

SITE MASTER FILE

C.1 General Information

C.1.1 Brief Information on the firm:

ALLIED Pharmaceutical Industries is a Syrian private Pharmaceutical company established in 1987 by Dr. Adib shanan & Mr. M.Samir Al-smman, among the creative nature of DARAYA in the south west of Syria. The formulation Plant was inauguration for construction in the year 1994. More than 21 years passed from the first beginning of the company till now and the development is still continuous based on the concept of strength of truth.

The ALLIED attributes its success to its technological strength developed at its in house Research facility.

Collaboration & technology transfer which has helped in development of non infringing process, & providing technical support to its manufacturing facilities.

The plant has its facilities for:

- Product Research & Development.
- Analytical Research & Development.
- Stability testing.
- Quality Control.
- Quality Assurance.
- Manufacturing facility of Antiseptic Liquid, Liquid oral dosages form, Semisolid dosages form, and sterile Gauze dressing.
- Warehousing.
- Engineering.
- In 1998 the company have been got the GMP (Good Manufacturing Practice) and the GLP (Good Laboratory Practice) certificates from the Ministry of Health in the Syrian Arab Republic.
- In 2000 the company get the ISO 9002 certificate issued by the Swiss company (SGS).
- In 2002 the company received the ISO 9001:2000 certificate which is the most developed certificate in quality compliance of products with the international specifications, as well as different appreciation certificates due to the great role of the company on supporting the economy and scientific research.
- In 2008 the company was get other quality certificates ISO 18001 and ISO 14001.
- The products of our company are of high quality and cover internal and some of external markets.

C.1.2 Pharmaceutical Manufacturing Activities is licensed by the competent authorities.

Pharmaceutical Manufacturing Activities is licensed by competent authorities .the Ministry of Health has granted the license under license No. 5250

C.1.3 Any other manufacturing activities carried out at the site

No non- pharmaceutical Manufacturing activities other than pharmaceutical activities specified in schedule are carried out at this site.

C.1.4 Name & exact address of the site including 24hrs. Telephone No. & Fax.**C.1.4.1 Site Address:**

ALLIED Pharmaceutical Industries
P.O. Box: 3826
Damascus – Syria
Tel. No. +963 11 3312746 - 6712093
Fax. No. +963 11 3312041 – 67299444
E-mail: shanan@scs-net.org

C.1.4.2 Contact persons:

Dr. Adib Chanan General Manger.
Tel. + 963 11 3312618
Fax + 963 11 3312746
E-mail: shanan@scs-net.org – info@alliedpharma.net
Web site: www.alliedpharma.net

C.1.4.3 Contact persons (At site)

Mr. M. Samir Al-smman
Tel. + 963 11 6712093
Fax. + 963 11 67299444

C.1.5 Type of actual product manufacturing on the Site & any other toxic or hazardous substance handle (in dedicated facility or on campaign basis)

This plant is designed to manufacture liquid orals, liquid antiseptic, semisolids dosages & gauze dressing dosages forms under the various therapeutic categories. This facility is designed with considerable scope for expansion & flexibility.

No toxic or hazardous substances are being handled in this plant .If there is a need to handle toxic or hazardous substances, proper safety standards & written procedure will be instituted & sufficient training to the personnel will be imparted.

Pharmaceutical dosage forms for human use only are manufactured at the site. No product for veterinary use is manufactured.

C.1.6 short description of the site

The ALLIED pharmaceutical industries are located in green area of Damascus gouta (west Darrya) the plant is located 15 Km from Damascus.

C.1.7 No. of Employees engaged in plant Quality Assurance, Quality control, Engineering, Production, Storage & Distributions & other departments.

Department	Full Strength
• Production	35
• Quality control	10
• Quality Assurance	05
• Warehouse	07
• Engineering	05
• Finance & Administration	14
• Medical Representatives	29
Total	105

C.1.8 Use of outside scientific analytical or other technical assistance, name & address of the contractors

No outside scientific analytical except when in-house testing facility is not available.

C.1.9 short description of Quality Management Systems of the firm responsible for Manufacture consist of

Quality policy, procedures & processes, self inspection, Audit program, Review Mechanism of the Quality system, Vendor Qualification Procedure and release for sale procedure for Finished product.

C.1.9.1 Quality Policy

The management & staff of ALLIED pharmaceutical Industries are committed towards manufacturing & marketing of pharmaceutical products following an integrated quality system meeting the customer and regulatory requirements ensuring the quality, safety and efficacy of the product.

