAC & PARACETAMOL TABLETS	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Colour : Approved colour used Excipients qs
3	NITROFURANTOIN SUSTAINED RELEASE TABLETS	Each film coated tablet contains Nitrofurantoin IP 100mg (as sustained release form) Colour: Approved colour used Excipients qs
4	MONTELUKAST SODIUM AND LEVOCETIRIZINE HYDROCHLORIDE TABLETS IP	Each film coated tablet contains: Montelukast Sodium IP Equivalent to Montelukast 10mg Levocetirizine hydrochloride IP 5mg Excipients q.s. Colour: Approved colour used
5	ACECLOFENAC CONTROLLED RELEASE TABLETS	Each uncoated controlled release tablet contains Aceclofenac IP 200mg Excipients qs. Colour: Approved Colour used
6	OFLOXACIN AND ORNIDAZOLE TABLETS	Each film coated tablet contains Ofloxacin IP 200mg Ornidazole IP 500mg Excipients qs Colour: Approved colour used
7	GLIMEPIRIDE AND METFORMIN HCL PROLONGED RELEASE TABLETS	Each film coated tablet contains: Glimepiride IP 1mg Metformin Hydrochloride IP 1000mg (As sustained release form) Excipients qs Colour: Approved colour used
8	GLIMEPIRIDE AND METFORMIN HCL PROLONGED RELEASE TABLETS	Each film coated tablet contains: Glimepiride IP 2mg Metformin Hydrochloride IP 1000mg (As sustained release form) Excipients qs Colour: Approved colour used
9	CETIRIZINE TABLETS BP 10MG (For Export)	Each film coated tablet contains: Cetirizine Hydrochloride BP 10mg Excipients q.s. Colour: Approved colour used
10	PANTOPRAZOLE GASTRO-RESISTANT TABLETS IP 40MG	Each Gastro-resistant tablet contains: Pantoprazole sodium IP 40mg Equivalent to Pantoprazole Excipients q.s.; Colour : Approved colour used

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S. No.	Product Name	Composition
11	FOLIC ACID TABLETS BP 5MG (For Export)	Each uncoated tablet contains: Folic acid BP 5mg Excipients qs
12	ERYTHROMYCIN STEARATE TABLETS BP 250 MG (For Export)	Each film coated tablet contains: Erythromycin Stearate BP Equivalent to Erythromycin 250mg Excipients qs Colour: Approved Colour Used
13	MECOBALAMIN AND GABAPENTIN TABLETS	Each film coated tablet contains Mecobalamin IP 500mcg Gabapentin IP 100mg Excipients qs Colour: Approved colour used
14	PREGABALIN (SR) AND MECOBALAMIN TABLETS	Each film coated tablet contains Pregabalin IP 75mg (as sustained release form) Mecobalamin IP 1500mcg Excipients qs Colour: Approved colour used
15	PREGABALIN (SR) AND MECOBALAMIN TABLETS	Each film coated tablet contains Pregabalin IP 150mg (as sustained release form) Mecobalamin IP 1500mcg Excipients qs Colour: Approved colour used
16	ATENOLOL & AMLODIPINE TABLETS	Each film coated tablet contains: Atenolol IP 50mg Amlodipine Besylate IP Equivalent to Amlodipine 5mg Excipients q.s Colour : Approved colour used
17	LORNOXICAM & PARACETAMOL TABLETS	Each film coated tablet contains Lornoxicam 8mg Paracetamol IP 325mg Excipients q.s Colour: Approved colour used
18	AMLODIPINE TABLETS IP 5MG	Each uncoated tablet contains Amlodipine Besylate IP Equivalent to Amlodipine 5mg Excipients q.s Colour: Approved colour used
19	S-AMLODIPINE TABLETS IP 5MG	Each uncoated tablet contains S-Amlodipine Besylate IP Equivalent to S-Amlodipine 5mg Excipients q.s
20	S-AMLODIPINE TABLETS IP 2.5MG	Each uncoated tablet contains S-Amlodipine Besylate IP Equivalent to S-Amlodipine 2.5mg Excipients q.s

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S. No.	Product Name	Composition
21	BETAHISTINE TABLETS IP 8MG	Each uncoated tablet contains Betahistine Hydrochloride IP 8mg Excipients q.s
22	NEBIVOLOL & HYDROCHLOROTHIAZIDE TABLETS	Each film coated tablet contains Nebivolol Hydrochloride IP Equivalent to Nebivolol 5mg Hydrochlorothiazide IP 12.5mg Excipients q.s Colour: Approved colour used
23	SPARFLOXACIN TABLETS 200MG	Each film coated tablet contains: Sparfloxacin 200mg Excipients q.s Colour: Approved colour used
24	BETAHISTINE TABLETS IP 16MG	Each uncoated tablet contains Betahistine Hydrochloride IP 16mg Excipients q.s
25	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 600MG	Each film coated controlled release tablet contains Magnesium Valproate 600mg Excipients q.s Colour: Approved colour used
26	NEBIVOLOL TABLETS IP 5MG	Each uncoated tablet contains Nebivolol Hydrochloride IP Equivalent to Nebivolol 5mg Excipients q.s
27	TRAZODONE HYDROCHLORIDE TABLETS USP 100MG	Each film coated tablet contains Trazodone Hydrochloride USP 100mg Excipients q.s Colour: Approved colour used
28	DIACERIN AND ACECLOFENAC TABLETS	Each film coated tablet contains Diacerin IP 50mg Aceclofenac IP 100mg Excipients q.s Colour: Approved colour used
29	TELMISARTAN TABLETS IP 40MG	Each film coated tablet contains Telmisartan IP 40mg Excipients q.s Colour: Approved colour used
30	METOPROLOL TABLETS IP 50MG	Each film coated tablet contains Metoprolol Tartrate IP 50mg Excipients q.s Colour: Approved colour used
31	FEXOFENADINE HCL & MONTELUKAST TABLETS	Each film coated tablet contains Fexofenadine Hydrochloride IP 120mg Montelukast Sodium IP Equivalent to Montelukast 10mg Excipients q.s Colour: Approved colour used
32	RABEPRAZOLE GASTRO-RESISTANT TABLETS IP 20MG	Each Gastro -Resistant tablet contains : Rabeprazole sodium IP 20mg Excipients q.s

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S. No.	Product Name	Composition
33	METOPROLOL SUCCINATE PROLONGED RELEASE TABLETS IP 12.5MG	Each film-coated prolonged release tablet contains : Metoprolol succinate IP Equivalent to Metoprolol Tartrate 12.5mg Excipients q.s Colour: Approved colour used
34	METOPROLOL SUCCINATE PROLONGED RELEASE TABLETS IP 25MG	Each film-coated prolonged release tablet contains : Metoprolol succinate IP Equivalent to Metoprolol Tartrate 25mg Excipients q.s Colour: Approved colour used
35	METOPROLOL SUCCINATE PROLONGED RELEASE TABLETS IP 50MG	Each film-coated prolonged release tablet contains : Metoprolol succinate IP Equivalent to Metoprolol Tartrate 50mg Excipients q.s Colour: Approved colour used
36	METOPROLOL SUCCINATE PROLONGED RELEASE TABLETS IP 100MG	Each film-coated prolonged release tablet contains : Metoprolol succinate IP Equivalent to Metoprolol Tartrate 100mg Excipients q.s Colour: Approved colour used
37	DICLOFENAC PROLONGED-RELEASE TABLETS IP 100MG	Each film coated prolonged release tablet contains: Diclofenac sodium IP 100mg Excipients q.s Colour: Approved colour used
38	FLUCONAZOLE TABLETS IP 150MG	Each uncoated tablet contains Fluconazole IP 150mg Excipients q.s
39	ETORICOXIB AND THIOLCHICOSIDE TABLETS	Each film coated tablet contains Etoricoxib IP 60mg Thiocolchicoside IP 4mg Excipients q.s Colour: Approved colour used
40	GEMIFLOXACIN TABLETS IP 320MG	Each film coated tablet contains Gemifloxacin Mesylate IP Equivalent to Gemifloxacin 320mg Excipients q.s Colour: Approved colour used
41	TRAMADOL WITH PARACETAMOL TABLETS	Each film coated tablet contains Tramadol Hydrochloride IP 37.5mg Paracetamol IP 325mg Excipients q.s Colour: Approved colour used

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S. No.	Product Name	Composition
42	THIOLCHICOSIDE & ACECLOFENAC TABLETS	Each film coated tablet contains Thiocolchicoside IP 8mg Aceclofenac IP 100mg Excipients q.s Colour: Approved colour used
43	DESLORATADINE TABLETS USP 10MG	Each uncoated tablet contains Desloratadine USP 10mg Excipients q.s
44	FEXOFENADINE TABLETS IP 180MG	Each film coated tablet contains Fexofenadine Hydrochloride IP 180mg Excipients q.s Colour: Approved colour used
45	ATENOLOL TABLETS IP 50 MG	Each film coated tablet contains Atenolol IP 50mg Excipients q.s Colour: Approved colour used
46	OLMESARTAN MEDOXOMIL AND HYDROCHLOROTHIAZIDE TABLETS IP	Each film coated tablet contains Olmesartan Medoxomil IP 40mg Hydrochlorothiazide IP 12.5mg Excipients q.s Colour: Approved colour used
47	PANTOPRAZOLE GASTRO-RESISTANT TABLETS IP 20MG	Each Gastro -Resistant tablet contains Pantoprazole Sodium IP Equivalent to Pantoprazole 20mg Excipients q.s Colour: Approved colour used
48	FLUCONAZOLE TABLETS IP 200MG	Each uncoated tablet contains Fluconazole IP 200mg Excipients q.s
49	DOMPERIDONE TABLETS IP 10MG	Each uncoated tablet contains Domperidone Maleate IP Equivalent to Domperidone 10mg Excipients q.s Colour: Approved Colour used
50	SILDENAFIL TABLETS IP 50MG	Each film coated tablet contains Sildenafil Citrate IP Equivalent to Sildenafil 50mg Excipients q.s Colour: Approved colour used
51	ACECLOFENAC & THIOLCHICOSIDE TABLETS	Each film coated tablet contains Aceclofenac IP 100mg Thiocolchicoside IP 4mg Excipients q.s Colour: Approved colour used
52	METFORMIN HYDROCHLORIDE PROLONGED RELEASE TABLETS IP 500MG	Each film coated prolonged release tablet contains Metformin Hydrochloride IP 500mg Excipients q.s Colour: Approved colour used

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S. No.	Product Name	Composition
53	METFORMIN HYDROCHLORIDE PROLONGED RELEASE TABLETS IP 850MG	Each film coated prolonged release tablet contains Metformin Hydrochloride IP 850mg Excipients q.s Colour: Approved colour used
54	CONTROLLED RELEASE TABLETS OF NITROGLYCERIN 2.6MG	Each uncoated tablet contains Diluted Nitroglycerin IP Equivalent to Nitroglycerin 2.6mg Excipients q.s Colour: Approved colour used
55	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 200MG	Each film coated controlled release tablet contains Magnesium Valproate 200mg Excipients q.s Colour: Approved colour used
56	NIMESULIDE TABLETS 100MG	Each uncoated tablet contains Nimesulide BP 100mg Excipients q.s Colour: Approved colour used
57	PARACETAMOL TABLETS IP 650MG	Each uncoated tablet contains Paracetamol IP 650mg Excipients q.s
58	PARACETAMOL TABLETS IP 500MG	Each uncoated tablet contains Paracetamol IP 500mg Excipients q.s
59	DICLOFENAC SODIUM & PARACETAMOL TABLETS	Each uncoated tablet contains: Diclofenac Sodium IP 50mg Paracetamol IP 325mg Excipients q.s
60	METOPROLOL TABLETS IP 100MG	Each film coated tablet contains Metoprolol Tartrate IP 100mg Excipients q.s Colour: Approved colour used
61	MONTELUKAST & OLOPATADINE TABLETS	Each film coated tablet contains Montelukast Sodium IP Equivalent to Montelukast 10mg Olopatadine Hydrochloride 5mg Excipients q.s Colour: Approved colour used
62	LEVETIRACETAM TABLETS IP	Each film coated tablet contains Levetiracetam IP 250mg Excipients q.s Colour: Approved colour used
63	LEVETIRACETAM TABLETS IP	Each film coated tablet contains Levetiracetam IP 500mg Excipients q.s Colour: Approved colour used
64	LEVETIRACETAM TABLETS IP	Each film coated tablet contains Levetiracetam IP 750mg Excipients q.s

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S. No.	Product Name	Composition
65	DOXOFYLINE TABLETS IP 400MG	Each uncoated tablet contains Doxofylline IP 400mg Excipients q.s
66	KETOCONAZOLE TABLETS IP 200MG	Each uncoated tablet contains Ketoconazole IP 200mg Excipients q.s
67	ILAPRAZOLE TABLETS	Each Enteric-coated tablet contains Ilaprazole 10mg Excipients q.s Colour: Approved colour used
68	TADALAFIL TABLETS 2.5MG	Each Film coated tablet contains Tadalafil IP 2.5mg Excipients q.s Colour: Approved colour used
69	TADALAFIL TABLETS IP 10MG	Each Film coated tablet contains Tadalafil IP 10mg Excipients q.s Colour: Approved colour used
70	TOLPERISONE HYDROCHLORIDE TABLETS 150MG	Each Film coated tablet contains Tolperisone Hydrochloride 150mg Excipients q.s Colour: Approved colour used
71	FLUPIRTINE MALEATE SUSTAINED RELEASE TABLETS	Each uncoated sustained release tablet contains Flupirtine Maleate 100mg Excipients q.s
72	ROXITHROMYCIN TABLETS IP 50MG	Each film coated tablet contains Roxithromycin IP 50mg Excipients q.s Colour: Approved colour used
73	AZITHROMYCIN TABLETS USP 250 MG (For Export)	Each film coated tablet contains: Azithromycin USP Equivalent to anhydrous Azithromycin 250mg Excipients q.s. Colour : Approved colour used
74	AZITHROMYCIN TABLETS USP 500 MG (For Export)	Each film coated tablet contains: Azithromycin USP Equivalent to anhydrous Azithromycin 500mg Excipients q.s. Colour : Approved colour used
75	SERRATIOPEPTIDASE TABLETS IP 10MG	Each film coated tablet contains Serratiopeptidase IP 10mg (as enteric coated granules) (20,000 Serratiopeptidase units) Excipients q.s Colour: Approved colour used

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S. No.	Product Name	Composition
76	NEBIVOLOL WITH S-AMLODIPINE TABLETS	Each film coated tablet contains Nebivolol Hydrochloride IP Equivalent to Nebivolol 5mg S-Amlodipine Besylate IP Equivalent to S-Amlodipine 2.5mg Excipients qs Colour : Approved colour used
77	LEVOCETRIZINE TABLETS IP	Each film coated tablet contains: Levocetirizine Hydrochloride IP 5mg Excipients qs Colour : Approved colour used
78	ETORICOXIB TABLETS IP	Each Film coated Tablet contains: Etoricoxib IP 60mg Excipients qs Colour : Approved colour used
79	ETORICOXIB TABLETS IP	Each Film coated Tablet contains: Etoricoxib IP 90mg Excipients qs Colour : Approved colour used
80	ETORICOXIB TABLETS IP	Each Film coated Tablet contains: Etoricoxib IP 120mg Excipients qs Colour : Approved colour used
81	NIMESULIDE & PARACETAMOL TABLETS	Each uncoated tablet contains: Nimesulide BP 100mg Paracetamol IP 325mg Excipients qs Colour : Approved colour used
82	BETAHISTINE TABLETS IP	Each uncoated tablet contains : Betahistine Hydrochloride IP 8mg Excipients qs Colour : Approved colour used
83	BETAHISTINE TABLETS IP	Each uncoated tablet contains : Betahistine Hydrochloride IP 16mg Excipients qs Colour : Approved colour used
84	BETAHISTINE TABLETS IP	Each uncoated tablet contains : Betahistine Hydrochloride IP 24mg Excipients qs Colour : Approved colour used
85	RAMIPRIL TABLETS IP	Each uncoated tablet contains: Ramipril IP 2.5mg Excipients qs

