QUALITY MANUAL

Maximize Wellness

MAXWELL PHARMA

Plot No.:6 &7 Sector-5, Parwanoo, Distt. Solan-173220 (H.P)

APPROVED BY	SIGNATURE	DATE
QA MANAGER		04/06/2023

MAXWELL PHARMA PARWANOO H.P. PLOT NO. 6 SEC-5

APPROVAL SIGNATURES

The Quality Manual of Plant has been prepared by, Checked by and Approved for implementation by the under signed.

PREPARED BY	SIGNATURE	DATE
Executive QA	Roshan	02/06/2023

CHECKED BY	SIGNATURE	DATE
Production Manager	G P Singh	02/06/2023
Q. C. Manager	Saty	03/06/2023

APPROVED BY	SIGNATURE	DATE
Q. A. Manager		04/06/2023

APPROVED BY	SIGNATURE	DATE
QA MANAGER		04/06/2023

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1.0 INTRODUCTION: This document describes the Quality Management System at MAXWELL PHARMA In today's keen market competition; it is "QUALITY"" and "QUALITY", alone which in the end will sustain a product in the market. MAXWELL PHARMA is always keen to evolve systems to take care of statutory requirements viz. National and other International Regulatory Authorities to set up stringent Quality Standards for the manufactured goods. This in turn helps in increasing and maintaining consumer acceptance and subsequently the market leadership.

2.0 QUALITY AT MAXWELL PHARMA

We at MAXWELL PHARMA have a firm commitment of all our personnel involved in various activities of the company to assure "QUALITY" of our products at all levels i.e. a firm commitment to market products with highest "'QUALITY", conforming to the laid down specifications and adherence to cGMP regulations in all operations. General requirements of Factory and Premises as per current `Schedule M' of the Drugs and Cosmetics Rules 1945 of the country and the international regulatory requirements are met with. The various operations are carried out under appropriately controlled and specified conditions wherever required.

QUALITY POLICY

"WE TAKE PLEDGE TO SERVE WITH AFFORDABLE AND QUALITY MEDICINES TO POPULACE AT LARGE. WE WILL MOVE TOWARDS HEALTHIER TOMORROW BY KEEP ON MAKING PHARMACEUTICAL FORMULATIONS IN STRICT CONTROL AND RESEARCH TO DELIVER PRODUCTS OF WORLD CLASS QUALITY."

"WE ARE COMMITTED TO UNDERSTAND AND MEET THE CUSTOMERS EXPECTATIONS AND PROVIDE QUALITY PRODUCT TO THEIR FULL SATISFACTION WHICH SHALL ENSURE VALUE FOR MONEY." WE ARE ALSO COMMITED TO MEET ALL LEGAL & STATUTORY REQUIREMENTS AT MAXWELL PHARMA **WE** ARE COMMITTED FOR CONTINUOUS BUSINESS GROWTH ENSURING INCREASED PROFITABILITY THROUGH MOTIVATED AND TRAINED WORK FORCE & BY ADOPTING THE MANTRA OF CONTINUOUS IMPROVEMENT.

3.0 OBJECTIVES OF QUALITY ASSURANCE DEPARTMENT

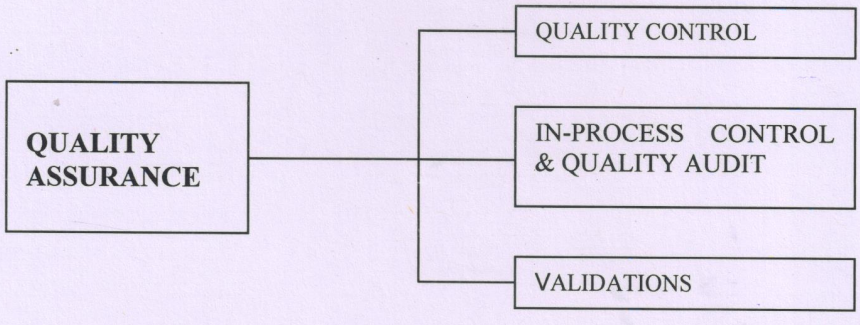
The overall objective of "QUALITY ASSURANCE DEPARTMENT" is to ensure that: -

1.1 The desired `QUALITY' is built in the product at each and every stage of manufacturing.

1.2 The same is retained in the product throughout the shelf life of the product.

4.0 "QUALITY ASSURANCE DEPARTMENT"

Our plant has a well-equipped Quality Assurance Department, staffed by competent technical personnel directly responsible to the management and independent of all other departments.