Striving for excellence through continuous up gradation of resources and facilities to meet the ever-changing demands with respect to technologies and systems, aiming at continuous quality improvement and customer satisfaction, giving due consideration for the protection of the environment. Providing training, safe working environment and opportunities for all its employees to grow along with the organization and striving for the better cause of the community.

C.1.9.2 Quality Assurance (QA)

Quality assurance is an independent department headed by Manager – Quality Assurance has the overall responsibility of ensuring.

- cGMP implementation
- Approval distribution of SOPs, and their review.
- Approval of protocol for DQ, IQ, OQ, PQ of equipments and process qualification.
- Approval of specifications, test methods and master production records
- Conducting internal audits, vendor audits, product quality reviews, complaints investigation and monitoring change control.
- Supervision of the materials dispensing in-process checking and sampling as per the Master Production Records.
- Review of Master Production Record and Product release.
- Stability surveillance of products as per the Standard Operating Procedure.
- Analytical review of Quality records.
- Documentation control.

C.1.9.3 Quality Management System
General

- ALLIED Pharmaceutical Industries has a well-planned Quality management system.
- All the raw materials and packing materials are produced from approved vendors.
- All the materials, sampled by QC personnel as per SOP are tested and approved or rejected by Quality Control Department.
- Materials are tested as per the current approved standard test procedure.
- Rejected materials except printed packaging materials will be isolated and returned to the supplier or destroyed. Printed packaging material will be destroyed in the premises.
- Approved materials are stored as per the prescribed storage conditions.
- Only approved materials are issued to production.
- All raw materials will have retesting or expiry dates as per SOP.
- Reserve samples of all raw materials are maintained as per SOP.
- The production/process areas are checked and cleaned for Production by Quality assurance Personnel.
- The productions Operation are inspected by QA.
- The in process tests are independently monitored by in process Quality Control like volume, weight variation, impregnation, overprinting and lack test etc.

- The in-process sampling is carried out by in-process control personnel.
- All the in-process samples and the final products are tested as per approved and validated methods and specifications by QC.
- QC gives the opinion of conformance to specifications.
- Analytical and batch manufacturing records are reviewed by QA.
- QA will release the approved product batches after verifying all the records and cGMP compliance.
- QC is responsible for the analysis and approval of raw materials, packaging materials, and finished products.
- QA has the final word in the approval or rejection of any input into the product or associated directly with the product.

Documentation Control

This is carried out by QA and consisting of

- Documentation cell, where the entire documents are prepared, distributed and stored.
- Record room, where all the batch records etc. are stored for the period as per statutory requirements.

Change control system

Changes to the Validated Equipment Master Production Records, Specifications, Test Methods, Standard Operating Procedures, Packaging, Labeling, Source of Active Raw Material, Facility and Master documentation is controlled by SOP "**Change Control Program**"

The QA head is the Change Control Coordinator.

The change is made by consensus of all stakeholders departments.

C.1.9.4 Self inspection / internal audits of functional departments like Production, QC, Warehouse, Engineering, etc, are controlled by Cross Functional Audit Team. These audits are carried out according to a schedule, using an internal Audit Checklist as outlined in SOP.

C1.9.5 all the manufacturing stages are inspected by IPQC records of all the results of inspection and that of testing of incoming materials, in-process materials and finished products are formally checked against approved specification. Product assessment includes the review and evaluation of the executed batch product.

No batch of product is released for sale prior to release by QA.

C.1.9.6**Vendors of raw materials both Actives & in Actives are**

- Qualified after a satisfactory evaluation of samples of three separate lots from the vendor. An on-site inspection & Audit carried by in house expertise or any officially accredited body.
- Vendors of primary / printed packing materials are Qualified after a satisfactory evaluation (testing) of samples of one lot from the vendor and on site inspection carried by in-house expertise or any officially accredited body.

The procedures are outlined in relevant SOP.

C.1.9.7

Release of the product for sale will be done only after satisfactory judgment of quality by QA personal.

C.2**Personnel****C.2.1****Organization Chart showing the arrangement for QA including Production and Quality Control****C.2.2****Qualification, Experience and Responsibility of key Personnel.**

Following where the education and work experience of key personnel involved in Operations, Quality Control, Quality Assurance, Engineering, Production, Commercial department and the scientific office.