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S. No.	Product Name	Composition
93	PARACETAMOL AND PAMABROM TABLETS	Each Film-coated tablet contains: Paracetamol IP 325mg Pamabrom USP 25mg Excipients qs Colour: Approved colour used
94	ACETAMINOPHEN CHEWABLE TABLETS USP 80mg (For Export)	Each chewable Tablet contains: Acetaminophen USP 80mg Excipients qs
95	LORATADINE TABLETS USP 10mg (For Export)	Each uncoated tablet contains: Loratadine USP 10mg Excipients qs
96	ACETAMINOPHEN TABLETS USP 500mg (For Export)	Each tablet contains: Acetaminophen USP 500mg Excipients qs
97	FOLIC ACID TABLETS IP	Each uncoated tablet contains: Folic Acid IP 5mg Excipients qs Colour: Approved colour used
98	METFORMIN HYDROCHLORIDE PROLONGED-RELEASE AND GLIMEPIRIDE TABLETS IP	Each film coated tablet contains: Metformin Hydrochloride IP 500mg (As prolonged release form) Glimepiride IP 1mg Excipients qs Colour: Approved colour used
99	METFORMIN HYDROCHLORIDE PROLONGED-RELEASE AND GLIMEPIRIDE TABLETS IP	Each film coated tablet contains: Metformin Hydrochloride IP 500mg (As prolonged release form) Glimepiride IP 2mg Excipients qs Colour: Approved colour used
100	GLIMEPIRIDE TABLETS IP 1MG	Each uncoated tablet contains: Glimepiride IP 1mg Excipients qs Colour: Approved colour used
101	GLIMEPIRIDE TABLETS IP 2MG	Each uncoated tablet contains: Glimepiride IP 2mg Excipients qs Colour: Approved colour used
102	METFORMIN HYDROCHLORIDE SUSTAINED- RELEASE AND VOGLIBOSE TABLETS	Each film coated tablet contains: Metformin Hydrochloride IP 500mg (As sustained release form) Voglibose IP 0.3mg Excipients qs Colour: Approved colour used
103	ROSUVASTATIN TABLETS IP 5MG	Each film coated tablet contains: Rosuvastatin Calcium IP Equivalent to Rosuvastatin 5mg Excipients qs Colour: Approved colour used

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104	ROSUVASTATIN TABLETS IP 10MG	Each film coated tablet contains: Rosuvastatin Calcium IP Equivalent to Rosuvastatin 10mg Excipients qs Colour: Approved colour used
105	TELMISARTAN AND AMLODIPINE TABLETS IP	Each film coated tablet contains: Telmisartan IP 40mg Amlodipine Besylate IP Equivalent to Amlodipine 5mg Excipients qs Colour: Approved colour used
106	TELMISARTAN AND AMLODIPINE TABLETS IP	Each film coated tablet contains: Telmisartan IP 80mg Amlodipine Besylate IP Equivalent to Amlodipine 10mg Excipients qs Colour: Approved colour used
107	TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS IP	Each film coated tablet contains: Telmisartan IP 40mg Hydrochlorothiazide IP 12.5mg Excipients qs Colour: Approved colour used
108	TELMISARTAN AND HYDROCHLOROTHIAZIDE TABLETS IP	Each film coated tablet contains: Telmisartan IP 80mg Hydrochlorothiazide IP 12.5mg Excipients qs Colour: Approved colour used
109	IBUPROFEN TABLETS BP 400mg (For Export)	Each film coated tablet contains: Ibuprofen BP 400mg Excipients qs
110	IBUPROFEN TABLETS BP 600mg (For Export)	Each film coated tablet contains: Ibuprofen BP 600mg Excipients qs
111	IBUPROFEN TABLETS BP 800mg (For Export)	Each film coated tablet contains: Ibuprofen BP 800mg Excipients qs
112	RANITIDINE TABLETS BP 150mg (For Export)	Each film coated tablet contains: Ranitidine Hydrochloride BP Equivalent to Ranitidine 150mg Excipients qs
113	RANITIDINE TABLETS BP 300mg (For Export)	Each film coated tablet contains: Ranitidine Hydrochloride BP Equivalent to Ranitidine 300mg Excipients qs
114	ATENOLOL TABLETS BP 100mg (For Export)	Each uncoated tablet contains: Atenolol BP 100mg Excipients qs
115	ALBENDAZOLE TABLETS USP 400MG (For Export)	Each uncoated Chewable tablet contains: Albendazole USP 400mg Excipients q.s.; Colour: Approved colour used


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S. No.	Product Name	Composition
116	METRONIDAZOLE TABLETS BP 250MG (For Export)	Each uncoated tablet contains: Metronidazole BP 250mg Excipients q.s.
117	SALBUTAMOL TABLETS BP 4MG (For Export)	Each uncoated tablet contains: Salbutamol Sulfate BP 4mg Equivalent to Salbutamol Excipients q.s.
118	GRISEOFULVIN TABLETS BP 125MG (For Export)	Each uncoated tablet contains: Griseofulvin BP 125mg Excipients q.s.
119	CALCIUM & VITAMIN D3 TABLETS IP	Each Film-coated Tablet contains: Calcium Carbonate IP Equivalent to Elemental Calcium 500mg Vitamin D3 IP 250IU Excipients q.s. Colour: Approved colour used
120	CO-TRIMOXAZOLE TABLETS BP	Each uncoated tablet contains: Trimethoprim BP 80mg Sulfamethoxazole BP 400mg Excipients q.s.
121	CO-TRIMOXAZOLE TABLETS BP	Each uncoated tablet contains: Trimethoprim BP 160mg Sulfamethoxazole BP 800mg Excipients q.s.
122	METRONIDAZOLE TABLETS BP 250MG (For Export)	Each uncoated tablet contains: Metronidazole BP 250mg Excipients q.s. Colour: Approved colour used
123	ATORVASTATIN TABLETS IP 10MG	Each film coated tablet contains Atorvastatin Calcium IP Equivalent to Atorvastatin 10mg Excipients q.s. Colour: Approved colour used
124	ATORVASTATIN TABLETS IP 20MG	Each film coated tablet contains Atorvastatin Calcium IP Equivalent to Atorvastatin 20mg Excipients q.s. Colour: Approved colour used
125	ATORVASTATIN TABLETS IP 40MG	Each film coated tablet contains Atorvastatin Calcium IP Equivalent to Atorvastatin 40mg Excipients q.s. Colour: Approved colour used
126	ATORVASTATIN TABLETS IP 80MG	Each film coated tablet contains Atorvastatin Calcium IP Equivalent to Atorvastatin 80mg Excipients q.s. Colour: Approved colour used

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S. No.	Product Name	Composition
127	CALCIUM & VITAMIN D3 TABLETS IP 500MG	Each film coated tablet contains: Calcium Carbonate from an organic source (Oyster shell) Equivalent to Elemental Calcium 500mg Vitamin D3 IP 250IU Excipients q.s. Colour: Approved colour used
128	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE (Sustained release) TABLETS	Each film coated tablet contains: Glibenclamide IP 5mg Metformin Hydrochloride IP 850mg (as Sustained release) Excipients q.s. Colour: Approved colour used
129	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE (Sustained release) TABLETS	Each film coated tablet contains: Glibenclamide IP 2.5mg Metformin Hydrochloride IP 500mg (as Sustained release) Excipients q.s. Colour: Approved colour used
130	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE (Sustained release) TABLETS	Each film coated tablet contains: Glibenclamide IP 5mg Metformin Hydrochloride IP 500mg (as Sustained release) Excipients q.s. Colour: Approved colour used
131	GLIBENCLAMIDE AND METFORMIN HYDROCHLORIDE TABLETS IP	Each film coated tablet contains: Glibenclamide IP 2.5mg Metformin Hydrochloride IP 400mg Excipients q.s. Colour: Approved colour used
132	DICLOFENAC SODIUM AND SERRATIOPEPTIDASE TABLETS	Each film coated tablet contains: Diclofenac Sodium IP 50mg Serratiopeptidase IP 10mg Excipients q.s. Colour: Approved colour used
133	AMLODIPINE BESYLATE TABLETS USP 5MG (FOR EXPORT)	Each tablet contains: Amlodipine Besylate USP Equivalent to Amlodipine 5mg Excipients q.s. Colour: Approved colour used
134	AMLODIPINE BESYLATE TABLETS USP 10MG (FOR EXPORT)	Each tablet contains: Amlodipine Besylate USP Equivalent to Amlodipine 10mg Excipients q.s. Colour: Approved colour used
135	METRONIDAZOLE TABLETS BP 200MG (FOR EXPORT)	Each film coated tablet contains: Metronidazole BP 200mg Excipients q.s. Colour: Approved colour used

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S. No.	Product Name	Composition
136	VOGLIBOSE TABLETS IP 0.2MG	Each uncoated tablet contains: Voglibose IP 0.2MG Excipients qs Colour: Approved colour used
137	VOGLIBOSE TABLETS IP 0.3MG	Each uncoated tablet contains: Voglibose IP 0.3MG Excipients qs Colour: Approved colour used
138	DUTASTERIDE TABLETS 0.5MG	Each Film-coated tablet contains: Dutasteride IP 0.5MG Excipients qs Colour: Approved Colour used
139	THICOLCHICOSIDE TABLETS 4MG	Each Film-coated Tablets contains: Thiocolchicoside IP 4 MG Excipients qs Color: Approved Colour used
140	SILODOSIN TABLETS 4MG	Each Film-coated Tablets contains: Silodosin 4 MG Excipients qs Color: Approved Colour used
141	SILODOSIN TABLETS 8MG	Each Film-coated Tablets contains: Silodosin 8 MG Excipients qs Color: Approved Colour used
142	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 300MG	Each Film-coated Controlled Release Tablet contains: Magnesium Valproate 300 MG Excipients q.s Colour: Approved Colour used
143	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 400MG	Each Film-coated Controlled Release Tablet contains: Magnesium Valproate 400 MG Excipients q.s Colour: Approved Colour used
144	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 500MG	Each Film-coated Controlled Release Tablet contains: Magnesium Valproate 500 MG Excipients q.s Colour: Approved Colour used
145	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 200MG	Each Enteric-coated Controlled Release Tablet contains: Magnesium Valproate 200 MG Excipients q.s Colour: Approved Colour used
146	MAGNESIUM VALPROATE CONTROLLED RELEASE TABLETS 400MG	Each Enteric-coated Controlled Release Tablet contains: Magnesium Valproate 400 MG Excipients q.s Colour: Approved Colour used

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S. No.	Product Name	Composition
147	FUROSEMIDE TABLETS BP 40MG (FOR EXPORT)	Each uncoated tablet contains: Furosemide BP 40 MG Excipients q.s.
148	SECNIDAZOLE TABLETS 500MG (FOR EXPORT)	Each film coated tablet contains: Secnidazole 500 MG Excipients q.s.
149	ALBENDAZOLE CHEWABLE TABLETS USP 400MG (FOR EXPORT)	Each Uncoated Chewable Tablet contains: Albendazole USP 400 MG Excipients q.s.
150	ALBENDAZOLE CHEWABLE TABLETS USP 200MG (FOR EXPORT)	Each Uncoated Chewable Tablet contains: Albendazole USP 200 MG Excipients q.s.
151	DICLOFENAC POTASSIUM TABLETS USP 50MG (FOR EXPORT)	Each Film Coated Tablet contains: Diclofenac Potassium USP 50 MG Excipients q.s.
152	NITROFURANTOIN TABLETS USP 100MG (FOR EXPORT)	Each Uncoated Tablet contains: Nitrofurantoin USP 100 MG Excipients q.s.
153	ACICLOVIR TABLETS BP 200MG (FOR EXPORT)	Each tablet contains: Aciclovir BP 200 MG Excipients q.s.
154	ACICLOVIR TABLETS BP 400MG (FOR EXPORT)	Each tablet contains: Aciclovir BP 400 MG Excipients q.s.
155	ACICLOVIR TABLETS BP 800MG (FOR EXPORT)	Each tablet contains: Aciclovir BP 800 MG Excipients q.s.
156	ERYTHROMYCIN STEARATE TABLETS USP 500MG (FOR EXPORT)	Each film coated tablet contains: Erythromycin Stearate USP 500 MG Equivalent to Erythromycin Excipients q.s.
157	MELOXICAM TABLETS BP 7.5 MG (FOR EXPORT)	Each Tablet contains: Meloxicam BP 7.5 mg Excipients q.s.
158	MELOXICAM TABLETS BP 15 MG (FOR EXPORT)	Each Tablet contains: Meloxicam BP 15 mg Excipients q.s.
159	DESLOTRADINE TABLETS USP 5 MG (FOR EXPORT)	Each film coated tablet contains: Desloratadine USP 5 mg Excipients q.s.
160	HYDROCHLOROTHIAZIDE TABLETS BP 50 MG (FOR EXPORT)	Each tablet contains: Hydrochlorothiazide BP 50 mg Excipients q.s.
161	PANTOPRAZOLE SODIUM DELAYED RELEASE TABLETS USP 40 MG (FOR EXPORT)	Each delayed release tablet contains: Pantoprazole Sodium USP equivalent to Pantoprazole 40 mg Excipients q.s.
162	CHLORPHENIRAMINE MALEATE TABLETS USP 4 MG (FOR EXPORT)	Each tablet contains: Chlorpheniramine Maleate USP 4 mg Excipients q.s.

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S. No.	Product Name	Composition
163	DICLOFENAC TABLETS BP 50 MG (FOR EXPORT)	Each film coated tablet contains: Diclofenac Sodium BP 50 mg Excipients q.s.
164	DICLOFENAC TABLETS BP 100 MG (FOR EXPORT)	Each film coated tablet contains: Diclofenac Sodium BP 100 mg Excipients q.s.
165	RABEPRAZOLE ENTERIC COATED TABLETS 20 MG (FOR EXPORT)	Each enteric coated tablet contains: Rabeprazole Sodium 20 mg Excipients q.s.
166	PARACETAMOL SUSTAINED RELEASE TABLETS 1000MG	Each Uncoated bilayered tablet contains: Paracetamol IP (As Immediate release) 300 mg Paracetamol IP (As Sustained release) 700 mg Excipients q.s. Colour: Approved colour used.
167	VILDAGLIPTIN TABLETS 50 MG	Each tablet contains: Vildagliptin 50 mg Excipients q.s.
168	VILDAGLIPTIN TABLETS 100 MG	Each tablet contains: Vildagliptin 100 mg Excipients q.s.
169	VILDAGLIPTIN TABLETS 50 MG (FOR EXPORT)	Each tablet contains: Vildagliptin 50 mg Excipients q.s.
170	VILDAGLIPTIN TABLETS 100 MG (FOR EXPORT)	Each tablet contains: Vildagliptin 100 mg Excipients q.s.
171	RIFAXIMIN TABLETS 550 MG	Each film coated tablet contains: Rifaximin BP 550 mg Excipients q.s. Colour: Approved colour used.
172	RIFAXIMIN TABLETS 200 MG	Each film coated tablet contains: Rifaximin BP 200 mg Excipients q.s. Colour: Approved colour used.
173	RIFAXIMIN TABLETS 400 MG	Each film coated tablet contains: Rifaximin BP 400 mg Excipients q.s. Colour: Approved colour used.
174	RIFAXIMIN DISPERSIBLE TABLETS	Each uncoated dispersible tablet contains: Rifaximin BP 200 mg Excipients q.s. Colour: Approved colour used.
175	METOCLOPRAMIDE TABLETS BP 10 MG (FOR EXPORT)	Each Uncoated tablet contains: Metoclopramide Hydrochloride BP Eq. to Anhydrous Metoclopramide Hydrochloride 10 mg Excipients q.s.
176	METRONIDAZOLE TABLETS BP 500 MG (FOR EXPORT)	Each film coated tablet contains: Metronidazole BP 500 mg Excipients q.s.

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S. No.	Product Name	Composition
177	TINIDAZOLE TABLETS 500 MG (FOR EXPORT)	Each film coated tablet contains: Tinidazole BP 500 mg Excipients q.s
178	TENELIGLIPTIN TABLETS 20 MG	Each film coated tablet contains: Teneligliptin Hydrobromide Hydrate Eq. to Teneligliptin 20 mg Excipients q.s Colour: Approved colour used
179	GASTRO-RESISTANT DICLOFENAC TABLETS BP 50 MG (FOR EXPORT)	Each enteric coated tablet contains: Diclofenac Sodium BP 50 mg Excipients q.s.
180	GASTRO-RESISTANT DICLOFENAC TABLETS BP 100 MG (FOR EXPORT)	Each enteric coated tablet contains: Diclofenac Sodium BP 100 mg Excipients q.s.
181	ALLOPURINOL TABLETS USP 300 MG (FOR EXPORT)	Each tablet contains: Allopurinol USP 300 mg Excipients q.s
182	ESOMEPRAZOLE DELAYED RELEASE TABLETS 40 MG (FOR EXPORT)	Each enteric coated tablet contains: Esomeprazole Magnesium trihydrate USP Equivalent to Esomeprazole 40 mg Excipients q.s.
183	LOSARTAN POTASSIUM TABLETS USP 50 MG (FOR EXPORT)	Each film coated tablet contains: Losartan Potassium USP 50 mg Excipients q.s
184	TELMISARTAN TABLETS USP 80 MG (FOR EXPORT)	Each film coated tablet contains: Telmisartan USP 80 mg Excipients q.s.
185	SIMVASTATIN TABLETS USP 20 MG (FOR EXPORT)	Each film coated tablet contains: Simvastatin USP 20 mg Excipients q.s.
186	SIMVASTATIN TABLETS USP 40 MG (FOR EXPORT)	Each film coated tablet contains: Simvastatin USP 40 mg Excipients q.s.
187	ATORVASTATIN CALCIUM TABLETS USP 40 MG (FOR EXPORT)	Each film coated tablet contains: Atorvastatin Calcium USP equivalent to Atorvastatin 40 mg Excipients q.s.
188	CLARITHROMYCIN TABLETS USP 500 MG (FOR EXPORT)	Each film coated tablet contains: Clarithromycin USP 500 mg Excipients q.s.
189	CHLORPHENAMINE MALEATE TABLETS BP 4 MG (FOR EXPORT)	Each tablet contains: Chlorphenamine Maleate BP 4 mg Excipients q.s.
190	CARBAMAZEPINE TABLETS BP 200 MG (FOR EXPORT)	Each tablet contains: Carbamazepine BP 200 mg Excipients q.s.
191	SALBUTAMOL TABLETS BP 4MG (FOR EXPORT)	Each tablet contains: Salbutamol Sulphate BP Equivalent to Salbutamol 4 mg Excipients q.s.