5.0 DOCUMENTS

Documentation is one of the most important aspects of any Organization. For each and every activity carried out in the organization there must be a written down and authorized procedure. At MAXWELL PHARMA. Each activity has an authorized document. All the original documents are kept in Quality Assurance Department as "Master Copy". Q. A. Head issues approved photocopies of the documents to the concerned departments for their reference. Quality Assurance Department has following Documents.

5.1 Methodology.

5.2 Quality Assurance SOP

5.3 Site Master File (SMF)

5.4 Master Formula Record (MFR).

5.5 Batch Manufacturing Record (BMR)

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5.6 Raw Material Specification. (RMS)

5.7 Packing Material Specification (PMS)

5.8 Control Specimen of Packing Material. (CS)

5.9 Finished Products Specification. (FPS)

5.10 Standard Operating Procedures (SOP)

5.11 Validation Master Plan (VMP)

5.1 METHODOLOGY:

This document is prepared to achieve all the objectives listed under 'schedule M' of the Drugs and Cosmetics Rules 1945. It consists of laid down standard procedures to be followed for the manufacture of drugs right from ordering of Raw Materials to dispatch of finished goods to the market & further follow up of the products up to the end of their shelf life.

5.2 QUALITY ASSURANCE PROCEDURE

Quality Assurance SOP that provide details of various activities to be performed for implementing each element of quality system mentioned in the codes of GMP. QA SOP are written and approved by Quality Assurance Department. Approved original copies of the QA SOP are kept at Quality Assurance Department. Q.A. Department issues authorized photocopies to the concerned departments of the manufacturing units for their reference.

5.3 SITE MASTER FILE:

This document describes the details about the site and the activities carried out at the site. It gives the details of the location and the description of the facility. The detail about the products manufactured at the site is mentioned in this document.

5.4 MASTER FORMULA RECORD (MFR):

One original copy of Master Formula Record for a product is issued by QA Department to Production Department. Master Formula Record consists of all details for manufacturing of the product, materials to be used, manufacturing procedure in detail, equipments to be used, packaging material to be used, packing pattern and pack size,

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shelf life, standard yield. Q.A. Department issues approved copy to concerned Production Department. Each batch of every Product is manufactured as per its Master Formula Record.

5.5 BATCH MANUFACTURING RECORD (BMR):

Batch Manufacturing Record is issued by Quality Assurance Department after authorization and allocating BPR number.

5.6 RAW MATERIAL SPECIFICATIONS (RMS):

For all the raw materials received at MAXWELL PHARMA.there is written Raw Material Specifications (RMS) approved by Quality Assurance Department. All the raw materials are analyzed & released on compliance with these specifications.

5.7 PACKING MATERIAL SPECIFICATION (PMS):

For all the Packaging materials received at MAXWELL PHARMA,there are written Packing Material Specification (PMS) approved by Quality Assurance Department. All the packaging materials are tested and released on compliance of these specifications.

5.8 STANDARD PACKS AND SPECIFICATION (SPS):

For all the Finished Products, packing instructions are written in Standard Packs and Specifications (SPS) approved by Quality Assurance Department. All Finished Products are packed on compliance with these specifications.

5.9 FINISHED PRODUCTS SPECIFICATIONS (FPS):

For all the Finished Products, there is written Finished Product Specifications (FPS) approved by Quality Assurance Department. All Finished Products are analysed and released on compliance with these specifications.

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5.10 STANDARD OPERATING PROCEDURE (SOP):

Standard Operating Procedure for each and every critical activity carried out in the factory are prepared. Approved original copies of the Standard Operating Procedures are kept in the Quality Assurance Department. Q.A. Department issues authorized photocopies to the concerned departments for their reference.

5.11 MASTER VALIDATION PLAN

This Document describes the details of validation policy of MAXWELL PHARMA. It outlines the validation to be carried out for the facility, process, equipments, analytical methods and utilities along with the schedule of validation.

6.0 QUALITY CONTROL

"QUALITY CONTROL" is the core functional area of our activity. The Quality Control system encompasses control on all the incoming Raw Materials, Packaging Materials, and Finished Products till they are transferred to Finished Goods Stores for dispatch or distribution for sale. The Quality Control Laboratory is appropriately located so as to co-ordinate properly with Manufacturing Department.

The Quality Control Laboratory is divided into three sections.

6.1. Chemical Testing Laboratory.

6.2. Instrument Room.

6.3. Microbiological Laboratory.

6.1. CHEMICAL TESTING LABORATORY:

The laboratory area is well illuminated, ventilated and air-conditioned. The working platform is made with smooth tiles.

Flooring is made of smooth Kota Stone walls are made up of modular panels and easy to clean.

A separate wash area for cleaning of the glassware is provided. A separate room for storage of Chemical & Reagent and documents storage is provided.