Title	Name	Highest Education	Experience in years
General Manager	Dr. Adib Chanan	PhD (pharmacist)	39 years
General Manager	Mr. Samir Al-samman	B.Sc.	20 years
Technical Manager	Dr. Fadel Sadaka	PhD (pharmacist)	35 years
Production Manager	Dr. A. Rabea Chanan	B.Sc. (pharmacist)	07 years
Q. C. Manager	Dr. Samar Al-Kaada	B.Sc. (pharmacist)	08 years
Engineering	Eng. Hatem Yosef	B.Sc.	05 years
Commercial Manager	Dr. Iyad Chanan	B.Sc. (pharmacist)	03 years
Chief of powder and shampoo department	Dr. Lara Al-smman	B.Sc. (pharmacist)	03 years
Chief of liquid dosage form	Dr. Dalya Al-smman	B.Sc. (pharmacist)	03 years
Chief of cream and ointment department	Dr. Amjad Chanan	B.Sc. (pharmacist)	01 years

C.2.3 Outline of arrangement for basic and in service training, and how records are maintained

New staff interview, selection and recruitment is based on the job requirement and the candidates education, scholastic achievements and aptitude for work.

New staff recruited for QC, Warehouse and QA departments will have a graduate degree in appropriate discipline.

Those staff selected for other departments like Production and Engineering will have professional degree. Previous work experience will be necessary for senior positions.

Technicians for various departments are required to qualify ITI / Matriculation besides previous work experience.

C.2.3.1 Policy on training

Training is an integral part of the organizational building and development. Each employee will undergo training periodically depending upon the organizational need, the job requirement, and special skill development.

Broadly the training needs are divided into 5 categories:

Induction training

Every employee shall undergo induction training in the first few days of his joining the organization. this will introduce the new employee to the organizational structure, philosophy and employee benefits.

cGMP training

it is mandatory that every employee shall undergo GMP training to his or her area of work.

on the job training

After completion of induction training the employee undergoes on the job training before being engaged on the job. the employee will be trained on all the Quality impacting procedure pertaining to his job. this training shall be imparted by specialized internal or external instructors.

Training on specific skills

Staff shall be imparted advanced training on specific area of operation either internally or externally, depending upon the need.

Continuing education

Continuing education will be imparted periodically, to upgrade the job knowledge and skills.

Training Records are maintained and updated in the form of “personnel Training Card” “Training log book” and “Training Attendance Register”

C.2.4 Health requirement for personnel engaged in Production

All personnel are checked for medical and physical fitness before the date of joining for duty. Periodic medical checkup is carried out at on yearly basis and suitable remedial measures are advised wherever necessary. Appropriate records are maintained.

C.2.5 personnel hygiene requirement including clothing (Growing entry procedure)

All personnel are educated by training and demonstration on personal and toilet hygiene requirements. They are encouraged to report any sickness and subsequently be advised to stay at home and if fit for work to work in non-critical areas. Smoking; Chewing etc, is strictly prohibited in the campus, food and beverages is to be consumed only in the canteen.

All the personnel engaged in QA, QC, Production, Engineering, Warehouse and House Keeping wears clean uniforms and foot wear appropriate for the duties they perform.

Those personnel engaged in production in sterile areas and Raw Material Dispensing Wears Secondary Uniforms in addition to primary uniform Protective apparel, such as head , face and hand covering will be worn as needed to protect drug products from contamination.

C.3 PREMISES AND EQUIPMENT**C.3.1 Description of manufacturing area**

Layout plan of each production area with indication of scale, label areas and annotate plan with names are indicated in fig1 & fig.2 .

The construction design of manufacturing area is a module concept, where the under ground floor consists of manufacturing facility, raw material stores , finished goods quarantine, and packing areas .

Oral liquid is having facility of compounding, holding, filling and packaging in there respective cubical, Antiseptic liquid module is having facility of compounding, holding, filling and packaging in their respective cubicles and finished goods warehouse are available in first floor.

Semisolid module is having facility of compounding, holding, tube filling and packaging in respective cubical of semisolid module.

The semisolid module is having facility of compounding, holding, filling and packaging in there respective cubical.

Apart from manufacturing, ground floor consists of administrative office and warehouse office and reception.

There is segregated cafeteria on the 2nd floor for serving purpose only. First floor consists of QA, QA documentation area, training hall, and walk in chambers for stability study, control sample area, QC, and service floor.

The main entry and exit points have air curtains and traps for restriction of entry to flying and crawling insects.

C.3.2 Nature of construction and finishes

All the manufacturing areas are roofed with Reinforced Cement Concrete with smooth finished inner wall surface and sand finished from exterior surface. Coding is done at all manufacturing areas the material of construction of each area is given below:

	Department	Material of construction
Flooring	Warehouse	Epoxy coated with corners coving
	Production	Epoxy coated in mfg. area corners coving
	Quality Control	Granite stone

	Department	Material of construction
Walls	Production	Anti- fungal, Oil painted
	Other areas	Synthetic Oil based enamel satin
External	Rest of the Facility	The external surfaces of buildings are painted with santex mat
Doors & Windows		Fiber Glass Doors and Glass Windows .