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S. No.	Product Name	Composition
192	CO-TRIMOXAZOLE TABLETS BP 960 MG (FOR EXPORT)	Each uncoated tablet contains: Trimethoprim BP 160 mg Sulfamethoxazole BP 800 mg Excipients q.s.
193	FUROSEMIDE TABLETS BP 500MG (FOR EXPORT)	Each uncoated tablet contains: Furosemide BP 500 mg Excipients q.s.
194	SILDENAFIL CITRATE TABLETS 100 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP 100 mg Excipients q.s.
195	SILDENAFIL TABLETS USP 100 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP Equivalent to sildenafil 100 mg Excipients q.s.
196	CIPROFLOXACIN AND TINIDAZOLE TABLETS (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 250 mg Tinidazole BP 300 mg Excipients q.s.
197	SILDENAFIL TABLETS USP 50 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP equivalent to sildenafil 50 mg Excipients q.s.
198	ONDANSETRON ORALLY DISINTEGRATING TABLETS IP	Each uncoated tablet contains: Ondansetron Hydrochloride IP equivalent to Ondansetron 4 mg Excipients q.s. Colour: Approved colour used.
199	CLOPIDOGREL TABLETS IP 75 MG	Each film coated tablet contains: Clopidogrel Bisulphate equivalent to clopidogrel 75 mg Excipients q.s.
200	SILDENAFIL CITRATE TABLETS 50 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP 50 mg Excipients q.s.
201	DICLOFENAC SODIUM & SERRATIOPEPTIDASE TABLETS	Each enteric coated tablet contains : Diclofenac Sodium IP 50 mg Serratiopeptidase IP 10 mg (equivalent to 20,000 enzyme activity units of Serratiopeptidase) Excipients q.s. Colour: Approved colour used.
202	DEFLAZACORT TABLETS	Each film coated tablet contains: Deflazacort 6 mg Excipients q.s. Colour: Approved colour used.

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S. No.	Product Name	Composition
203	LEVOFLOXACIN TABLETS USP 250 MG (FOR EXPORT)	Each film coated tablet contains: Levofloxacin Hemihydrate USP Equivalent to Levofloxacin 250 mg Excipients q.s. Colour: Approved colour used.
204	LEVOFLOXACIN TABLETS USP 500 MG (FOR EXPORT)	Each film coated tablet contains: Levofloxacin Hemihydrate USP Equivalent to Levofloxacin 500 mg Excipients q.s. Colour: Approved colour used.
205	LEVOFLOXACIN TABLETS USP 750 MG (FOR EXPORT)	Each film coated tablet contains: Levofloxacin Hemihydrate USP Equivalent to Levofloxacin 750 mg Excipients q.s. Colour: Approved colour used.
206	FLUCONAZOLE TABLET USP 150 MG (FOR EXPORT)	Each film coated tablet contains: Fluconazole USP 150 mg Excipients q.s. Colour: Approved colour used.
207	GLIBENCLAMIDE TABLETS BP 5 MG (FOR EXPORT)	Each uncoated tablet contains: Glibenclamide BP 5 mg Excipients q.s.
208	GLIPIZIDE TABLETS BP 10 MG (FOR EXPORT)	Each uncoated tablet contains: Glipizide BP 10 mg Excipients q.s.
209	CLARITHROMYCIN TABLETS USP 250 MG (FOR EXPORT)	Each film coated tablet contains: Clarithromycin USP 250 mg Excipients q.s. Colour: Approved colour used.
210	MULTIVITAMINS & MINERALS (FOR EXPORT)	Each Film-coated Tablet contains: Vitamin A (as acetate) USP 3333IU Cholecalciferol (Vitamin-D3) USP 400 IU Thiamin Nitrate BP 10mg Riboflavin BP 2.5mg Pyridoxine Hydrochloride BP 3mg Cyanocobalamin BP 5mcg Ascorbic Acid BP 75mg Vitamin E (Alpha Tocopherol acetate) USP 10mg (16.7units) Nicotinamide BP 20mg Folic Acid BP 1mg Ferrous Fumarate BP 60mg Copper (as Cupric Oxide) 2mg Manganese (as Manganese Sulfate USP) 2mg Elemental Zinc (as Zinc Acetate BP) 15mg Iodine (as Potassium Iodide BP) 100mcg Magnesium (as Light Magnesium Oxide BP) 100mg Calcium Pantothenate BP 5mg Elemental Calcium (as Calcium Carbonate BP)

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		100mg Potassium (as Potassium Sulphate BP) 1mg Elemental Selenium (as Sodium Selenite BP) 40mcg Elemental Chromium (as Chromic Chloride USP) 25mcg Excipients qs Colour: Approved colour used
211	VILDAGLIPTIN 50 MG AND METFORMIN HCl 500 MG TABLETS	Each film coated tablet contains: Vildagliptin 50 mg Metformin HCl IP 500 mg Excipient q.s. Colour: Approved colour used.
212	VILDAGLIPTIN 50 MG AND METFORMIN HCl 850 MG TABLETS	Each film coated tablet contains: Vildagliptin 50 mg Metformin HCl IP 850 mg Excipient q.s. Colour: Approved colour used.
213	VILDAGLIPTIN 50 MG AND METFORMIN HCl 1000 MG TABLETS	Each film coated tablet contains: Vildagliptin 50 mg Metformin HCl IP 1000 mg Excipient q.s. Colour: Approved colour used.
214	LEVOCETIRIZINE DIHYDROCHLORIDE TABLETS USP 5 MG (FOR EXPORT)	Each film coated tablet contains: Levocetirizine Dihydrochloride USP 5 mg Excipients q.s.
215	METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS USP 1000 MG (FOR EXPORT)	Each uncoated extended release tablet contains: Metformin Hydrochloride USP 1000 mg Excipients q.s.
216	METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS USP 850 MG (FOR EXPORT)	Each uncoated extended release tablet contains: Metformin Hydrochloride USP 850 mg Excipients q.s.
217	METFORMIN HYDROCHLORIDE EXTENDED RELEASE TABLETS USP 500 MG (FOR EXPORT)	Each uncoated extended release tablet contains: Metformin Hydrochloride USP 500 mg Excipients q.s.
218	SILDENAFIL CITRATE TABLETS 25 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP 25 mg Excipients q.s.
219	SILDENAFIL TABLETS USP 25 MG (FOR EXPORT)	Each film coated tablet contains: Sildenafil citrate USP equivalent to sildenafil 25 mg Excipients q.s.
220	VOGLIBOSE & METFORMIN HYDROCHLORIDE TABLETS (FOR EXPORT)	Each film coated tablet contains: Voglibose 0.2 mg Metformin Hydrochloride BP 500 mg Excipients q.s.
221	SERRATIOPEPTIDASE TABLETS 10 MG (FOR EXPORT)	Each film coated tablet contains: Serratiopeptidase 10 mg (equivalent to 20,000 enzyme activity units of Serratiopeptidase) Excipients q.s.

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S. No.	Product Name	Composition
222	SERRATIOPEPTIDASE TABLETS 5 MG (FOR EXPORT)	Each film coated tablet contains: Serratiopeptidase 5 mg (equivalent to 10, 000 enzyme activity units of Serratiopeptidase) Excipients q.s.
223	HYDROXYCHLOROQUINE TABLETS IP 200 MG	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 200 mg
224	HYDROXYCHLOROQUINE TABLETS IP 300 MG	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 300 mg
225	HYDROXYCHLOROQUINE TABLETS IP 400 MG	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 400 mg
226	AZITHROMYCIN TABLETS IP 250 MG	Each film coated tablet contains: Azithromycin IP Equivalent to Anhydrous Azithromycin 250 mg
227	AZITHROMYCIN TABLETS IP 500 MG	Each film coated tablet contains: Azithromycin IP Equivalent to Anhydrous Azithromycin 500 mg
228	METFORMIN HYDROCHLORIDE TABLETS IP 500 MG	Each uncoated tablet contains: Metformin Hydrochloride IP 500 mg
229	SALBUTAMOL TABLETS BP 2 MG (FOR EXPORT)	Each uncoated tablet contains: Salbutamol Sulfate BP Equivalent to Salbutamol 2 mg
230	PREDNISONE TABLETS USP 10 MG (FOR EXPORT)	Each uncoated tablet contains: Prednisone USP 10 mg
231	PREDNISONE TABLETS USP 5 MG (FOR EXPORT)	Each uncoated tablet contains: Prednisone USP 5 mg
232	IVERMECTIN TABLETS USP 6 MG (FOR EXPORT)	Each uncoated tablet contains: Ivermectin USP 6 mg
233	ENALAPRIL TABLETS BP 2.5 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate BP 2.5 mg
234	ENALAPRIL TABLETS BP 5 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate BP 5 mg
235	ENALAPRIL TABLETS BP 10 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate BP 10 mg
236	ENALAPRIL TABLETS BP 20 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate BP 20 mg
237	ENALAPRIL MALEATE TABLETS USP 2.5 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate USP 2.5 MG
238	ENALAPRIL MALEATE TABLETS USP 5 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate USP 5 MG
239	ENALAPRIL MALEATE TABLETS USP 10 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate USP 10 MG
240	ENALAPRIL MALEATE TABLETS USP 20 MG (FOR EXPORT)	Each uncoated tablet contains: Enalapril Maleate USP 20 MG

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S. No.	Product Name	Composition
241	NIMESULIDE & PARACETAMOL TABLETS (FOR EXPORT)	Each uncoated tablet contains: Nimesulide BP 100mg Paracetamol BP 325mg Excipients qs
242	DICLOFENAC SODIUM AND PARACETAMOL TABLETS (FOR EXPORT)	Each uncoated tablet contains: Diclofenac Sodium BP 50 mg Paracetamol BP 500 mg Excipients q.s.
243	LORATADINE TABLETS USP 10mg (FOR EXPORT)	Each film coated tablet contains: Loratadine USP 10 mg Excipients q.s.
244	METFORMIN PROLONGED-RELEASE TABLETS BP (FOR EXPORT)	Each Uncoated Prolonged-release tablet contains: Metformin Hydrochloride BP 500mg Excipients q.s
245	METFORMIN PROLONGED-RELEASE TABLETS BP (FOR EXPORT)	Each Uncoated Prolonged-release tablet contains: Metformin Hydrochloride BP 1000mg Excipients q.s
246	METFORMIN PROLONGED-RELEASE TABLETS BP (FOR EXPORT)	Each Uncoated Prolonged-release tablet contains: Metformin Hydrochloride BP 850mg Excipients q.s
247	ROXITHROMYCIN TABLETS IP 150 MG	Each film coated tablet contains: Roxithromycin IP 150 mg Excipients q.s
248	ROXITHROMYCIN TABLETS IP 300 MG	Each film coated tablet contains: Roxithromycin IP 300 mg Excipients q.s
249	LEVETIRACETAM TABLETS USP 250 MG (FOR EXPORT)	Each film coated tablet contains: Levetiracetam USP 250mg Excipients q.s
250	LEVETIRACETAM TABLETS USP 500 MG (FOR EXPORT)	Each film coated tablet contains: Levetiracetam USP 500mg Excipients q.s
251	LEVETIRACETAM TABLETS USP 750 MG (FOR EXPORT)	Each film coated tablet contains: Levetiracetam USP 750mg Excipients q.s
252	OFLOXACIN TABLETS USP 200MG (FOR EXPORT)	Each film coated tablet contains: Ofloxacin USP 200mg Excipients qs
253	OFLOXACIN AND ORNIDAZOLE TABLETS (FOR EXPORT)	Each film coated tablet contains: Ofloxacin USP 200mg Ornidazole 500mg Excipients qs
254	LEVOCETIRIZINE HYDROCHLORIDE AND MONTELUKAST SODIUM TABLETS (FOR EXPORT)	Each film coated tablet contains: Levocetirizine hydrochloride USP 5mg Montelukast Sodium Equivalent to Montelukast USP 10mg Excipients qs

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S. No.	Product Name	Composition
255	CIPROFLOXACIN TABLETS BP 250 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin 250 mg
256	CIPROFLOXACIN TABLETS BP 500 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin 500 mg
257	CIPROFLOXACIN TABLETS BP 750 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride BP Equivalent to Ciprofloxacin 750 mg
258	CIPROFLOXACIN TABLETS USP 250 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 250 mg
259	CIPROFLOXACIN TABLETS USP 500 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 500 mg
260	CIPROFLOXACIN TABLETS USP 750 MG (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 750 mg
261	TRAZODONE HYDROCHLORIDE TABLETS BP 100MG (FOR EXPORT)	Each film coated tablet contains: Trazodone Hydrochloride BP 100mg Excipients q.s
262	LORATADINE TABLETS BP 10mg (FOR EXPORT)	Each uncoated tablet contains: Loratadine BP 10mg Excipients q.s
263	LORATADINE TABLETS BP 10mg (FOR EXPORT)	Each film coated tablet contains: Loratadine BP 10mg Excipients q.s
264	ALLOPURINOL TABLETS BP 300 MG (FOR EXPORT)	Each tablet contains: Allopurinol BP 300 mg Excipients q.s
265	ERYTHROMYCIN STEARATE TABLETS BP 500 MG (FOR EXPORT)	Each film coated tablet contains: Erythromycin Stearate BP 500 MG Equivalent to Erythromycin Excipients q.s.
266	COLECALCIFEROL TABLETS BP (FOR EXPORT)	Each film coated tablet contains: Colecalciferol BP (Vitamin D3) 5000 IU Excipients q.s.
267	CHEWABLE ASCORBIC ACID TABLETS BP 500 MG (FOR EXPORT)	Each Uncoated Chewable tablet contains: Ascorbic Acid BP 500 mg Excipients q.s.
268	ASCORBIC ACID CHEWABLE TABLETS IP 500 MG	Each Uncoated Chewable tablet contains: Ascorbic Acid IP 500 mg Excipients q.s.
269	ASCORBIC ACID TABLETS IP 100 MG	Each Uncoated tablet contains: Ascorbic Acid IP 100 mg Excipients q.s.
270	AMLODIPINE BESYLATE TABLETS BP 5MG (FOR EXPORT)	Each tablet contains: Amlodipine Besylate BP Equivalent to Amlodipine 5 mg Excipients q.s.