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6.2. INSTRUMENT ROOM:

A separate, air conditioned and well-equipped Instrument Room is provided. All sophisticated instruments are kept in this area.

6.3. MICROBIOLOGICAL LABORATORY:

At MAXWELL PHARMA. A separate Microbiological Laboratory is provided. Microbiological Laboratory has separate Air Handling Unit (AHU) with HEPA filters to provide classified area for Microbiological testing. Separate room has been provided for Media Preparation and Autoclave. Microbiological Laboratory has joint less self-leveling epoxy flooring. Walls are made with modular partition with smooth surfaces, for easy cleaning. Coving is done for easy cleaning & to avoid accumulation of dust and microorganisms. Entrance to Microbiological testing room is through three air locks.

6.4 FUNCTIONS OF QUALITY CONTROL DEPARTMENT:

6.4.1. Sampling.

6.4.2. Testing.

6.4.3. Quality Review / Stability Studies.

6.4.4. Calibration of Instruments, Equipments & Glassware.

6.4.5. Periodic preparation & standardization of volumetric solutions. Preparation of Reagents.

6.4.6. Validation of Analytical Methods.

6.4.7. Reference Samples collection, preservation and destruction.

6.4.8. Preservation and destruction of Records.

6.4.9. Documentation.

7.0 SAMPLING

Sampling is a process of collecting a representative portion of material from a large quantity of batch. In order to check whether a batch of raw material / finished product conforms or not with the specifications prescribed for the same, it is necessary to test the same. It is

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impracticable to test every part of the batch. Therefore, it becomes imperative to draw samples, which are representative of the complete batch from which they are taken. Before going for sampling, the Q.C. Officer reviews

(i) GRN received from Raw Material Stores.

(ii) Specification of the raw material.

(iii) Sample quantity to be drawn.

(iv) Approved vendors list,

(v) Precautions to be taken while sampling etc.

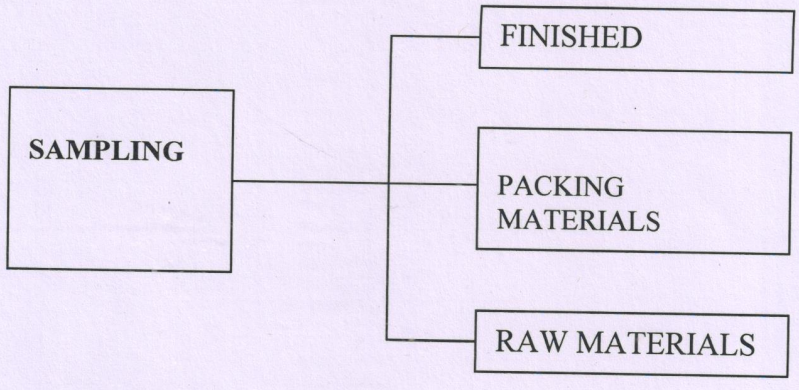
Before sampling, the consignment shall be re-verified for physical Damage if any 'and label details. If found satisfactory, sampling shall be executed. If found not satisfactory, material shall be shifted to `Rejected Area' for returning to the party or for destruction. Sampling of raw materials and packaging materials, is carried out as per the guidelines given in SOP:"Sampling of raw materials" and in SOP:" Sampling of packaging materials" respectively.

In case of Finished Products, the Q.C. Officer reviews

(i) The Test Request Form' for Bulk or Finished products samples from concerned Production department.

(ii) Sample quantity to be drawn.

(iii) Precautions to be taken while sampling etc. Sampling of Finished Products is carried out as per SOP" Sampling of finished products".



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7.1 SAMPLING OF RAW MATERIALS:

On receiving the GRN from Raw Material Stores the Quality Control Officer enters all the details regarding the consignment in the register for ` Analytical Reference Number (A.R. No.)' and does the sampling of the consignment as per the procedure described in SOP "Sampling of raw materials". He affixes the `UNDER TEST' and Stamped as SAMPLED on the sampled container indicating date of sampling and signature of the Quality Control Officer. SAMPLE FOR ANALYSIS' label with all the details is affixed to each container in which sample is collected.