A drainage system of adequate size is provided for the rain/flood water removal.

C3.2 Brief description of ventilation systems

The entire facility is equipped with 16 Air handling units, in which one is ventilation unit. All Air Handling Units have been validated. The maintenance personal monitors the pressure differentials, Temperature and RH wherever required according to pre decided schedule.

The temperature is controlled and maintained within the limits of 24 ± 2 °C in the manufacturing and Filling area and 25 ± 3 °C is in warehouse area Heat sensitive materials are stored in controlled areas below 25°C.

The air changes are more than 20 per hour in critical process and packing areas. Secondary packing hall is having more than 15 air changes per hour . Process Areas are positively pressurized compared to the corridor with positive pressure of 5 Pascal within the class and 15 pascal w.r.t to another class of area respectively. The return air is passed through return air filters and 90% of it is again re-circulated with intake of 15% fresh air. The return air raisers are located in critical process areas only. Filters are arranged in the series and final air is passed through HEPA with 99.99% efficiency.

The pre-filters are cleaned as per the schedule or during the product change over which ever is early as described in the SOP for cleaning of the filters. In case of pressure differential failure, all the production activities are stopped and the filters are cleaned or replaced with new filters accordingly.

Validation frequently of Air Handling Unit for Class-7 Air velocity is yearly and Particle count check is carried out every six monthly .The differential pressure ΔP , and Relative Humidity are being monitored on daily basis .

C.3.4 Special areas for the handling of highly toxic, hazardous and sensitizing Materials.

No hazardous, toxic and sensitizing materials are used at this site.

C.3.5 Brief description of water system

There is a dedicated water system for manufacturing facility .the source of water is ground water which is collected in storage tank .Raw water is pumped through sand carbon filter followed by 5 micron filter which is further fed to RO-DI and then High intensity Ozone disinfection unit system. The output water from RO-DI system is stored in 5000 L storage tank made up of SS 316L .The purified water is distributed to all user points thought distribution loop made of SS316. An online conductivity meter is provided to monitor the conductivity of output purified water. All the user

points are kept in continuous circulation at a minimum velocity of about 1800 litter/hour . There is a provision to drain the water in loop if the conductivity of the same increase and fresh water is supplied into the loops. The water system is monitored and controlled such a way that to get the purified water round the clock. The RO water is kept under continuous circulation for general use within the plant.

C.3.5.1 Capacity of the system

The purified water system is having storage capacity of 6000 Lit with a generation capacity of 1250 Ltrs/hr. Purified water in the storage tank is kept under continuous re-circulation.

C.3.5.2 Construction materials of the vessel and pipe work

The purified water supply lines are made up of SS316 L and are electro polished.

All the joints are sanitary type triple coup lining. The storage tank is equipped with level transmitter for level indication, backpressure valve to prevent back pressure and vent filter for purification of air.

C.3.5.3 Specification of filters in the system

5 μ filters were used in the generation skid during treatment of water. A vent filter of 0.2 μ is provided to purified water storage tank. The vent filter is replaced after every 12 months and 5 μ filter is replaced as and when the pressure in the filter hose increases by 0.5 kg/cm² or after every 2 months which ever is earlier.

C.3.5.4 Specification of the water produced

The quality of water collected in storage tank after final treatment complies with the current EP requirement. Quality is regularly monitored throughout the system.

C.3.5.5 Sampling points and frequency of sampling

Routine sampling and testing is done in-order to assess the quality of water produced.

Sampling of storage tank is done daily and all other user points are sampled in a manner that ensures all points are covered once in a week.

C.3.5.6 The water system is having established procedure for sanitation and preventive maintenance

RO-DI system is sanitized whenever the system is shut down for a longer period of time or after every 03 months using per acetic acid as recommend by the manufacturer. The entire storage and distribution system is sanitized by 100PPm chlorine and hot water as per the respective SOPs.

C.3.6 Maintenance and Servicing of the Air Handling and Water Systems.

C.3.6.1 A well-planned preventive maintenance procedure is in place to avoid any breakdowns.

C.3.6.2 Detailed procedures for carrying out maintenance activities and the services being carried out by the engineers are defined in SOPs describing the preventive maintenance checks, repairs and details of services.

C.3.6.3 Maintenance routine check up's that effect product quality are clearly identified and documented. Engineering in charge is responsible for carrying out all the preventive maintenance operations.

C.3.6.4 All reports are maintained by maintenance personnel and are accessible to users. Any adverse findings are reported to the respective users by maintenance in charge.