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S. No.	Product Name	Composition
271	AMLODIPINE BESYLATE TABLETS BP 10MG (FOR EXPORT)	Each tablet contains: Amlodipine Besylate BP Equivalent to Amlodipine 10 mg Excipients q.s.
272	PANTOPRAZOLE SODIUM DELAYED RELEASE TABLETS BP 40 MG (FOR EXPORT)	Each delayed release tablet contains: Pantoprazole Sodium BP equivalent to Pantoprazole 40 mg Excipients q.s.
273	CLOMIPRAMINE HYDROCHLORIDE PROLONGED RELEASE TABLETS 75 MG (CLOPRAMINE PR 75)	Each film coated prolonged release tablet contains: Clomipramine Hydrochloride IP 75 mg
274	TENELIGLIPTIN AND METFORMIN TABLETS	Each uncoated tablet contains Teneligliptin Hydrobromide Hydrate IP equivalent to Teneligliptin 20 mg Metformin hydrochloride IP 500 mg (as sustained release)
275	TENELIGLIPTIN AND METFORMIN TABLETS	Each uncoated tablet contains Teneligliptin Hydrobromide Hydrate IP equivalent to Teneligliptin 20 mg Metformin hydrochloride IP 1000 mg (as sustained release)
276	PREGABALIN AND NORTRIPTYLINE TABLETS	Each film coated tablet contains Pregabalin IP 75 mg Nortriptyline Hydrochloride IP equivalent to Nortriptyline 10 mg Excipients q.s. Colour: Approved colour used
277	GABAPENTIN AND NORTRIPTYLINE TABLETS	Each film coated tablet contains Gabapentin IP 100 mg Nortriptyline hydrochloride IP equivalent to Nortriptyline 10 mg Excipients q.s. Colour: Approved colour used
278	ARIPIRAZOLE TABLETS IP 5 mg	Each uncoated tablet contains Aripiprazole IP 5 mg
279	METHYLDOPA TABLETS IP 250 mg	Each film coated tablet contains Methyldopa IP equivalent to anhydrous Methyldopa 250 mg
280	ERYTHROMYCIN STEARATE TABLETS IP 250 mg	Each film coated tablet contains Erythromycin Stearate IP equivalent to Erythromycin 250 mg
281	ERYTHROMYCIN STEARATE TABLETS IP 500 mg	Each film coated tablet contains Erythromycin Stearate IP equivalent to Erythromycin 500 mg
282	LEVOFLOXACIN TABLETS IP 250 mg	Each film coated tablet contains Levofloxacin Hemihydrate IP equivalent to Levofloxacin 250 mg Excipients q.s. Colour: Approved colour used


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S. No.	Product Name	Composition
283	LEVOFLOXACIN TABLETS IP 500 mg	Each film coated tablet contains Levofloxacin Hemihydrate IP equivalent to Levofloxacin 500 mg Excipients q.s. Colour: Approved colour used
284	ENALAPRIL MALEATE TABLETS IP 5 mg	Each uncoated tablet contains Enalapril Maleate IP 5 mg Excipients q.s.
285	ENALAPRIL MALEATE TABLETS IP 10 mg	Each uncoated tablet contains Enalapril Maleate IP 10 mg Excipients q.s.
286	LAMIVUDINE TABLETS IP 100 mg	Each film coated tablet contains Lamivudine IP 100 mg Excipients q.s. Colour: Approved colour used
287	MONTELUKAST SODIUM AND LEVOCETIRIZINE HYDROCHLORIDE TABLETS IP	Each uncoated tablet contains Montelukast Sodium IP Equivalent to Montelukast 10mg Levocetirizine Hydrochloride IP 5mg Excipients q.s. Colour: Approved colour used
288	LISINOPRIL TABLETS BP 10 mg (FOR EXPORT)	Each uncoated tablet contains Lisinopril dihydrate BP equivalent to Lisinopril 10 mg
289	LISINOPRIL TABLETS BP 20 mg (FOR EXPORT)	Each uncoated tablet contains Lisinopril dihydrate BP equivalent to Lisinopril 20 mg
290	BROMOCRIPTINE TABLETS BP 2.5 mg (FOR EXPORT)	Each uncoated tablet contains Bromocriptine Mesilate BP equivalent to Bromocriptine 2.5 mg
291	SILDENAFIL TABLETS IP 25 mg	Each film coated tablet contains: Sildenafil Citrate IP Equivalent to Sildenafil 25 mg
292	SILDENAFIL TABLETS IP 100 mg	Each film coated tablet contains: Sildenafil Citrate IP Equivalent to Sildenafil 100 mg
293	SERRATIOPEPTIDASE TABLETS IP 5 mg	Each film coated tablet contains: Serratiopeptidase IP 5 mg (as enteric coated granules equivalent to 10, 000 enzyme activity units of Serratiopeptidase)
294	APIXABAN TABLETS 2.5 mg	Each film coated tablet contains Apixaban ..... 2.5mg
295	APIXABAN TABLETS 5.0 mg	Each film coated tablet contains Apixaban ..... 5.0mg
296	ASTROVASTATIN CALCIUM TABLETS USP 20 mg (ATORCAP) (FOR EXPORT)	Each film coated tablet contains: Atorvastatin Calcium USP equivalent to Atorvastatin 20 mg

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S. No.	Product Name	Composition
297	CIPROFLOXACIN AND TINIDAZOLE TABLETS (FOR EXPORT)	Each film coated tablet contains: Ciprofloxacin Hydrochloride USP Equivalent to Ciprofloxacin 500 mg Tinidazole BP 600 mg
298	PANTOPRAZOLE SODIUM GASTRO-RESISTANT TABLETS IP 40 mg	Each Gastro-resistant tablet contains: Pantoprazole sodium IP Equivalent to Pantoprazole 40 mg
299	BETAHISTINE TABLETS IP 16 mg	Each uncoated tablet contains: Betahistine Hydrochloride IP 16mg
300	PANTOPRAZOLE SODIUM GASTRO-RESISTANT TABLETS IP 40 mg	Each Gastro-resistant tablet contains: Pantoprazole Sodium IP Equivalent to Pantoprazole 40mg
301	RABEPRAZOLE GASTRO-RESISTANT TABLETS IP 40 mg	Each Gastro-resistant tablet contains: Rabeprazole Sodium IP 20mg
302	ACECLOFENAC WITH THIOLCHOLCHICOSIDE TABLETS	Each Film Coated tablet contains: Thiocolchicoside IP 4 mg Aceclofenac IP 100mg
303	DIVALPROEX SODIUM TABLETS IP 250MG	Each enteric coated tablet contains: Divalproex Sodium IP equivalent to Valproic Acid 250mg
303	DIVALPROEX EXTENDED RELEASE TABLETS IP 250MG	Each film coated extended release tablet contains: Divalproex Sodium IP equivalent to Valproic Acid 250mg

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## Capsules

S. No.	Product Name	Composition
1	GASTRO-RESISTANT OMEPRAZOLE CAPSULES BP 20MG (For Export)	Each hard gelatin capsule contains: Omeprazole BP 20mg (as enteric coated pellets)
2	RABEPRAZOLE GASTRO RESISTANT AND DOMPERIDONE SUSTAINED RELEASE CAPSULES	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20mg (as Enteric coated Pellets) Domperidone IP 30mg (as sustained release form) Colour: Approved colour used
3	LANSOPRAZOLE GASTRO-RESISTANT CAPSULES IP	Each hard gelatin capsule contains: Lansoprazole IP 15mg (As Enteric coated Pellets)
4	ATORVASTATIN AND ASPIRIN CAPSULES	Each hard gelatin capsule contains: Atorvastatin Calcium IP Equivalent to Atorvastatin 10mg Aspirin IP 75mg
5	ATORVASTATIN AND ASPIRIN CAPSULES	Each hard gelatin capsule contains: Atorvastatin Calcium IP 10mg Equivalent to Atorvastatin 150mg Aspirin IP
6	PANTOPRAZOLE GASTRO RESISTANT AND DOMPERIDONE PROLONGED RELEASE CAPSULES IP	Each hard gelatin capsule contains: Pantoprazole sodium IP Equivalent to Pantoprazole 40mg (as enteric coated pellets) Domperidone Maleate IP 30mg Equivalent to Domperidone (as sustained release pellets)
7	ASPIRIN GASTRO-RESISTANT AND ROSUVASTATIN CAPSULES	Each hard gelatin capsule contains Aspirin Gastro-resistant Tablets IP 75mg Rosuvastatin Calcium IP Equivalent to Rosuvastatin 5mg (as graules)
8	ASPIRIN GASTRO-RESISTANT AND ROSUVASTATIN CAPSULES	Each hard gelatin capsule contains Aspirin Gastro-resistant Tablets IP 75mg Rosuvastatin Calcium IP Equivalent to Rosuvastatin 10mg (as graules)
9	TAMSULOSIN PROLONGED-RELEASE CAPSULES IP 0.4MG	Each hard gelatin capsule contains Tamsulosin Hydrochloride IP 0.4mg (As prolonged release pellets)
10	RABEPRAZOLE GASTRO-RESISTANT AND LEVOSULPIRIDE (SUSTAINED RELEASE) CAPSULES	Each hard gelatin capsule contains Rabeprazole Sodium IP 20mg (as Enteric coated pellets) Levosulpiride 75mg (As sustained release tablet) Excipients q.s

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S. No.	Product Name	Composition
11	PREGABALIN & MECOBALAMIN CAPSULES IP	Each hard gelatin capsule contains: Pregabalin IP 75mg Mecobalamin IP 750mcg Excipients qs
12	THIOLCHICOSIDE CAPSULES IP 4MG	Each hard gelatin capsule contains Thiolchicoside IP 4mg Excipients q.s
13	THIOLCHICOSIDE CAPSULES IP 8MG	Each hard gelatin capsule contains Thiolchicoside IP 8mg Excipients q.s
14	DIACERIN CAPSULES IP 50MG	Each hard gelatin capsule contains Diacerin IP 50mg Excipients q.s
15	ACEBROPHYLLINE CAPSULES 100MG	Each hard gelatin capsule contains: Acebrophylline 100mg Excipients q.s
16	RACECADOTRIL CAPSULES 100MG	Each hard gelatin capsule contains Racecadotril 100mg Excipients q.s
17	OMEPRAZOLE CAPSULES IP 20MG	Each hard gelatin capsule contains Omeprazole IP 20mg Excipients q.s
18	CALCIUM DOBESILATE CAPSULES	Each hard gelatin capsule contains Calcium Dobesilate Monohydrate BP 500mg Excipients q.s
19	SILODOSIN CAPSULES	Each hard gelatin capsule contains Silodosin 4mg Excipients q.s
20	SILODOSIN CAPSULES	Each hard gelatin capsule contains Silodosin 8mg Excipients q.s
21	ITRACONAZOLE CAPSULES	Each hard gelatin capsule contains Itraconazole USP 100mg (as pellets) Excipients q.s
22	DOXYCYCLINE CAPSULES IP 100MG	Each hard gelatin capsule contains Doxycycline Hydrochloride IP Equivalent to Doxycycline 100mg Excipients q.s
23	DOXYCYCLINE CAPSULES IP 200MG	Each hard gelatin capsule contains Doxycycline Hydrochloride IP Equivalent to Doxycycline 200mg Excipients q.s
24	KETOPROFEN CAPSULES IP 50 MG	Each hard gelatin Capsule Contains: Ketoprofen IP 50 mg Excipients q.s.
25	GASTRO-RESISTANT OMEPRAZOLE CAPSULES BP 40MG (FOR EXPORT)	Each hard gelatin capsule contains: Omeprazole BP 40mg (as enteric coated pellets)



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S. No.	Product Name	Composition
26	PIROXICAM CAPSULES BP 10 MG (FOR EXPORT)	Each hard gelatin capsule contains: Piroxicam BP 10 mg
27	PIROXICAM CAPSULES BP 20 MG (FOR EXPORT)	Each hard gelatin capsule contains: Piroxicam BP 20 mg
28	PIROXICAM CAPSULES USP 10 MG (FOR EXPORT)	Each hard gelatin capsule contains: Piroxicam USP 10 mg
29	PIROXICAM CAPSULES USP 20 MG (FOR EXPORT)	Each hard gelatin capsule contains: Piroxicam USP 20 mg
30	RABEPRAZOLE AND DOMPERIDONE CAPSULES (FOR EXPORT)	Each capsule contains: Rabeprazole Sodium BP 20mg (as enteric coated pellets) Domperidone BP 30mg (as sustained released pellets ) Excipients qs
31	INDOMETHACIN CAPSULES USP 25 MG (FOR EXPORT)	Each hard gelatin capsule contains: Indomethacin USP 25 mg
32	INDOMETHACIN CAPSULES USP 50 MG (FOR EXPORT)	Each hard gelatin capsule contains: Indomethacin USP 50 mg
33	TETRACYCLINE CAPSULES BP 250 MG (FOR EXPORT)	Each hard gelatin capsule contain: Tetracycline Hydrochloride BP 250 mg
34	TETRACYCLINE CAPSULES BP 500 MG (FOR EXPORT)	Each hard gelatin capsule contain: Tetracycline Hydrochloride BP 500 mg
35	TETRACYCLINE HYDROCHLORIDE CAPSULES USP 250 MG (FOR EXPORT)	Each hard gelatin capsule contain: Tetracycline Hydrochloride USP 250 mg
36	TETRACYCLINE HYDROCHLORIDE CAPSULES USP 500 MG (FOR EXPORT)	Each hard gelatin capsule contain: Tetracycline Hydrochloride USP 500 mg
37	RACECADOTRIL CAPSULES 100 MG IP	Each hard gelatin capsule contains : Racecadotril IP 100 mg
38	PREGABALIN CAPSULES IP 75 mg	Each hard gelatin capsule contains Pregabalin IP 75 mg
39	PREGABALIN CAPSULES IP 150 mg	Each hard gelatin capsule contains Pregabalin IP 150 mg
40	PREGABALIN CAPSULES IP 300 mg	Each hard gelatin capsule contains Pregabalin IP 300 mg
41	OMEPRAZOLE GASTRO - RESISTANT CAPSULES IP 40 MG	Each hard gelatin capsule contains: Omeprazole IP 40 mg (as enteric coated pellets)
42	RABEPRAZOLE SODIUM AND DOMPERIDONE (SR) CAPSULES	Each hard gelatin Capsule contains: Rabeprazole Sodium IP 20mg (as enteric coated Pellets) Domperidone IP 30mg (as sustained release pellets)

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**Powders**

S. No.	Product Name	Composition
1	SACCHROMYCES BOULARDII SACHETS	Each Sachet contains: Lyophilized Sacchromyces Boulardii 282.5mg (Corresponding to 250 mg of yeast) Excipient qs.
2	MONTELUKAST GRAULES 4MG/SACHET	Each Sachet contains: Montelukast Sodium IP Equivalent to Montelukast 4mg Excipient qs.
3	PARACETAMOL AND PHENYLEPHRINE GRANULES	Each Sachet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Excipients qs
4	ORAL REHDRATION SALTS IP	Each Sachet Contains: Sodium Chloride IP 2.6g Dextrose(anhydrous) IP 13.5g Potassium Chloride IP 1.5g Sodium Citrate IP 2.9g Excipients q.s
5	ORAL REHYDRATION SALTS BP (For Export)	Each Sachet contains: Sodium Chloride BP 2.6g Potassium Chloride BP 1.5g Sodium Citrate BP 2.9g Anhydrous Glucose BP 13.5g Excipients q.s
6	POLYETHYLENE GLYCOL GRANULES	Each Sachet 17g contains Polyethylene Glycol 3350 USP 17g
7	POLYETHYLENE GLYCOL GRANULES	Each Sachet 8.5g contains Polyethylene Glycol 3350 USP 8.5g
8	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet(15g) contains: L-Arginine IP 5g Zinc Sulphate Monohydrate IP Equivalent to elemental Zinc 10mg Folic Acid IP 2.5mg Excipients q.s Colour: Approved colour used
9	L-ARGININE, L-LEUCINE, L-ISOLEUCINE, L-VALINE, L-LYSINE, L-PHENYLALANINE AND GLYCINE SACHET	Each sachet (7.5g) contains: L-Arginine IP 3g L-Leucine USP 125mg L-Isoleucine USP 100mg L-Valine USP 75mg L-Lysine Hydrochloride USP150mg L-Phenylalanine USP 50mg Glycine IP 50mg Excipients q.s. Colour: Approved colour used



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S. No.	Product Name	Composition
10	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet(10g) contains: L-Arginine IP 3g Zinc Sulphate Monohydrate IP Equivalent to elemental Zinc 10mg Folic Acid IP 2.5mg Excipients qs Colour: Approved colour used
11	RACECADOTRIL SACHET IP 10MG	Each sachet contains: Racecadotril IP 10MG Excipients qs
12	RACECADOTRIL SACHET IP 30MG	Each sachet contains: Racecadotril IP 30MG Excipients qs
13	FOSFOMYCIN TROMETAMOL POWDER 3G	Each sachet contains: Fosfomycin Trometamol BP Equivalent to Fosfomycin 3G Excipients qs
14	MACROGOL GRANULES	Each 10.4 g of powder in Sachet contains: Macrogol 4000 IP 10g
15	POLYETHYLENE GLYCOL 3350 POWDER FOR ORAL SOLUTION	Each 8.5 g sachet contains : Polyethylene glycol 3350 USPNF 8.5g
16	L-ARGININE, ZINC WITH FOLIC ACID GRANULES	Each sachet (5g) contains: L-Arginine IP 3 g Zinc Sulphate Monohydrate IP Eq. elemental Zinc 10 mg Folic Acid IP 2.5 mg
17	L-ARGININE, FOLIC ACID & ZINC GRANULES	Each sachet (5g) contains: L-Arginine IP 3 g Folic Acid IP 2.5 mg Zinc Sulphate Monohydrate IP Eq. elemental Zinc 10 mg
18	L-ARGININE, FOLIC ACID & ZINC GRANULES	Each sachet (5g) contains: L-Arginine IP 3 g Folic Acid IP 2.5 mg Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg
19	L-ARGININE, FOLIC ACID & ZINC GRANULES	Each sachet (6g) contains: L-Arginine IP 3 g Folic Acid IP 2.5 mg Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg Excipients qs
20	L-ARGININE, FOLIC ACID & ZINC GRANULES	Each sachet (10g) contains: L-Arginine IP 5 g Folic Acid IP 2.5 mg Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg

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S. No.	Product Name	Composition
21	AZITHROMYCIN FOR ORAL SUSPENSION USP 200mg/5ml (FOR EXPORT)	Each 5ml of reconstituted suspension contains: Azithromycin USP Equivalent to Anhydrous Azithromycin 200mg
22	AZITHROMYCIN ORAL SUSPENSION BP 200mg/5ml (FOR EXPORT)	Each 5ml of reconstituted suspension contains: Azithromycin BP Equivalent to Anhydrous Azithromycin 200mg
23	FLUCONAZOLE FOR ORAL SUSPENSION USP 50mg/5ml (FOR EXPORT)	Each 5ml of reconstituted suspension contains: Fluconazole USP 50mg
24	L-ARGININE GRANULES	Each sachet(5g) contains: L-Arginine IP 3 g
25	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (6g) contains: L-Arginine IP 3 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg Folic Acid IP 2.5 mg
26	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet(15g) contains: L-Arginine IP 5g Zinc Sulphate Monohydrate IP Equivalent to elemental Zinc 10mg Folic Acid IP 2.5mg
27	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (6g) contains: L-Arginine IP 3 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg Folic Acid IP 2.5 mg
28	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (10g) contains: L-Arginine IP 5 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10 mg Folic Acid IP 2.5 mg
29	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (6g) contains: L-Arginine IP 3 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10mg Folic Acid IP 2.5 mg
30	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (10g) contains: L-Arginine IP 3 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10mg Folic Acid IP 2.5 mg
31	L-ARGININE, ZINC & FOLIC ACID GRANULES	Each sachet (15g) contains: L-Arginine IP 5 g Zinc Sulphate Monohydrate IP equivalent to elemental Zinc 10mg Folic Acid IP 2.5 mg

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Sign &amp; Date:

25/07/22

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## Appendix-2

	<b>SITE MASTER FILE</b>	Document No.:	WPPL/SMF
		Revision No. :	04
	<b>LIST OF PRODUCTS</b>	Effective Date:	25/07/22
		Review Date :	2 Years

## Ointments/Gel/Cream

S. No.	Product Name	Composition
1	CLOTRIMAZOLE CREAM BP 1% w/w (For Export)	Each gram contains Clotrimazole BP 10mg Excipients qs to 1g
2	DICLOFENAC GEL BP 1% w/w (For Export)	Each gram contains Diclofenac Diethylamine BP 11.6 mg Equivalent to Diclofenac Sodium 10mg Excipients qs to 1g
3	KETOCONAZOLE CREAM BP 2% w/w (For Export)	Each gram contains Ketoconazole BP 20mg Excipients qs to 1g
4	SUCRALFATE, METRONIDAZOLE & LIGNOCAINE CREAM	Each gram contains Sucralfate IP 70mg Metronidazole IP 10mg Lignocaine Hydrochloride Equivalent to Anhydrous Lignocaine Hydrochloride 40mg Cream-base qs
5	ACICLOVIR CREAM BP 5% w/w (For Export)	Each gram contains Aciclovir BP 50mg Excipient qs. to 1g
6	MUPIROCIN OINTMENT USP 2% w/w (For Export)	Each gram contains Mupirocin USP 20mg Excipient qs. to 1g
7	DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE & MENTHOL GEL	Contains Diclofenac Diethylamine IP 1.16% w/w Equivalent to Diclofenac Sodium 1%w/w Linseed Oil BP 3%w/w Methyl Salicylate IP 10%w/w Menthol IP 5%w/w Benzyl Alcohol (As preservative) IP 1% w/w Gel Base qs.
8	NEOMYCIN SULFATE AND BACITRACIN ZINC OINTMENT USP  (For Export)	Each gram contains Neomycin Sulfate USP 5mg Bacitracin Zinc USP 250IU Equivalent to Bacitracin Excipients qs to 1 g
9	DICLOFENAC DIETHYLAMINE, LINSEED OIL, METHYL SALICYLATE, CAPSAICIN & MENTHOL GEL	Contains Diclofenac Diethylamine BP 1.16% w/w Equivalent to Diclofenac Sodium 1% w/w Linseed Oil BP 3% w/w Methyl Salicylate IP 10% w/w Capsaicin USP 0.025% w/w Menthol IP 5% w/w Benzyl Alcohol (As preservative) IP 1% w/w Gel Base qs.



## LIST OF PRODUCTS

Revision No. :	04
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Effective Date:	25/07/22
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Review Date :	2 Years
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Page 34 of 35

Sign & Date:

ЗАДАЧА СОРУ



## Appendix-2

	<b>SITE MASTER FILE</b>	Document No.:	WPPL/SMF
		Revision No. :	04
	<b>LIST OF PRODUCTS</b>	Effective Date:	25/07/22
		Review Date :	2 Years

S. No.	Product Name	Composition
22	POVIDONE IODINE & ORNIDAZOLE OINTMENT	Composition: Povidone-Iodine IP 10.0% w/w (Available Iodine 1.0% w/w) Ornidazole IP 1.0% w/w Water Soluble Ointment Base qs
23	PERMETHRIN CREAM 5% W/W	Composition: Permethrin BP 5 % w/w Cream Base qs
24	FERACRYLUM GEL 1% W/W	Feracrylum Water Soluble Gel Base q.s.
25	FERACRYLUM GEL 3% W/W	Feracrylum Water Soluble Gel Base q.s.
26	NEOMYCIN AND POLYMYXIN B SULPHATE AND BACITRACIN ZINC OINTMENT USP	Each gram contains Neomycin Sulfate USP 3400 Units Polymyxin B Sulfate USP 5000 Units Bacitracin Zinc USP 400 Units Ointment Base q.s
27	ISOPROPYL RUBBING ALCOHOL GEL 70 % v/v	Isopropyl alcohol IP 70% V/V Gel Base q.s
28	TRIMETHOXYSILYL QUATERNARY AMMONIUM CHLORIDE 0.40% W/V GEL	Trimethoxysilyl Quaternary Ammonium chloride 0.40% W/V Gel Base q.s
29	ISOPROPYL ALCOHOL, HYDROGEN PEROXIDE AND GLYCEROL GEL	Isopropyl Alcohol IP 75% V/V Hydrogen Peroxide solution IP 0.125% V/V Glycerol IP 1.45% V/V Gel Base q.s
30	MUPIROCIN OINTMENT IP 2.0% W/W	Composition: Mupirocin IP 2.0% w/w Preservatives: Methyl Paraben IP 0.16 % w/w Propyl Paraben IP 0.033% w/w
31	EXTRA NEUTRAL ALCOHOL (DENATURED ) 70%V/V GEL	Extra Neutral Alcohol( Denatured ) Equivalent to Ethanol 70% v/v Gel Base q.s.
32	BETAMETHASONE OINTMENT IP 0.05% w/w	Each gram contains Betamethasone Dipropionate IP equivalent to Betamethasone 0.05% w/w Ointment base q.s

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Sign &amp; Date:

MASTER COPY





WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

## Appendix 3

## GMP Certificate

UNCONTROLLED COPY

Sign & Date: .....

4/05/07/22





DEPARTMENT OF FOOD SAFETY AND DRUGS CONTROL ADMINISTRATION  
GOVERNMENT OF TAMILNADU  
359, Anna Salai, Chennai - 600 006, Tamil Nadu.

**CERTIFICATE OF GOOD MANUFACTURING PRACTICES\***

Certificate No: K Dfs. No: 17414/D1/4/2021, Dated: 07.04.2022

On the basis of the inspection carried out on 12.01.2022, 13.01.2022 and 23.03.2022 we certify that the site indicated on this certificate complies with Good Manufacturing Practices for the dosage forms, categories and activities listed in Table 1.

- 1 Name and address of site: M/s. Wellous Pharma Private Limited,  
R.S. No.333-2A & 2B2, Navamal Marutur Village,  
Kandamangalam Block, Villupuram District,  
Tamil Nadu - 605102.
- 2 Manufacturer's licence number: Form 25 Bearing No: TN00004921 Dated: 20.03.2018  
Form 28 Bearing No: TN00004922 Dated: 20.03.2018
- 3 Table 1:

Dosage form(s)	Category(ies)	Activity(ies)
Tablets, Hard Gelatin Capsules, External Preparation	General (Other Than Beta lactum, Sex Hormones & Cytotoxic	Manufacturer

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

This certificate remains valid until 31.12.2024 It becomes invalid if the activities and/or categories certified herewith are changed or if the site is no longer considered to be in compliance with GMP.

Name and function of responsible person:

K.Sivabalan, B.Pharm.,

Director of Drugs Control

**K. SIVABALAN B.Pharm**

Director of Drugs Control  
359, Anna Salai, Chennai - 600 006.

Email: [indcad@gmail.com](mailto:indcad@gmail.com)



\*This certificate is issued as per WHO norms



#### Explanatory notes

- 1) This certificate, which is in the format recommended by WHO, certifies the status of the Site listed in point 1 of the certificate.
- 2) The certification number should be traceable within the regulatory authority issuing the certificate.
- 3) Where the regulatory authority issues a licence for the site this number should be specified. Record "not applicable" in case where there is no legal framework for the issuing of a licence.
- 4) The certificate remains valid until the specified date. The certificate becomes invalid if the activities and/or categories certified are changed or if the site is no longer considered to be in compliance with GMP.
- 5) The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in Quality Assurance of Pharmaceuticals: a compendium of guidelines and related materials. Good manufacturing practices and inspection, Volume 2, 1999, World Health Organization, Geneva and subsequent updates.





WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

## **Appendix 4**

### **List of contract laboratories and service providers**

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Sign & Date: .....

*G. S. S. S.*  
7/5/2022



## Appendix-4

## SITE MASTER FILE

Document No.: WPPL/SMF

Revision No. : 04

## LIST OF CONTRACT LABORATORIES &amp; SERVICE PROVIDERS

Effective Date: 25/07/22

Review Date : 2 Years

S. No	Activity	Contract Agency	Address
1	Technical Laboratories	M/s. Synthiya Research Labs Pvt. Ltd.	148/2, Old Villupuram Road, West Anna Nagar, Villianur, Puducherry - 605 110.
		M/s. Ideal Analytical and Research Institution	Plot No: 98, 3 <sup>rd</sup> Cross Street, Lourdu Nagar, Kanuvapettai, Villianur, Puducherry-605 110.
		M/s. A to Z Pharmaceutical Pvt Ltd.	No:12, Balaji Nagar, Ambattur, Chennai 600053, Phone- 044-26585855.
		M/s. Tamilnadu Test House Private Limited	Srisai Building Plot No.31 & 32, Lakshmi Kanthammal Street, Rajiv Nagar, Vanagaram, Chennai - 600 077. P: 91 7550053001 E: info@tn-th.com
		M/s. Neoscience Labs Pvt. Ltd.	91, Maheshwar Nagar, Sithalapakkam, Chennai - 600126, India. P: 91-44-29872432 E: Info@neosciencelabs.com
		M/s. SMS Labs Service Private Limited	39/6, Thiruvalluvar High Road, Puduchatram Post, Thirumazhisai Via, Poonamallee Taluk, Chennai-600124.
		M/s. Chennai Mettix Lab Private Limited	Jothi Complex, 83, M.K.N Road, Guindy, Chennai-600032.
		M/s. Ramya Sai Analytical Services	Plot No. 60-007, TS Agro Industries Development Corporation Limited, HMT Township, Chintal, Quthubullapur Mandal, Mechal/Malkajgiri (Dist), Hyderabad-500 054. Telangana.
2	Periodic evaluation & Calibration of Stability Chambers & Incubators.	M/s. Shankar Scientific Supplies	New no.9, Thiruvengadam Nagar, II Street, Kandanchavadi, Chennai - 600 096.
3	Calibration of Measuring / Monitoring Devices	M/s. Benlab	No.1, Kalathumettu Street (Near PIPDIC electronic Park) Thirubuvanal, Pondicherry - 605 107. Cell: 9443480143, 8903689035. 0413 - 2641443.
4	Periodic evaluation of Air handling systems	M/s. Air Calibre Systems	48/23, Vinayakar Koil st, Krishnaswami nagar, Ramanathapuram, Coimbatore, 641 045
5	Pest and Rodent Control	M/s. PCI Pest control Pvt. Ltd.	Plot no.9, muthaiya nagar, (Opp.to kamalam theater, Thiruppadripuliyur, cuddalore - 607 002.

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Sign &amp; Date: 25/07/22

MASTER COPY



## Appendix-4

## SITE MASTER FILE

Document No.: WPPL/SMF

Revision No. : 04

Effective Date: 25/04/22

Review Date : 2 Years

## LIST OF CONTRACT LABORATORIES &amp; SERVICE PROVIDERS

S. No	Activity	Contract Agency	Address
6	House Keeping	M/s. RSP Enterprises	No.483, Kali Koll Street, chinnababusamuthiram & Post, Kandamangalam Via, Villupuram Dist - 605 102.
		M/s. Shantha Labour Contractor	No.20, Marlamman Koll Street, Nathamedu, Karlyamanikkam, Pondicherry - 605106.
7	Uniform cleaning	M/s. Lindstrom Services India Private Limited	No.68A, Dairy Road, Sidco Industrial Estate, Ambattur, Chennai - 600098.

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Sign &amp; Date:

4/5/2022

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WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

## Appendix 5 Organogram

UNCONTROLLED COPY  
Sign & Date: *9/5/2022*





## SITE MASTER FILE

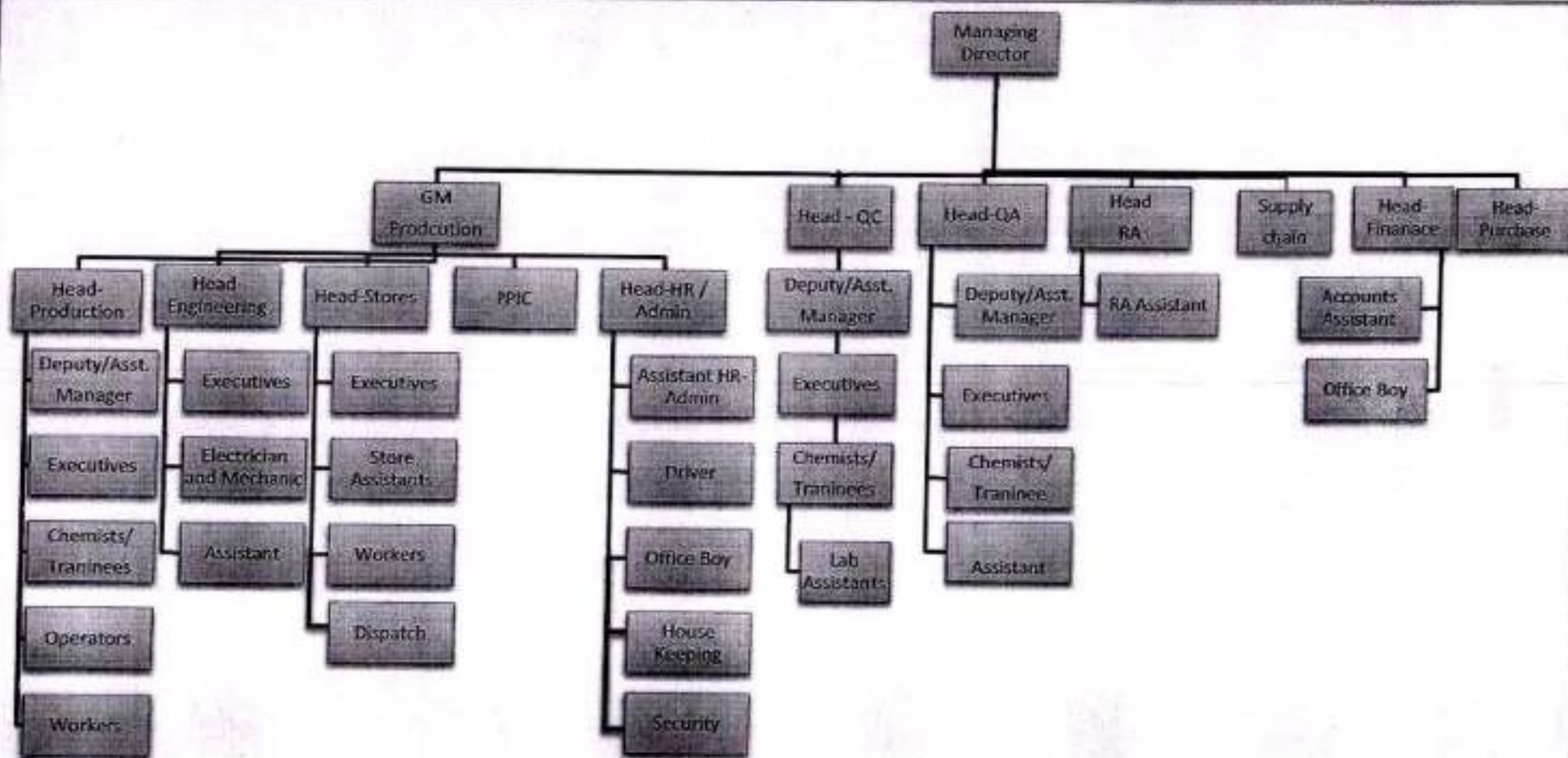
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Revision No. :	04
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Effective Date:	25/07/22
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Review Date :	2 Years
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## ORGANOGRAM