7.2. SAMPLING OF PACKAGING MATERIAL:

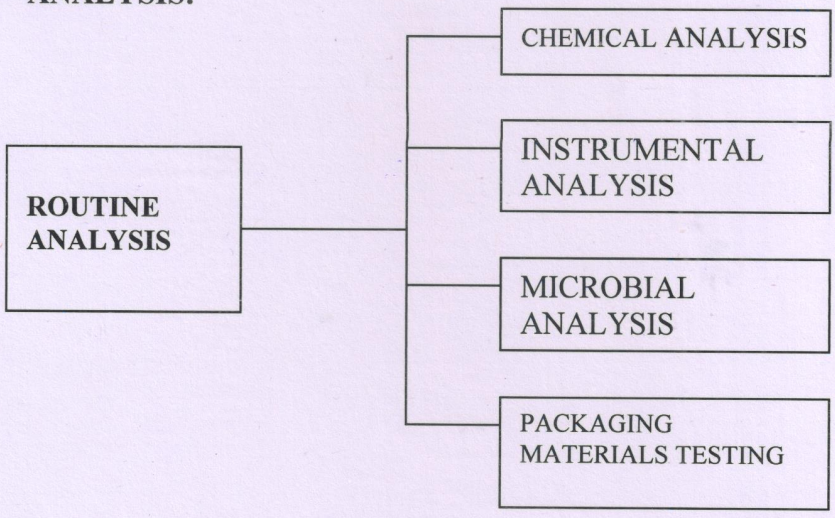
On receiving the request from Packaging Material Stores the Quality Control Officer does the sampling of the consignment as per SOP: Sampling of packaging materials". While sampling QC Officer observes the physical appearance & the cleanliness of the consignment.

7.3. SAMPLING OF INTERMEDIATE AND FINISHED PRODUCTS:

7.3.1 Sampling of Bulk (blend / Bulk solution): After receipt of Test Request Form Q.C.Request/ Report' for Bulk from concerned Production department, a Bulk sample is drawn by QC Officer, as per sop no. SOP:" Sampling of finished products" after ensuring that the total processing is completed.

7.3.2 Sampling of Final Pack: On completion of packaging the sampling of the final pack is carried out by Q.C. Officer as per SOP:" Sampling of finished products" after receiving Test Request Form ' for Final pack product from Production Department.

8.0 ANALYSIS:



The Raw Materials and Finished Products are subjected to chemical and microbiological tests as described in the Raw Material Specifications / Finished Product Specifications. The Raw Material Specification & Finished Product Specifications are made taking into consideration Pharmacopoeial Specifications and in-house specifications, which are developed, by making use of the standard analytical references in literatures.

8.1 RAW MATERIAL ANALYSIS:

The quality of pharmaceutical formulations is largely governed by the quality of the raw materials used in it. Testing of raw materials, therefore, is of utmost importance. The purpose of testing of any raw material is,

i) To confirm that the material is what it is claimed to be.

ii) That it has the characteristics that will provide the desired quality in the dosage form produced from it.

iii) To provide an assurance for keeping the quality of the final product.

Representative sample of raw material is tested for compliance with laid down Raw Material Specification (RMS) or with the respective Pharmacopoeia. The testing of raw materials by chemical method includes the various limit tests for impurities like Arsenic, Lead, Chloride, and Sulphate, Copper and Bromide or any other possible

impurities. Sulphated ash, Melting point, Specific optical rotation, Loss on drying, Water content & Assay (Purity) etc.

For all Active Pharmaceutical Ingredients (API) used for manufacturing a separate sample from minimum 4 container is pooled and subjected to complete analysis as per the Raw Material Specification (RMS) or respective Pharmacopoeia.

If number of containers is more than 4, follow the $\sqrt{n+1}$ Formula.

8.1.1 RELEASE OF RAW MATERIALS:

The raw material meeting the laid down specifications is approved and released by Quality Control Department for use in Production. Each and every container of material released by Quality Control Department is affixed with authorized `PASSED' label issued by Quality Control Department. Passed labels have the following details,

i) Name of the Material.

ii) Analytical Reference Number (A.R. No.).

iii) Goods receipt Number

iv) Assay value. (For API)

v) Retest Date.

vi) Signature of Q.C. Officer.

vii) Date of Release.

8.2 FINISHED PRODUCT ANALYSIS:

An important factor in ensuring consistency of quality of a finished product is compliance with the Finished Product Specifications (FPS) of the product. Before it is released for sale it is essential that every batch of product meet these specifications. We at MAXWELL PHARMA, analyze Finished Products at bulk stage & final Pack verification as per FPS.

8.2.1 ANALYSIS OF BULK SAMPLE:

To comply with the requirements of Schedule `M' of Drugs and Cosmetic Acts 1940, each batch of a product at bulk stage is analysed as per respective Finished Product Specification and if meets the requirements `APPROVED' slip is issued by QC Department.

If any batch does not comply with the respective Finished Products Specification (FPS) the REJECTED' slip is issued by QC Department.

8.2.2 ANALYSIS OF FINAL PACK:

To comply with the requirements mentioned under Rule 74 & 78 of Drugs & Cosmetic Acts 1940, each batch is analysed at pack finished stage i.e. after completion of packaging, as per the Finished Product Specification.