C.3.7 Brief description of major production and QC laboratory equipments

Equipments design and construction

- All the major equipments are made to meet cGMP requirements.
- All the product contact parts are made of SS 316 and non-contact parts are made of SS 304.
- The equipments are designed to facilitate an easy and effective cleaning.
- All the internal surfaces are mirror polished and outer surfaces are buffed to a smooth finish.

Quality Control Instruments

- Quality Control Lab is provided with all the instruments and equipments required to test the raw material, in- process material , finished products and packaging materials.
- All the instruments and equipments are validated before being put into operation.
- All the glassware used are calibrated
- Testing / Analysis is carried out as per Standard Test Procedures (STPs) & General Test Procedure (GTPs)
- All the analytical methods are validated.
- All the analysts are trained and evaluated on Standard Operating Procedures (SOPs) , Standard Test Procedures (STPs)or General Test Procedures (GPs)
- Microbiology lab is equipped with necessary equipments and instruments to Analyse the microbial attributes of raw material, potable Water and purified, finished products, sterility test.

Calibration

- All the instruments and equipments are calibrated as per the SOPs and calibration program.
- All the glassware used are calibrated as per SOPs.

C.3.8 Maintenance of the equipments

- Preventive Maintenance and breakdown Maintenance is carried out in the Plant.
- Preventive Maintenance Procedure and schedules are prepared for each piece of equipment during the validation phase itself.
- The maintenance personal are trained and qualified on the Preventive Maintenance Procedures.
- The maintenance history of all equipments is documented.

- Any major breakdown / replacement of components which may affect the process will be evaluated . Revalidation , if required will be carried out.
- Any change in the design of the validated equipment will be governed by the Change control SOP.

C.3.9 Qualification, Validation & Calibration

Qualification & validation

As per the Validation Policy of ALLIED Pharmaceutical Industries, all the equipments will be validated for Installation, operation and Performance. Validation Protocol for each equipment shall be prepared, approved, executed and certified.

The installation qualification (IQ) Protocol provides systematic approach of documenting the verification that all the major components are provided and installed as per the purchase order specifications, design intentions and manufacture's recommendations. The IQ protocol will also include verifications that all the required utilities are in place and connected. The protocol includes "Installation verification" checklist to check various key aspects of the installation and also lists various SOPs, operating instructions and Preventive Maintenance Procedures required for operating and maintaining the system. It also provides the list of materials of constructions used for the contact and the non-contact parts.

The operational Qualification (OQ) Protocol for the equipment includes the calibration of the instrumentation, verification of SOPs, operating instructions, preventive maintenance procedures, testing of safety features and interlocks, the testing of control panel and the operational testing of various components.

The Performance Qualification (PQ) Protocol includes the objective, procedure for test run, protocol execution history, and task report and acceptance criteria

The computer systems and software, wherever used, are validated for access control and data integrity.

Calibration

Each instrument / measuring device which requires calibration will be calibrated periodically in-house using SOPs by external agency .The results of calibration are documented in the form of calibration certificate and

maintained on file. The instruments are tagged to indicate their calibration status. All the personnel handling the calibration are trained and qualified.

C.3.10 Sanitation

Written specifications and procedures for cleaning manufacturing areas and equipments are available. The following procedures are followed.

General Cleaning of Production Area

This procedure includes daily cleaning of process areas, packing areas and the outer corridors of the production block. Daily cleaning is carried out at the beginning or end of the shift or upon a specific requirement. During daily cleaning of the process and packing area no production related activity is allowed. Proper labels are displayed. Housekeeping personnel transfer the waste and scrap collected to the scrap yard.

Process area cleaning procedures

Process area cleaning is carried out as per the Standard Cleaning Procedures (SOPs) three types of cleaning has been identified:

- Full Cleaning – Area cleaning procedure between product change over.
- Dry Cleaning – Area cleaning procedure between same products with different strength.
- Wet Cleaning – Area cleaning procedure when cleaned machines are ideal more than 10 days and after continue 7 batches.

Separate cleaning procedures are defined for every process equipment. All the cleaning procedures are validated through a protocol.

Cleaning and sanitation of floor drains

Cleaning and sanitation of floor drains is governed by Standard Cleaning Procedures.

C.4 Documentation

C.4.1 Arrangement for Preparation , Revision , distribution of necessary document for manufacture

All operations related to warehouse , Production , Quality Assurance and Maintenance will be carried out strictly as per written Standard Operating

Procedures. Documents signifying compliance of approved procedures will be maintained.