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Sign & Date:

MASTER COPY





WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

**Appendix 6**  
**Lay out**  
**AHU zone**  
**Pressure zone**  
**Men and Material flow**  
**Manufacturing process flow chart**  
**for each dosage forms**

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Sign & Date:

4/25/07/22

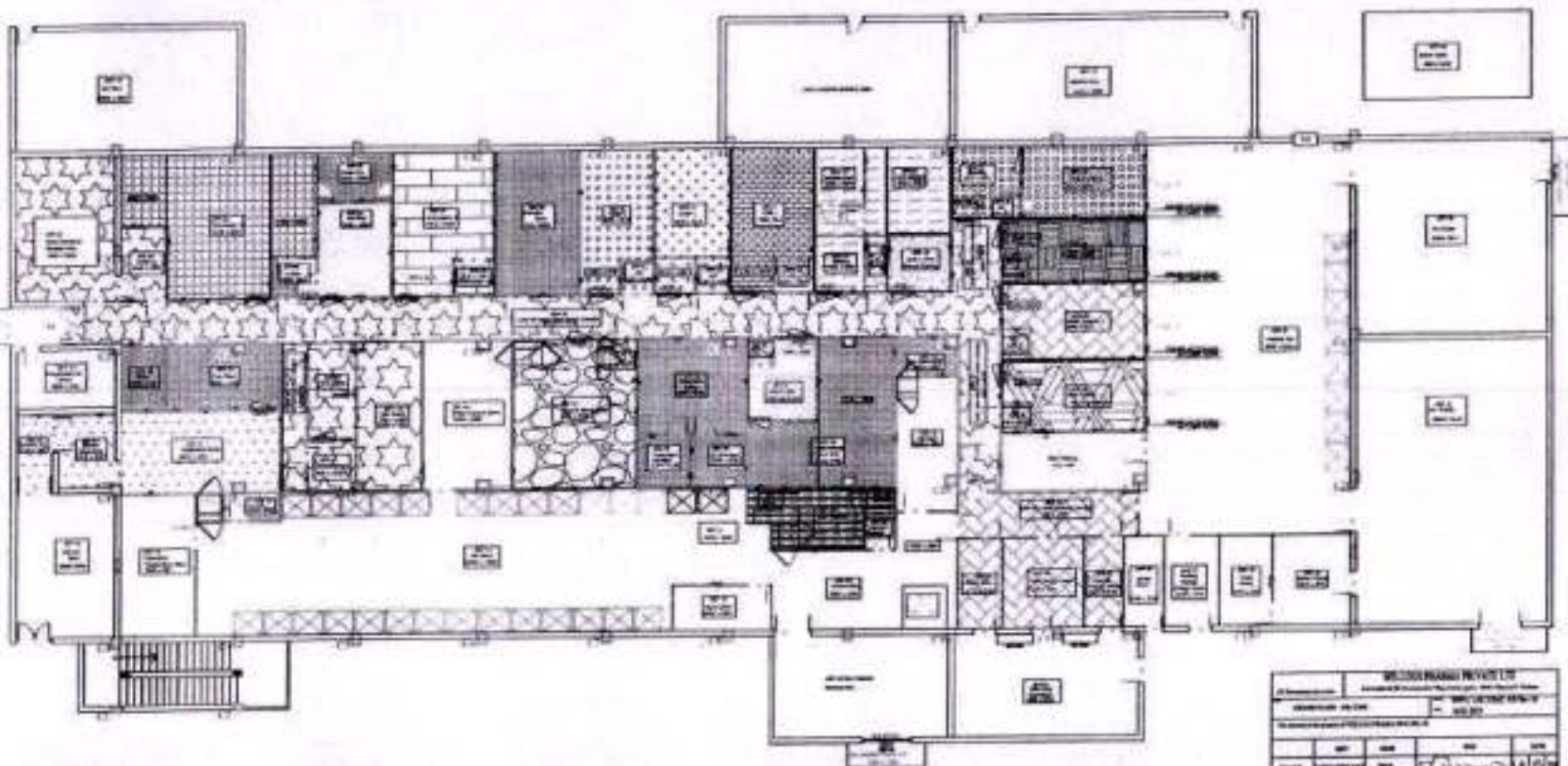































# AHU ZONING

-  AHU - 01
-  AHU - 02
-  AHU - 03
-  AHU - 04
-  AHU - 05
-  AHU - 06
-  AHU - 07
-  AHU - 08
-  AHU - 09
-  AHU - 10
-  AHU - 11
-  AHU - 12
-  AHU - 13
-  AHU - 14
-  AHU - 15
-  AHU - 16
-  AHU - 20
-  AHU - 21
-  VENT - 01

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REVISIONS				
NO.	DESCRIPTION	DATE	BY	CHKD.
1	ISSUED FOR CONSTRUCTION	19/08/19	U. Padiyil	
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3	ISSUED FOR CONSTRUCTION	19/08/19	U. Padiyil	
4	ISSUED FOR CONSTRUCTION	19/08/19	U. Padiyil	
5	ISSUED FOR CONSTRUCTION	19/08/19	U. Padiyil	
6	ISSUED FOR CONSTRUCTION	19/08/19	U. Padiyil	
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Sign & Date: U. Padiyil 19/08/19

CONTROLLED COPY

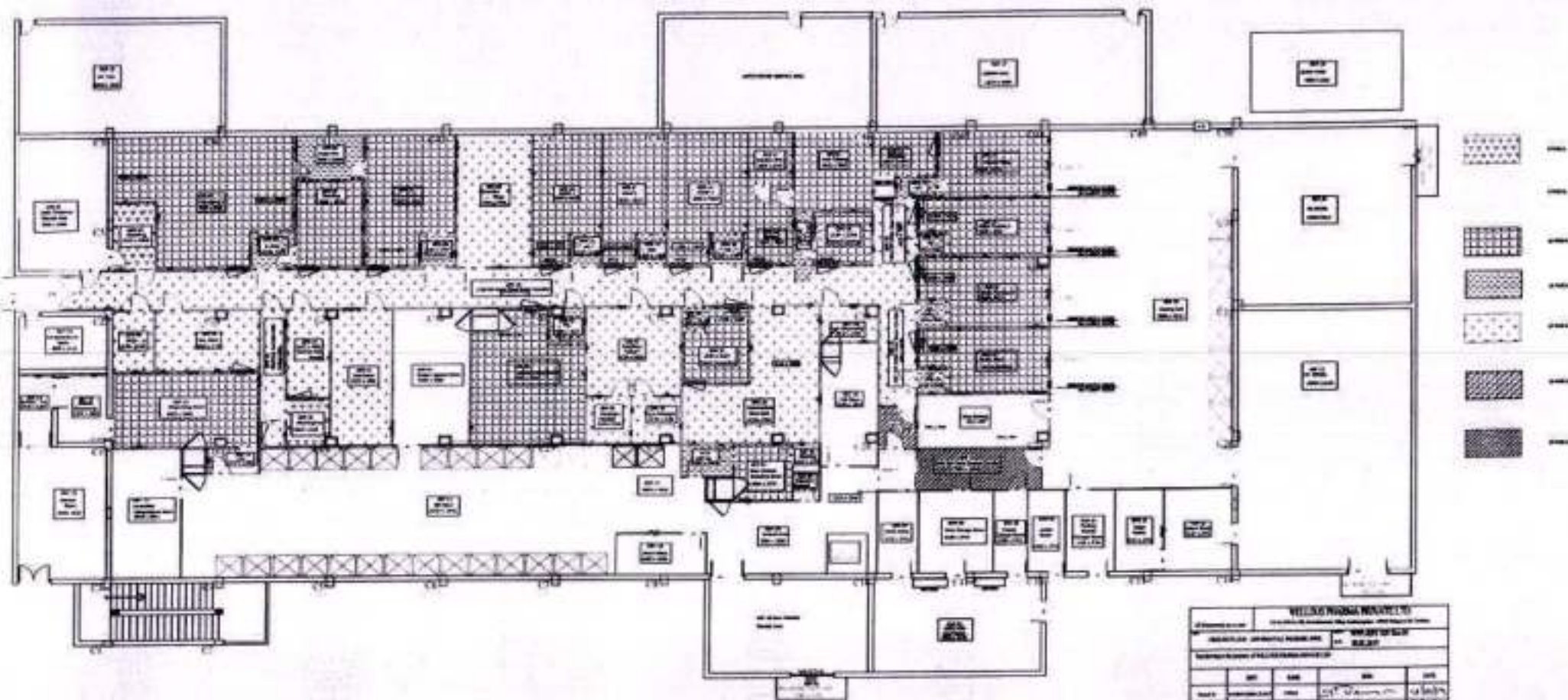
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MASTER COPY









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FOR THE USE OF THE BUILDING OWNER, ARCHITECT, AND OTHER STAKEHOLDERS				
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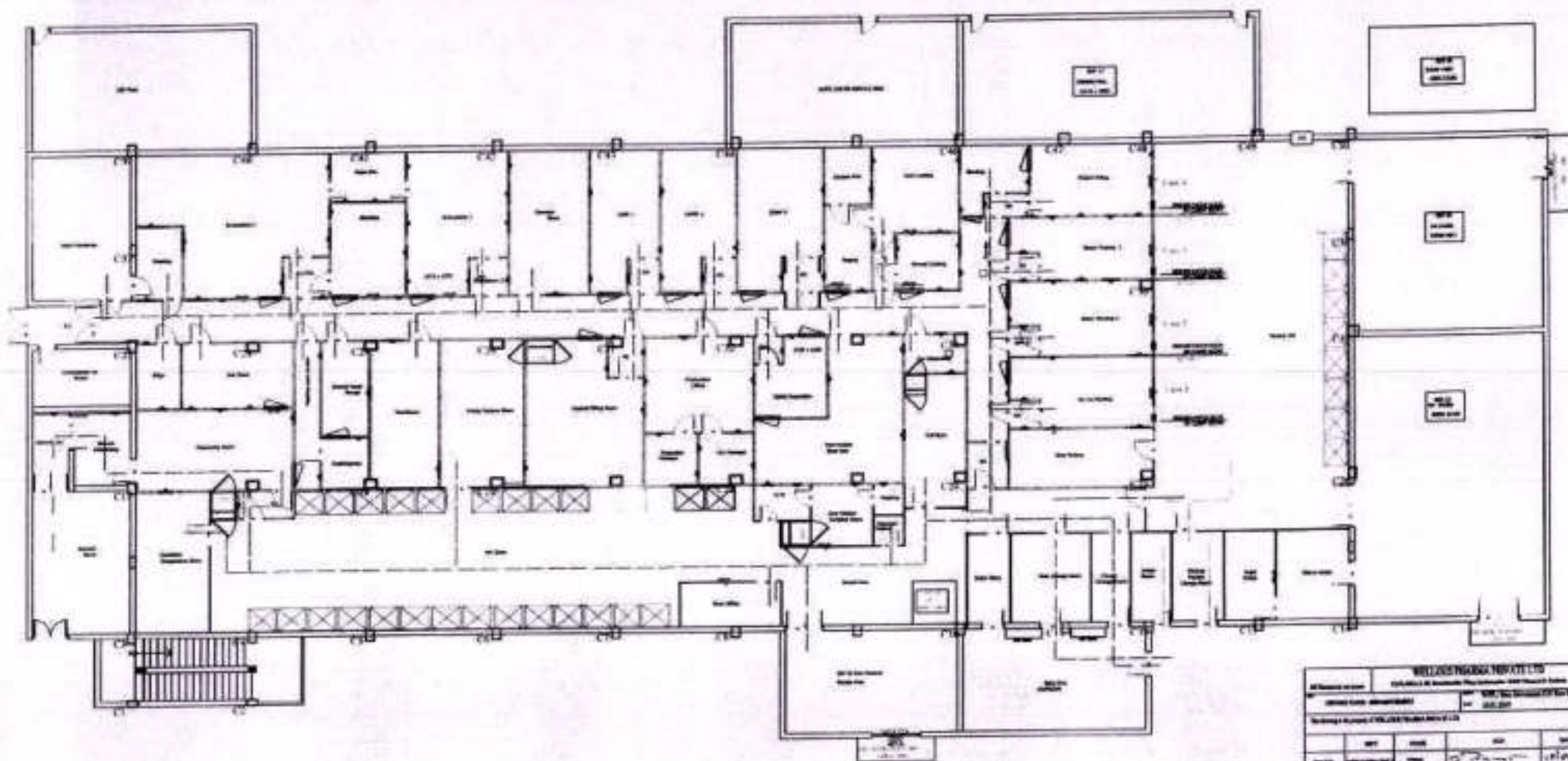
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UNCONTROLLED COPY  
Sign & Date: U. Paul  
25/04/20

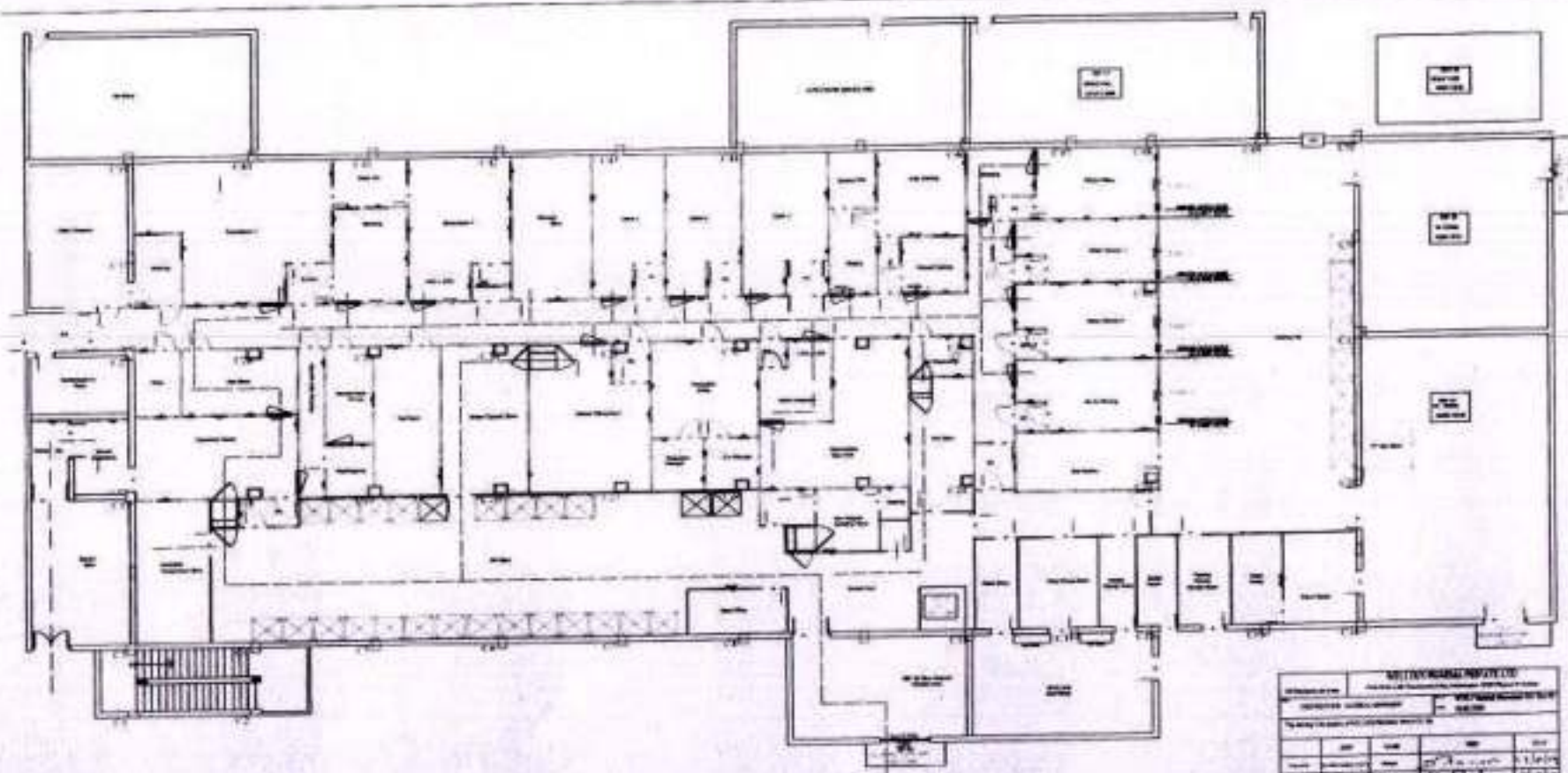
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19/03/19