A stringent release limits are fixed for the finished products than the Pharmacopoeial limits. i.e. If the Limits specified in the Pharmacopoeias for Finished product is 90 % to 110 % of label claim. We have our internal standard limits for initial release as 95 % to 110 % of label claim. QC officer prepares reports of analysis and the same are retained as a part of Batch Manufacturing Record.

8.3 INSTRUMENTAL ANALYSIS:

Instrumental analysis plays a very vital role in analysis because of its precision and accuracy in results. Raw Materials and Finished Products at one stage or another need to be analysed using instruments.

The Quality Control Department at MAXWELL PHARMA is well equipped with various sophisticated instruments. Apart from the Instrument manuals, Standard Operating Procedure (SOP's) is available at the place of work to facilitate instrument operation, calibration & maintenance. Voltage stabilizer is installed to protect all the instruments from power fluctuation. UPS power backup is provided to avoid power failures. The instruments & their surroundings are kept clean and tidy. All laboratory instruments are calibrated regularly and serviced as and when required for their effective/intended performance. A record of the same is maintained by Q.C. Department.

8.4. PACKAGING MATERIAL ANALYSIS:

Packaging Material plays a very vital role in today's Pharma Industry. It is the packaging material, which creates a good, or a bad first impression about the quality of the product.

Packaging Material is the material which is used to pack the product for the purpose of distribution/sale.

In MAXWELL PHARMA all packaging materials are tested as per respective Packing Material Specification (PMS). Most of the tests are physical in nature. The text matter and colour shade are compared with its block proof and colour shade card which are approved by QA Department with respect to the legal requirements of Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic Rules 1945.

The approved Block Proof for text matter and the Colour shade cards received from supplier and approved by Packaging development department at corporate office & are retained by QC Department. Reports of testing are made and preserved by Q.C. Department.

In case of DB boxes, cartons, literatures, sticker labels & foil, the specimen of item tested is attached to the individual report for ready reference.

8.4.1 RELEASE OF PACKAGING MATERIALS:

Packaging Materials meeting the laid down specifications are approved and released for use in the Production by affixing `PASSED' label over it by Quality Control Department. "PASSED" labels are issued for each and every pallets of the packing material. Record of testing of packaging materials are prepared and maintained by Q.C. Department.

Passed labels will have the following details,

i) Name of the Material.

ii) Test Report Number (T .R. No.).

iii) Signature of Q.C. Officer.

Iv) Date of receipt.

v) Date of Release.

8.4.2 REJECTION OF PACKAGING MATERIALS:

Any packaging material that does not meet the laid down specifications is rejected and carries authorized `REJECTED' label issued by Quality Control Department.

The material so rejected is then transferred to Rejected Area and returned to the Vendor at the earliest. And in case of printed materials i.e. labels, cartons and foil etc. are destroyed in our

premises in the presence of the supplier's or contract manufacturer's representative. Records of the same are maintained.

9.0 CALIBRATION

Calibration is defined as, " The comparison of a measurement standard or instrument of known accuracy with another standard or instrument to detect, correlate, report and/or eliminate by adjustment any variation in the accuracy of the item being compared." Calibration is an essential part of Quality Control that helps to eliminate errors before they occur.

Proper calibration helps to produce material and products, which meets the laid down specifications, which in turn helps in producing good quality products. This also helps in reducing cost of the product by avoiding failures; rework expenses, repetition in analysis, etc.

The objectives of calibration are,

I) To determine the difference or the amount of error between known and unknown readings.

II) Adjust the output of the equipment being measured to bring it to a desired value.

9.1. CALIBRATION OF INSTRUMENTS:

Our laboratory is well equipped with various analytical instruments useful in pharmaceutical analysis. For efficient work performance, these instruments are periodically calibrated and serviced at predetermined schedules.

9.1.1. All the instruments are checked for their satisfactory performance.

9.1.2. All the instruments are calibrated periodically as per Pharmacopoeia or Instrument Literature.

9.1.3. Record for calibration and servicing is maintained as per respective Work Instructions.

9.2. CALIBRATION OF VOLUMETRIC FLASK, BURETTES, PIPETTES ETC.:

As Good Laboratory Practice volumetric glassware are calibrated for its verification at the time of receipt as per SOP "Sanitization of Quality Control Department". Records of calibration are maintained with the Q.C. Department.

9.3. CALIBRATION OF THERMOMETERS & HYGROMETERS:

As a Good laboratory Practice Thermometers & Hygrometers are calibrated for their verification at the time of receipt as well as periodic calibration is also done as per SOP "Calibration". Q.C. Department maintains records of the same.