The Batch Manufacturing will be carried out as per the Master Production Record. The preparation, issue and control of the Master Production Record are controlled through an SOP.

Master production records give a complete account of the manufacturing process history of each batch starting from dispensing of raw materials, and packaging materials, to the transfer of packed finished products. The method of manufacture and the various tests and analysis done at various stages of manufacture are duly recorded. A separate Master Production Record shall be prepared for each batch size of formulation.

All the Master Production Records are reviewed at the completion of the batch manufacture by Quality Assurance Department, before the batch release.

The executed and reviewed Master Production Records are archived in Documentation Cell.

C.4.2 Any other documentation related to product quality, which is not mentioned elsewhere. (Specification, SOP, Validation document, Reconciliation procedure, Equipment Specifications)

Microbiological controls on air and water

Air:

All processing areas are routinely monitored for microbial contamination (for aerobic microbial count and combined molds and yeasts count). Wherever the compressed air comes in contact with the drug product, it is filtered through a 0.2 u filter. The filtered air is monitored for aerobic microbial count and combined molds and yeasts count.

Water:

Both purified water and potable water are routinely tested chemically and microbiologically. Purified water is tested by microbiologically for total aerobic microbial count, total coliform total combined mould & Yeast count and pathogens (Pseudomoies aeruginosa, Staphylococcus aureus, Salmonella species, Escherichia coli).

Potable water is tested chemically as per in-house specifications, microbiologically checked for total aerobic microbial count , total coliform ,total combined mould &Yeast count and pathogens (Pseudomoies aeruginosa, Staphylococcus aureus, Salmonella species, Escherichia coli).

C.4.3 Documents preparation, issue and control

All the documents like SOPs, STPs, GTPs, and Master Production Records are prepared as per the relevant SOPs. The documents, after approval are stored in Documentation Cell, which will be under the control of Quality Assurance Department.

All the approved documents will be issued to the user departments through proper issue controls only by the Documentation Cell through proper records for easy traceability of documents.

C.5 PRODUCTION**C.5.1 Brief description of production operation using wherever possible flow charts and sheet.****Description**

The facility is designed in conformance with the cGMP requirements .The layout facilitates a smooth flow of men and materials. The environment is controlled for temperature. The clean air is circulated with sufficient air changes and required Pressure gradients to avoid any cross contamination.

Production operation**A. Charging of components**

All the components of a batch will be formulated such that not less 100% of the labeled or established amount of active ingredients will be present in the finished product.

The components of a batch will be checked for their identity, quantity and quality and weighed, measured or subdivided if necessary.

Weighing will be done by Production – officer against " Batch Manufacturing Record" checked by Warehouse Personnel.

All the containers containing components will be identified with component name, code, weight, QC number and also product name, strength and batch number for which the component will be issued.

Production officer checks and ensure that the area and equipment will be properly cleaned and clearance is obtained from IPQC before charging the components.

Charging of components will be done by production and is independently checked by QA.

B. Process

The processing of Oral liquid, Antiseptic, sterile gauze dressing and semisolid shall be done in respective manufacturing and packing areas.

The process is carried out according to batch manufacturing and batch packing record under the direct supervision of expert of staff.

C. In-process controls

At every critical stage of the manufacturing, in-process controls will be carried out, written procedures will be established and followed.

The frequency and limits will be defined in the Master Production Records.

Sampling will be done by Quality Assurance department as per the sampling plan. These samples will be tested for identity, strength, quality and purity as per the written procedures and approved or rejected by the Quality Control department. The Analytical report duly signed by the Head of Quality Control will be sent to the Quality Assurance department, which is filed along with the master Production Record.

The batches are released only after the review and approval of the executed Master Production Record.

D. Hold time of in-process materials

The hold time of the in-process materials at each stage of production will be established.

E. Calculation of yield

For every batch, the yield will be recorded at the conclusion of every critical phase of processing and packing. The actual yield will be calculated at the end of the packaging of a batch / lot.

The actual yield will be calculated as a percentage of theoretical yield, which is the ratio of actual yield to the theoretical yield stated as a percentage.

Expected yield at each stage of manufacture are defined in the Master Production Record. Any deviation in the yield is investigated and recorded in the master Production Record.

F. Process deviation and controls

Any deviation in the process will be duly recorded, reviewed and approved as per the SOPs.

C.5.2 Arrangement for handling of Starting Material, Packing material, Bulk & finished products

The Raw Material, Packing Material and the finished Goods Warehouse have well defined material Receipt, Quarantine , Sampling , Approved Material Storage, Rejected Material Storage, Label Storage and control , and material Dispensing Areas. All operations are carried out through Standard Operating Procedures (SOPs).