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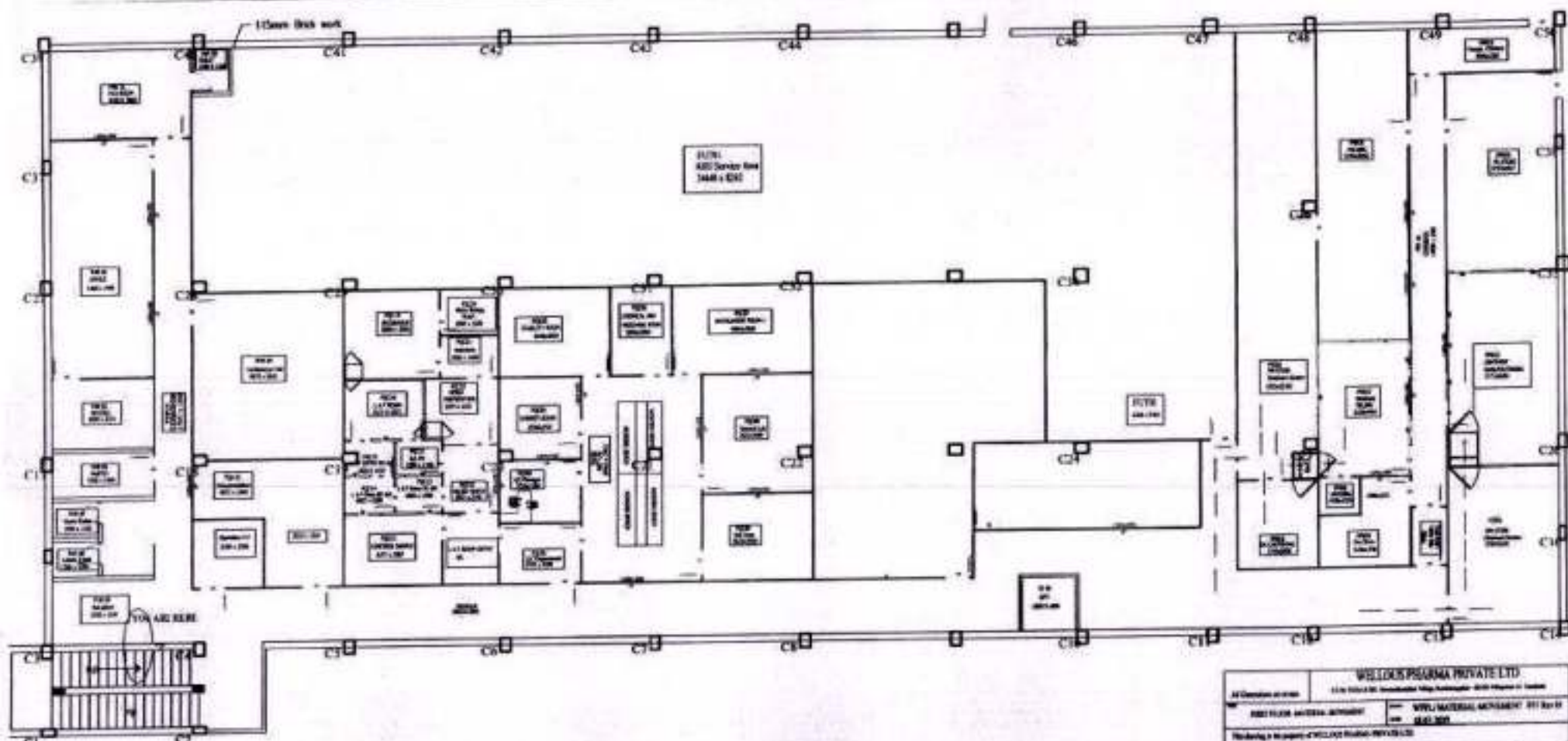
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WELLS PRISMA PRIVATE LTD.				
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11th Floor, 11th Floor, 11th Floor, 11th Floor, 11th Floor				
11th Floor, 11th Floor, 11th Floor, 11th Floor, 11th Floor				
NO.	DATE	NAME	DESIGN	DATE
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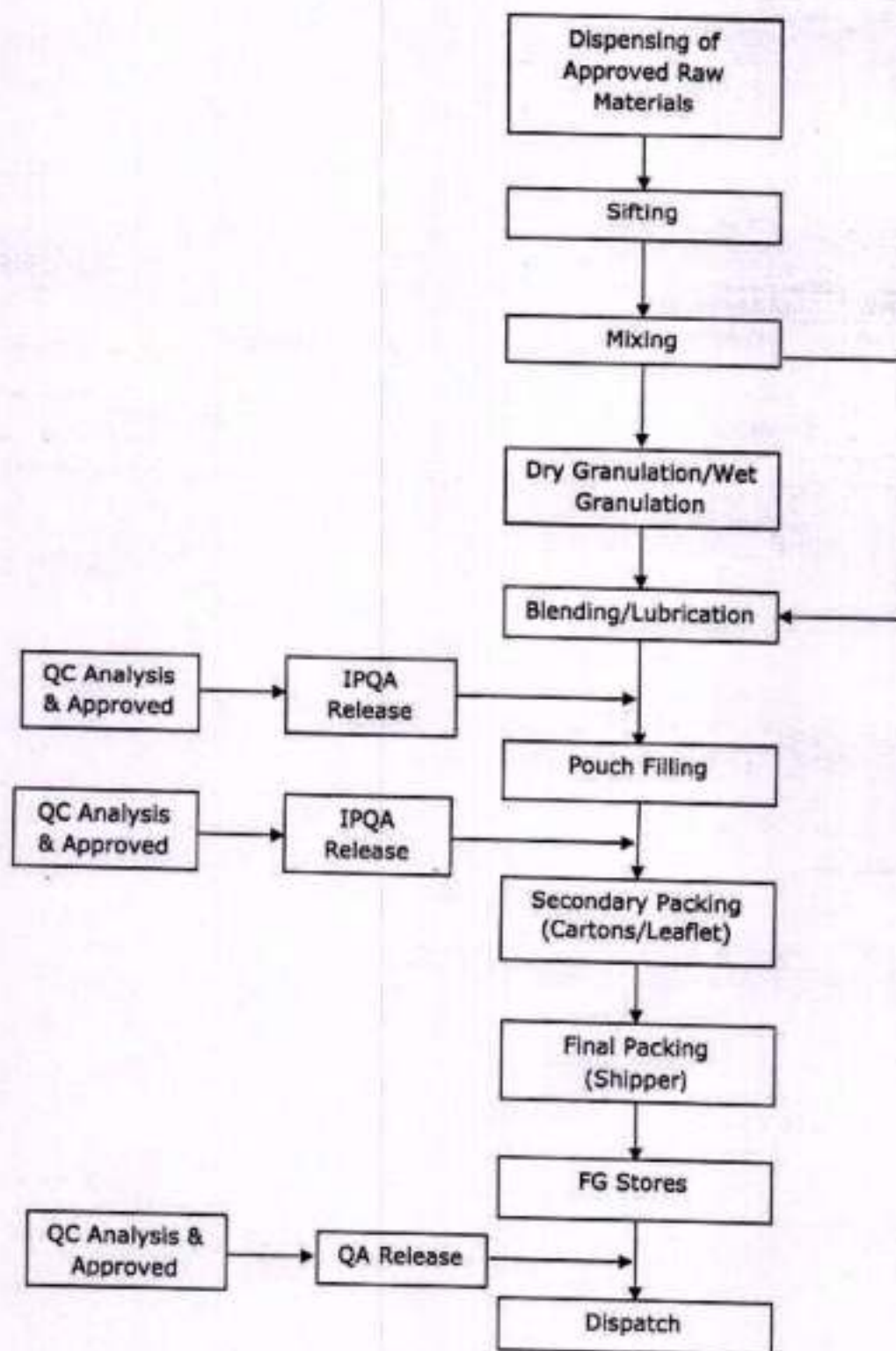
Document No.: WPPL/SMF

Revision No. : 04

Effective Date: 25/07/22

Review Date : 2 Years

## DRY POWDER MANUFACTURING ACTIVITIES FLOW CHART



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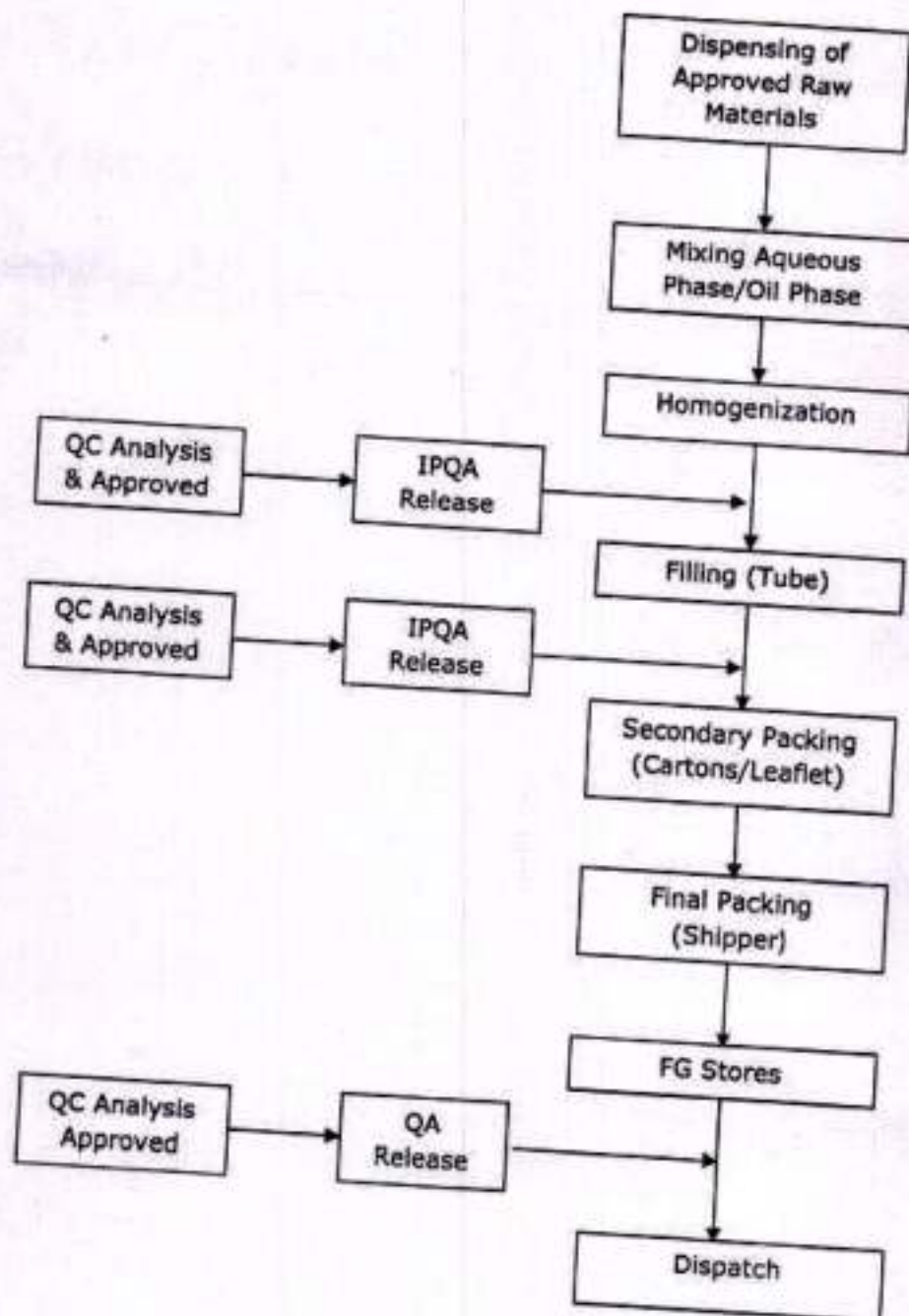




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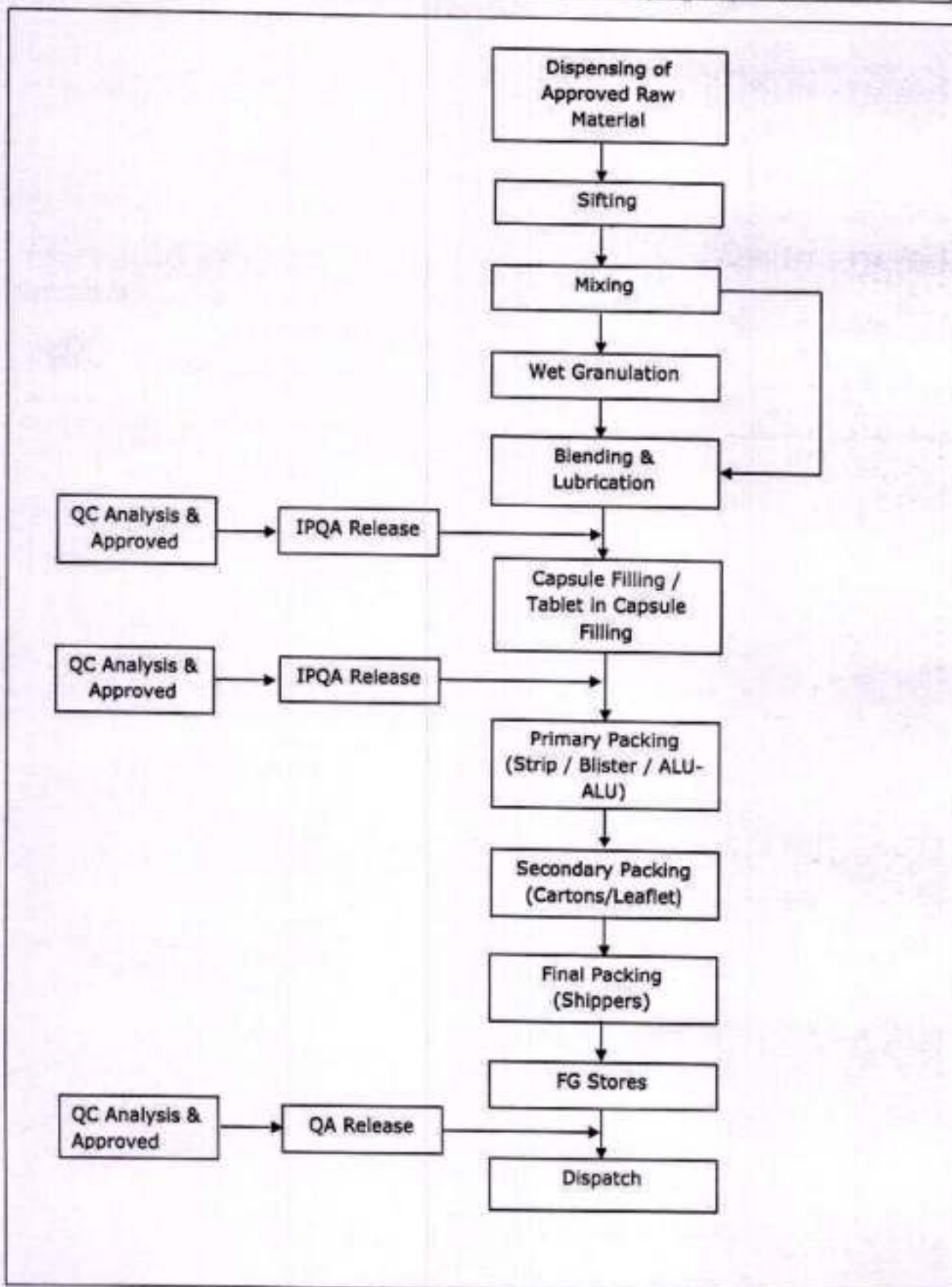
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## Appendix-6

	<b>SITE MASTER FILE</b>	Document No.:	WPPL/SMF
		Revision No. :	04
	<b>CAPSULES MANUFACTURING ACTIVITIES FLOW CHART</b>	Effective Date:	25/07/22
		Review Date :	2 Years