9.4. PREPARATION & STANDARDIZATION OF VOLUMETRIC SOLUTIONS:

As a Good Laboratory Practice volumetric solutions are prepared and standardized as per respective Work Instructions. The standardized solutions are stored in clean and dry glass bottles. A label is put on the bottle having details such as Name of the solution, Molarity factor of the solution, Batch No., Date of preparation, valid up to and Sign of Officer who has prepared it. Molarity factor of standardized solution is valid till it is clear and free from contamination or for one month whichever is earlier. Solution is re-standardized after one month if solution is found to be clear & free from contamination, however the solution cannot be used after two months from the date of preparation. Records of preparation and standardization are maintained by Q.C. Department.

9.5. PREPARATION OF REAGENTS AND INDICATORS:

As a Good Laboratory Practice the reagents and indicators required for routine analysis are prepared as per the Pharmacopoeial procedures. Such reagents and indicators are stored in a clean glass bottles having label indicating Name of Reagent / Indicator, Date of preparation, Validity and Sign of the officer who has prepared it.

These reagents and indicators are valid for three months or till it shows any changes in the physical appearance whichever is earlier. The reagent / indicator preparation record is maintained by the Q.C. Department.

10.0 REFERENCE STANDARDS

Reference Standards are very important in all types of analysis. Characteristics and suitability for the intended purpose. Reference standards are maintained and distributed by the respective Pharmacopoeial commissions. In case of non-Pharmacopoeial drugs, the approved vendor provides the Reference Standards. Reference Standards are stored separately in desiccators.

Records of procurement and consumption of Reference Standards is maintained by Q.C. Department.

11.0 WORKING STANDARDS

As reference standards are very expensive and available only in small quantities they cannot be used routinely for analysis. Working standards are made against reference standards and used for daily analysis. Substances, which have been analysed, released and having highest purity is selected for preparation of working standard. Assay is determined in duplicate by two analysts and average of the four readings is taken as potency for the substance. Working Standards are kept in tightly packed vials, and stored in desiccators in a cool place. Working Standards are valid for one year. Records of preparation and consumption of working standards are maintained by Q.C. Department.

12.0 QUALITY REVIEW STUDY

Stability profile of a drug as a raw material may be indicative of, but not necessarily consistent with, its behavior as a part of a Finished Product (i.e. formulation). Product stability is significantly influenced by the method or process of formulation and packaging thereafter. Along with chemical changes, physically observable changes such as colour change mottling, breaking, sticking, etc. Product stability studies are therefore very necessary.

These studies ultimately aim towards designing not only formulation techniques including packaging, but also bring out optimal storage conditions and useful shelf life. At Maxwell Pharma before launching any Product, it is tested for its stability. Stability studies are also carried out on all the products, which are put into the market. Stability study is an important function of the QC Department which involves periodic review regarding the quality of the products which are already in the market, by carrying out various physical, chemical tests. An annual program for carrying out this activity is made in advance covering the full range of products. Stability evaluation is carried out with objectives like,

I) Product shelf life reconfirmation.

II) Evaluation aspect of shelf life extension /reduction or overages optimization.

III) Evaluation aspect of shelf life, for a change in Product's packaging design.

STABILITY STUDY IS DIVIDED INTO TWO PARTS.

12.1 Stability Study by testing the product as per FPS.

12.2 Physical Observation.

12.1 STABILITY STUDY BY TESTING THE PRODUCT AS PER FPS:

Initial three batches of the new product are subjected to accelerated stability testing. Samples are collected for each product and stored at ambient temperature. One samples of each product is collected every 2 years. The periodic evaluation of above collected samples by testing as per respective Finished Product Specification (FPS) is carried out at predetermined intervals, as given below,

PRODUCTS SHELF LIFE (in months)	INTERVAL FOR PERIODIC EVALUATION (in months)			
24	12	18	24	30
30	12	24	30	36
36	12	24	36	42

The data of the testing is complied & maintained in Q.C. Department.

12.2 PHYSICAL OBSERVATION:

Samples for Quality Review (Physical Observation) study are collected from any one batch of every product in each month and stored at room temperature. These samples are checked with respect to physical parameters quarterly throughout it's shelf life. Record is maintained by Q.C. Department.

13.0 IN-PROCESS CONTROL & MONITORING

Quality of a product cannot be controlled by only testing the product at the end of production. This fact is well known and established. Whenever a product is manufactured, it consumes raw materials and involves processing which may range from simple to very complex. In order to ensure that during routine manufacturing of products, the products produced remain within established quality parameters, a program for In-process control and monitoring has been designed.