All the Raw Materials and Packing Materials are procured from approved Vendors. They are received and stored as per the SOPs . The materials received are checked for their identity and integrity. The materials are quarantined, sampled, tested as per the specifications and approved or rejected .

The approved materials are stored in the “Approved Storage Area”, under the recommended conditions of storage for each materials .

C.5.3 Arrangement for reprocess / rework

Reprocessing will be carried if permitted , through validated reprocess or reworking procedures specific to the individual products .

C.5.4 Arrangement for handling of reject ed materials and finish ed products

The rejected Raw Materials , Packing Materials and Finished Product are isolated. They will be destroyed as per the relevant Standard Operating Procedures .

C.5.5 Brief description of general policy for process validation Validation policy

ALLIED Pharmaceutical Industries is committed to validate each and every input that is likely to affect the quality of the drug product , to ensure that the intended input meets all the designed requirements resulting in a drug

product that conforms to the designed quality specifications every time and as long as it is used.

To ensure this ALLIED Pharmaceutical Industries, intends to

- Qualify all the equipments for installation, Operation and Performance
- Qualify all the Vendors of Raw material and packing material
- Validate all the manufacturing processes
- Validate all the analytical test method
- Validate all the cleaning procedures
- Qualify the personnel with appropriate educational qualification by imparting necessary training.

Process validation

All the process in the manufacture of a Drug product will be validated as per a designed and approved protocol. The protocol will be executed and certified.

C.6 Quality Control

C.6.1 Description of the Quality Control

Quality Control (QC) Department is responsible to approve or reject all drug substances, all components, drug product containers, closures, in-process materials, packaging materials, labeling and drug products.

All the specifications, Standard Test Procedures and General Test Procedures, Sampling Procedures for Raw materials, Packaging materials, In-process Materials and Drug Products shall be approved by QA Department.

All the analysis and sampling is to be performed as per these written and approved procedures. Any deviation from the written and approved specifications, test procedures, and sampling procedures or other laboratory control mechanisms shall be recorded and justified.

QC department shall calibrate the analytical instruments and equipment at suitable intervals in accordance with an established written program containing schedules, limits of accuracy and precision. If calibration requirements are not met, investigation will be carried out and appropriate action will be taken.

QC Department shall maintain reserve samples of drug substances and excipients. Reference standards, working standards, reagents and volumetric

solutions required for analysis also shall be maintained by QC department. QA department shall maintain reserve samples of drug product.

QC department shall monitor the microbial contamination of compressed air, purified water, potable water and environment of product process areas.

Sampling of in-process materials and finished products shall be performed by QA department and analysis of the samples shall be performed by QC department. Sampling and testing shall be adequate to assure that batches of in-process materials or drug products meet each appropriate specification.

However, in-process materials or drug products failing to meet established specifications shall be addressed as per SOP "Investigation of OOS". The material / product will be rejected if found necessary.

After receiving the QC analysis report for in-process materials or drug products, QA department shall perform the other relevant functions like GMP compliance Master Production Record checking etc. prior to release of the in-process materials or drug products.

C.7 CONTRACT MANUFACTURE AND ANALYSIS

C.7.1 Description of the way in which the cGMP compliance of the contractor acceptor is assessed.

Presently all Warehouses, QC and Production activities are undertaken at formulation Unite.

C.8 DISTRIEUTION COMPLAINTS AND PRODUCT RECALL

C.8.1 Arrangement and recording system for distribution

The area of the Finished Goods Warehouse is approximately 984 Sq .Meter All cGMP requirements and stipulated storage conditions will be followed to ensure safety and efficacy of Drug products.

The Finished Goods are stored as per the prescribed storage conditions prescribed for each product and conditions will be monitored and recorded. Product stock cards and, distribution and dispatch records are maintained with the relevant details for easy traceability and tracking of the product distribution.

C.8.2 Arrangement of handling of complaints & product recalls.

Complaints files

- A. Every product complaint received, whether written or oral, will be documented and responded as per the SOP on "Handling of Market Complaints ". The Complaint will be appropriately reviewed, investigated and a serious and unexpected adverse drug experience, the same will be reported to the concerned Regulatory Agency.
- B. Complaint Information From will be maintained along with report of investigation or correspondence associated with the complaint in the Complaint File Such records will be maintained as per the SOPs.
- The written record about a Complaint received will include the name and strength of the drug product, lot number, name of Complainant, nature of Complaint and reply to the Complainant
 - Where an investigation is conducted, findings of the investigation and follow-up will be maintained
 - In case an investigation is not desired, the reason and name of the responsible person taking this decision will be stated.