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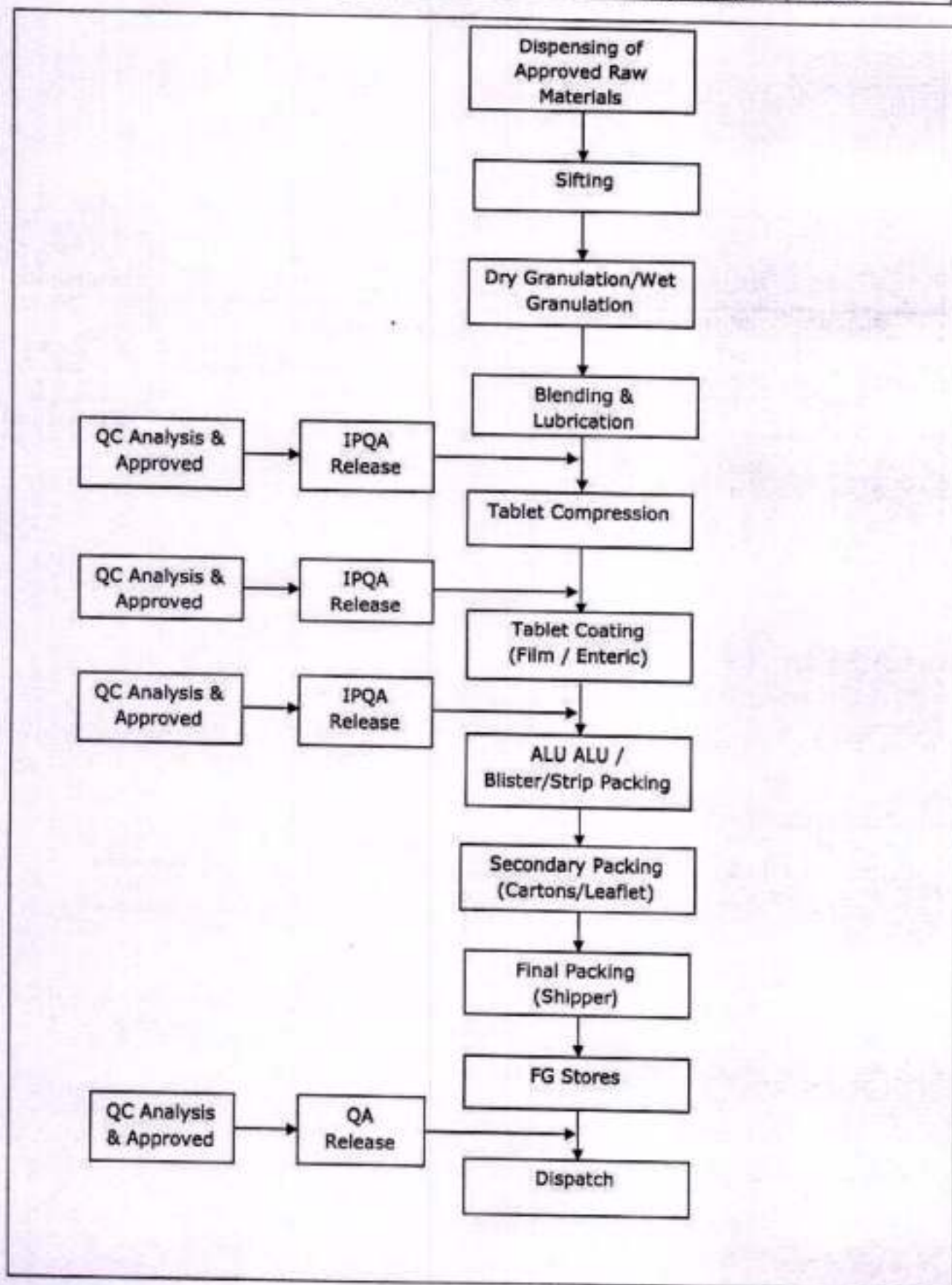
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# Appendix-6

	<b>SITE MASTER FILE</b>	Document No.:	WPPL/SMF
		Revision No. :	04
	<b>TABLETS MANUFACTURING ACTIVITIES FLOW CHART</b>	Effective Date:	25/04/22
		Review Date :	2 Years



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WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

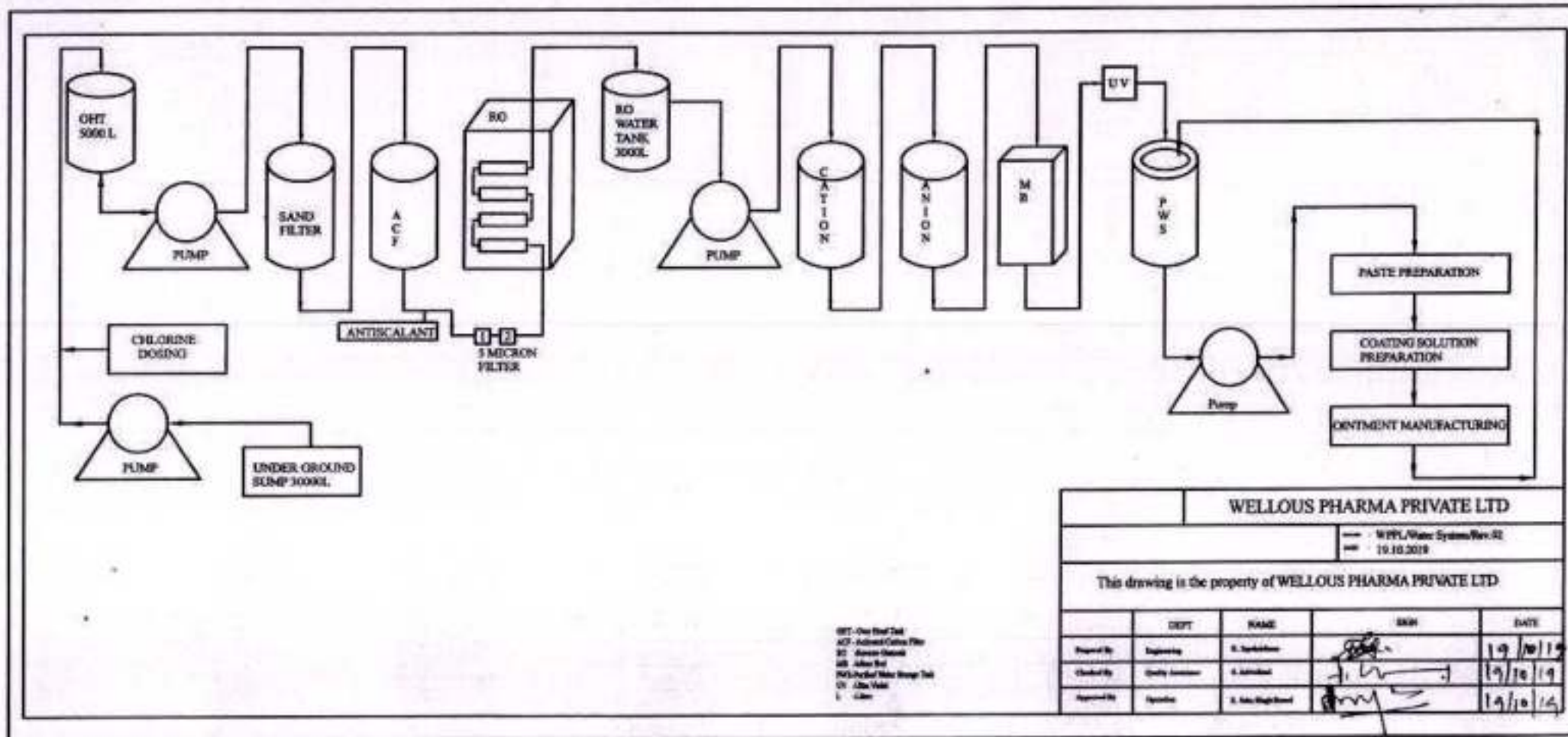
## **Appendix 7**

### **Schematic drawing of water system**

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WELLOUS PHARMA PRIVATE LIMITED, TAMILNADU

## **Appendix 8**


### **List of major production and laboratory equipment**

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Appendix 3

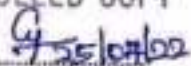
	SITE MASTER FILE	Document No.:	WPPL/SMF
		Revision No. :	05
		Effective Date:	25/07/22
		Review Date :	2 Years
LIST OF MAJOR PRODUCTION AND QUALITY CONTROL EQUIPMENT			

**PRODUCTION**

S. No.	Area Name	Equipment Name	Equipment Code	Make	Capacity
1	Dispensing Area	Dispensing Booth	ST/EQ/001	Pharmaintech	--
2	Sampling Area	Sampling Booth	ST/EQ/002	Pharmaintech	--
3	Granulation I	Rapid Mixer Granulator	PR/EQ/001	Gansons	400 Litres
		Sifter	PR/EQ/002	Gem pharma	30"
		Multimill	PR/EQ/003	Gem pharma	--
		Fluid Bed Drier	PR/EQ/004	Gem pharma	120 kg
4	Granulation II	Tray Drier	PR/EQ/005	Gem pharma	48 Trays
		Ribbon mixer	PR/EQ/006	Gem pharma	100 kg
		Multimill	PR/EQ/007	Gansons	--
		Sifter	PR/EQ/008	Gem pharma	30"
5	Paste Preparation area	Paste preparation Kettle	PR/EQ/009	Karpaga vinayagar	100 Litres
		Stirrer	PR/EQ/009A	Karpaga vinayagar	--
		Kettle	PR/EQ/009B	Karpaga vinayagar	--
6	Blending Area	Octagonal blender	PR/EQ/010	Karpaga vinayagar	1200 Litres
		Sifter	PR/EQ/018	Gem pharma	30"
7	Compression 1	Compression Machine	PR/EQ/037	Cad Mach	37 station
		Metal Detector	PR/EQ/037A	Crystal Enterprise	--
8	Compression 2	Compression Machine	PR/EQ/038	Cad Mach	27 station
		Dust Extractor	PR/EQ/012A	Fluid Pack	--
		De-duster	PR/EQ/038B	Fluid Pack	--
		De-duster	PR/EQ/038C	Fluid Pack	--
9	Compression 3	Compression Machine	PR/EQ/034	Cad Mach	45 station
		Metal Detector	PR/EQ/034A	Crystal Enterprise	--
		Metal Detector	PR/EQ/034B	Crystal Enterprise	--
10	Compression 4	Compression Machine	PR/EQ/011	Cad Mach	16 station
11	Coating Area	Conventional coating pan	PR/EQ/014	Bhuvaneswari	32"
		Conventional coating pan	PR/EQ/015	Bhuvaneswari	36"
12	Coating Area	Auto Coater	PR/EQ/035	Neomachine	48"
13	Solution Preparation area	Colloid mill	PR/EQ/016	Cadmach	--
14	Inspection Area	Inspection Conveyor	PR/EQ/013	Gansons	Max. 50 RPM
		Metal detector	PR/EQ/013A	Techno four	--
15	Pouch Blending Area	Double cone blender	PR/EQ/017	Karpaga vinayagar	300 Litres


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LIST OF MAJOR PRODUCTION AND QUALITY CONTROL EQUIPMENT			

S. No.	Area Name	Equipment Name	Equipment Code	Make	Capacity
16	Capsule Filling Area	SA 9 Filling machine	PR/EQ/023	PAM	--
		Polishing machine	PR/EQ/023A	PAM	--
		Empty Capsule sorter	PR/EQ/023B	PAM	--
		Vacuum pump	PR/EQ/023C	PAM	--
		Feeder and sorter	PR/EQ/023D	PAM	--
		Dust Collector	PR/EQ/023E	PAM	--
17	Pouch Filling Area	Pouch Packing Machine	PR/EQ/019	Pakona	60 RPM
		Sachet overprinting machine	PR/EQ/036	Markem Imaje	--
18	Blister Packing	Blister Packing machine	PR/EQ/021	Rapid pack	60-120 RPM
		De blistering machine	PR/EQ/021A	ACE technologies	--
19	Blister Packing	Blister Packing machine	PR/EQ/032	Rapid pack	60-120 RPM
		De blistering machine	PR/EQ/032A	ACE technologies	--
20	Alu-Alu Packing	Alu-Alu Packing machine	PR/EQ/022	IMA PG	Max 40 RPM
21	Strip packing	Strip packing machine	PR/EQ/020	Gansons	50-60 RPM
22	Secondary Packing	Packing conveyor-1	PR/EQ/027	SS Balaji engineering	--
		Packing conveyor-2	PR/EQ/028	SS Balaji engineering	--
		Packing conveyor-3	PR/EQ/029	SS Balaji engineering	--
		Packing conveyor-4	PR/EQ/030	SS Balaji engineering	--
		Packing conveyor-5	PR/EQ/031	SS Balaji engineering	--
23	Ointment Manufacturing	Ointment mixer	PR/EQ/024	Adhisakthi	150 kg
24	Ointment Filling	Ointment Filling Machine	PR/EQ/025	Parle koval	60 RPM
25	Secondary Packing-ointment	Packing Conveyor	PR/EQ/026	SS Balaji engineering	--
		Shrink Tunnel	PR/EQ/026A	Vikas pack	--
26	Carton coding Area	Overprinting Machine	PR/EQ/031	Markem Imaje	Min. 2000 carton/hr
		Overprinting Machine	PR/EQ/042	Markem Imaje	--
27	Spare	Metal Detector with De-duster	PR/EQ/043	Crystal Enterprise	--
		Dust Collector	PR/EQ/044	PAM	--
		Dust Extractor	PR/EQ/045	PAM	--


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<b>LIST OF MAJOR PRODUCTION AND QUALITY CONTROL EQUIPMENT</b>			

**QUALITY CONTROL**

S. No.	Instrument Name	Make	ID No.
1	HPLC	Shimadzu	QC/IN/001
2	UV Visible Spectrophotometer	Shimadzu	QC/IN/002
3	IR Spectrophotometer	Shimadzu	QC/IN/003
4	Analytical Balance 0.01 mg	Radwag	QC/IN/004
5	Analytical Balance 1 mg	Radwag	QC/IN/005
6	pH Meter	Eutech	QC/IN/006
7	Melting Point Apparatus	Inlab Equipments	QC/IN/007
8	Polarimeter	Advance	QC/IN/008
9	Hot Air Oven	Blollnkz	QC/IN/009
10	Hot Air Oven	Inlab Equipments	QC/IN/010
11	Karl fisher Apparatus	Lasco	QC/IN/011
12	Potentiometer	Lasco	QC/IN/012
13	Sonicator	Hwashin Tech	QC/IN/013
14	Fuming Cupboard	New Desing Lab	QC/IN/014
15	Refrigerator	Swestern	QC/IN/015
16	Digital Vernier Caliper	Mitutoyo	QC/IN/016
17	Thickness Gauge	Mitutoyo	QC/IN/017
18	Hardness Tester	Inlab Equipments	QC/IN/018
19	Friability Apparatus	Electrolab	QC/IN/019
20	Disintegration Tester	Electrolab	QC/IN/020
21	Dissolution Test Apparatus	Labindia	QC/IN/021
22	Stability Chamber 40/75	Newtronic	QC/IN/023
23	Stability Chamber 30/65	Newtronic	QC/IN/024
24	Tap Density Tester (USP)	Electrolab	QC/IN/025
25	Conductivity Meter	Labman	QC/IN/026
26	Water Bath	Hasthas	QC/IN/027
27	Bursting Strength Apparatus	Ubique	QC/IN/029
28	Muffle Furnace	Inlab	QC/IN/030
29	Electrical Bunsen	Guna Enterprises	QC/IN/031
30	UV Cabinet	Inlab Equipments	QC/IN/032

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## Appendix-8



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## LIST OF MAJOR PRODUCTION AND QUALITY CONTROL EQUIPMENT

S. No.	Instrument Name	Make	ID No.
62	Water Filter Unit (Microbiology)	Rankem	QC/IN/065
63	KBR press	Technosearch instruments	QC/IN/066
64	Column storage cabinet	Pcolsafe	QC/IN/067
65	Standard Weight Box	Sensortron	QC/IN/068
66	Sonicator	Hwashin Tech	QC/IN/069
67	Pass box	Pharmintech	QC/IN/070
68	Pass box	Pharmintech	QC/IN/071
69	Eye wash with shower	--	QC/IN/072
70	Digital Hygroclock	Sintimer	QC/IN/073
71	Digital Hygroclock	Sintimer	QC/IN/074
72	Desiccator	Borosil	QC/IN/075
73	Standby stability chamber	Inlab	QC/IN/076
74	Column washing bump	Thermo separation products	QC/IN/077
75	Pycnometer	Rankem	QC/IN/078
76	Alcoholic meter	Leimco	QC/IN/079
77	Alcoholic meter	Leimco	QC/IN/080
78	Table top Centrifuge	Remi	QC/IN/081
79	Precision balance	Essae	QC/IN/082
80	Hot Air Oven	Inlab Equipments	QC/IN/083
81	Refractometer	Advance Research Instruments & co	QC/IN/084

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