[1] In-Process Product Control Checks:

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[1.1] Routine In-Process Checks:

Quality Assurance Officers are involved in the routine In-process checks to highlight any deviation from the specified processes observed and to take corrective action whenever / wherever required. Visits are made every day in each shift to various Production departments to check & ensure the quality of the products with respect to,

13.1. Good house-keeping, Line identification, Line Clearance, Proper segregation of materials in all the areas.

13.2. Manufacturing operation as per Master Formula Record.

13.3. Uniformity of weight, Disintegration Time, friability, Hardness etc.

13.4. Visual Inspection.

13.5. Packaging as per the Standard Packs & Specification.

13.6. Overprinting batch details & Quality of Packaging.

13.7. Leak test.

13.8. Simultaneous & proper recording by Production Departments.

The observations are recorded for each and every batch of the product in In-process observations form. In addition to these, observations like printed packaging materials reconciliation, destruction of excess overprinted packaging materials etc. is performed based on prevailing conditions. Deviation, when noted, is informed in writing to concerned departments for necessary action. Various work instructions are being followed for effective In-process operational controls.

14.0 RESERVE SAMPLES

We are having a laid down standard procedure for Reserve Samples collection, Storage and destruction. Reference samples of both, Raw Materials and Finished Products are collected. All reference samples are stored in a separate air-conditioned room, in racks provided for them with proper segregation.

14.1 Raw materials control samples are collected along with "Sample for Analysis" & are stored for 2 years from the date of collection. Active Raw materials are stored for the period of 1 year after the expiry of the last batch produced from that material. Raw

Material control samples are preserved so that the same can be retested or can be reevaluated for its suitability in the product.

14.2 Finished products control samples are drawn so that they can be examine in future if required through- out the shelf life of the product & is mandatory as per Drugs & Cosmetics Act. Control samples for Finished Products are collected after completion of packing of each batch of each product and stored for 12 month its expiry period. The quantity of Control Samples of Finished Product collected is such that they are sufficient for two complete analyses.

14.3 Record of collection & retention of reference samples of Finished Product is separately maintained by Quality Assurance Department in a `Control Sample Register'.

15.0 FINISHED PRODUCT RELEASE TO MARKET

Release of Finished product to the market is a very important function of Q.A. Department.

After completion of Batch manufacturing and packaging the production department carries out reconciliation and Department Head checks the BPR thoroughly & submits to Q.A. Department.

QA In-charge verifies the complete BPR, which includes the QA In-process report, Finished Product analysis reports and after ensuring that the batch is manufactured as per the laid down systems and procedures the Batch is released to the market by issuing `Release Slip' to the Finished Goods Stores. If any batch does not comply with any of the following.

(i) With the respective Finished Product Specification.

(ii) Satisfactory QA In-process checks, etc.

The `Reject Slip' is issued. The final authority of Release or Rejection of any product lies with the QA In-charge. After release of the Batch to the market BPR is preserved by Q.A. Department. in separate files, product-wise in the record room.

16.0 DOCUMENTATION

Documentation is the prime requirement for systematic `Quality Control' work. All incoming Raw Materials, Packaging materials and finished products are subjected to various tests and measurements detailed out in the respective specifications for compliance before release. The

QC chemists analyze /check the Raw materials, Packaging materials, Finished products & record the details of their findings i.e. observations, weights, dilutions, readings, calculations and results in protocols of the test/analysis applied. The final report is made in the respective requisitions/report. Protocols are attached to the reports.

All the reports & protocols are checked & signed by Q.C. Head. Raw material reports & Packing material reports are filed in separate files Q.A. Reference number wise. Finished Product reports are attached to the respective Batch Process in Records.

As a part of Good Laboratories Practices, besides above documentation of routine analysis QC Department maintains following records.

16.1. Preparation and Standardization of volumetric solution.

16.2. Preparation of reagents.

16.3. Calibration and servicing records of laboratory instruments.

16.4. Volumetric Glassware calibration records.

16.5. Sanitization record.

16.6. Culture maintenance records.

16.7. Media preparation records.

16.8. Control samples collection & destruction record.

16.9. Procurement and consumption of reference standard.

16.10. Preparation and consumption records for working standards.

16.12. List of chemicals, reagents and mediums available.

16.13. Sterilization records.

16.14. Q.A. Report registers.

Each and every work performed by Q.A. /Q.C. Officer is documented as GLP / cGMP record.