Product recalls\returns

Drug product manufactured by ALLIED pharmaceutical Industries shall be recalled and the product batches may be asked to be returned for the following reasons:

- Potency problem
- Packing damage
- Visual signs of deterioration
- Product complaints
- Technical reasons like formulation change

The returned /recalled Drug Product will be quarantined and investigated and necessary action for the reprocessing or disposal or destruction will be taken as per the approved standard Operating Procedure.

C.9 SELF INSPECTION

C.9.1 Short description of self inspection system

Those functional and operational areas responsible for Dispensing, Analyzing, Manufacturing Packaging, Holding and Plant Utilities, will be audited by QA audit team periodically.

This audit will be carried out to check the compliance of Good Manufacturing Practices and to assure the Quality to the customer. Regular checks will be carried out to record any deviation and action plans will be issued to the concerned for immediate corrective action. Audits will be

carried to find out any deficiencies in the system and need modification of existing systems or introduction of new systems. Necessary remedial measures will be immediately instituted and reviewed. All the self-inspection and audits will be conducted as per the Standard Operating Procedures.

List of Products Manufactured:

A. Sterile products:

A.1 : Dressing Gauze

A.1.1 ALLIED Fuscitule 10×10cm

A.1.2 ALLIED Fuscitule 10×30cm

A.1.3 ALLIED steridien tull 10×10cm

A.1.4 ALLIED steridien tull 10×30cm

A.1.5 ALLIED povidone tull 10×10cm

A.1.6 ALLIED povidone tull 10×30cm

A.1.7 ALLIED tull 10×10cm

A.1.8 ALLIED tull 10×30cm

B . Non – sterile products:

B.1 liquid dosage forms:

- B.1.1 Povidone scrub foaming sol 4%
- B.1.2 Povidone scrub foaming sol 7.5%
- B.1.3 Povidone dermal sol .
- B.1.4 Povidone –G vaginal sol.
- B.1.5 Povidone –G vaginal sol + Kit .
- B.1.6 Povidone Kit .
- B.1.7 Povidone gargle sol .
- B.1.8 Hexamidine sol .
- B.1.9 Hexamidine transcutaneous sol .
- B.1.10 Savosept sol.
- B.1.11 Savo H.C. sol.
- B.1.10 Alcosept
- B.1.11 ALLIED Glutaraldehyde sol.
- B.1.12 Steridine mouth wash .
- B.1.13 D.T.L sol.
- B.1.14 Cidal 5% sol.
- B.1.15 MRC Insect repellent (spray)
- B.1.16 ALLIED osmolax
- B.2 Semi- solid dosage from .
- B.2.1 Povidone dermal cream .
- B.2.2 Povidone dermal ointment .
- B.2.3 Povidone shampoo
- B.2.4 Hexamidine dermal Cream .
- B.2.5 ALLIED Trisept
- B.2.6 ALLIED Trisept + Kit .
- B.2.7 Steridine cream

- B.2.8 Clozan liquid soap .
- B.2.9 Nazol shampoo.
- B.2.10 Cidal 2.5% suspension .
- B.2.11 Cidal 2.5% Cream.
- B.2.12 Cidal 5% Cream .
- B.2.13 Cidal shampoo .
- B.2.14 Panthidine cream .
- B.2.15 Cetamid cream .
- B.2.16 MRC Cream .

B.3 Solid Dosage from

- B.3.1 Povidone dusting Powder
- B.3.2 DTL soap .
- B.3.3 clozan soap

C . Cosmetic products

C.1 liquid dosage from .

- C.1.1 ALLIED Alluclor .

C.2 Semi-solid dosage from.

- C.2.1 ALLIED sunscreen cream SPF8
- C.2.2 ALLIED sunscreen cream SPF15
- C.2.3 ALLIED sunscreen cream SPF19
- C.2.4 ALLIED sunscreen cream SPF30
- C.2.5 ALLIED sunscreen cream SPF45
- C.2.6 ALLIED sunscreen cream SPF72
- C.2.7 Alliederm SPF 100
- C.2.8 Allied sunscreen milk SPF 25
- C.2.9 Allied sunscreen lipstick SPF 30

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المتحدة للصناعات الدوائية

Pharmaceutical Industries

- C.2.10 Allied body lotion.
- C.2.11 Allied baby oil + vit E
- C.2.12 D-panthenol – oily cream .
- C.2.13 Allied Cold cream.
- C.2.14 Allied Cold cream plus vit. C.
- C.2.15 Venissia cream.
- C.2.16 ALLIED K-15.

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