17.0 RETENTION & DESTRUCTION OF RECORDS

All BPR's are retained for a period of minimum one years from the date of manufacturing and destroyed thereafter. The records of destruction are maintained by Q.A. Department. All the raw material Analysis reports are retained for a period of minimum five years and destroyed thereafter. The record of destruction is maintained by QA Department. All the packing material analysis report are retained for a period of minimum five years and destroyed thereafter. The

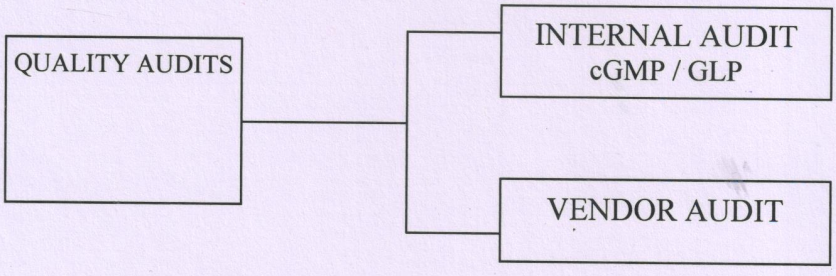
records of destruction are maintained by QA Department. All cGMP / GLP records are retained for a period of minimum five years and destroyed thereafter. The records of destruction are maintained by QA Dept.

18.0 QUALITY AUDITS

It is an ideal way to make an independent methodical examination and review of a function with intent to verify, ensure and report areas of non-compliance when compared with laid down standards.

The Quality Assurance function needs to include evaluations for regulatory compliance so that Management will have current information on compliance status of the Company. A Quality Audit is a formal review of a product, manufacturing process, equipment, facility or systems which conform with expected Quality Standards. Quality Audit program even includes audits of the Quality Control Department.

There are two major types of Quality Audits:



18.1 Internal Quality Audit cGMP / GLP or Self Inspection:

18.1.1 Quality Assurance Officers in their daily in-process rounds checks and confirm that laid down systems and procedures are followed in the company but this is a routine and they cannot cover all the areas, as they have to give more stress on manufacturing and packing of the products.

18.1.2 To have a complete check and audit of the all operations directly and indirectly

connected with manufacturing which covers Personnel, Premises, Environment, Warehousing, Dispensing, Production, Packing, Quality Assurance / Control & Distribution, Internal Quality Audit is carried out.

18.1.3 Self Inspection or Internal Quality Audit is a measure taken to confirm that staff at all level is following a laid down system and procedure for manufacturing and Quality Assurance. It is designed to find out shortcomings in Quality Assurance Systems and to suggest corrective actions.

18.1.4 Self Inspection is carried out by an individual of Quality Assurance Department or a team of persons within the organization having good knowledge of cGMP / regulatory requirements & laid down systems & procedure of the company.

18.1.5 Self Inspection is independent & impartial. Self-Inspection is carried out with an interval of at least six months.

18.1.6 Advantages of Self Inspection:

18.1.6.1 As Self Inspection is independent and impartial it gives a complete idea, whether, laid down systems and staff follows procedures at all levels in each section through out the company.

18.1.6.2 It helps in improving the Quality Systems with respect to latest developments in cGMP and International requirements.

18.1.6.3 It encourages and improves quality of work in all areas of manufacturing to meet the laid down standards.

18.2 Vendor Audits:

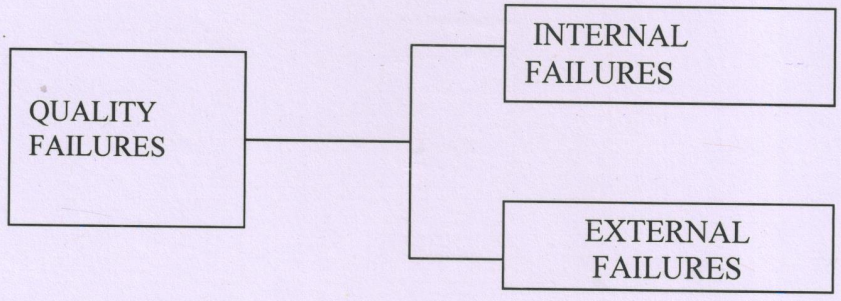
We have written policy for vendor qualification of Key Raw and Packing Materials.

- Vendor has been qualified on the basis Site / Virtual Audit with three batch sample analysis.
- If the vendor is USFDA/MHRA//TGA accredited site audit not required and qualified on the basis of three batch sample analysis.

- If vendor audit is not possible send the vendor qualification checklist to the vendor and vendor has been qualified on the basis of evaluation of questionnaire with three batch analysis of material.
- Vendor shall also be approved by evaluating DMF of material and analysis report of three batches sample.
- The vendor shall also be approved by reputation of the Organization and Continuous supply of material of minimum three lots meeting the required specifications.

19.0 FAILURE OF QUALITY

Quality Failures are of two types.



Company is paying due attention to minimize Quality Failures which results in higher profit. Quality Assurance Department plays a very important role in reducing Quality Failure by means of in-process checks and Quality control.

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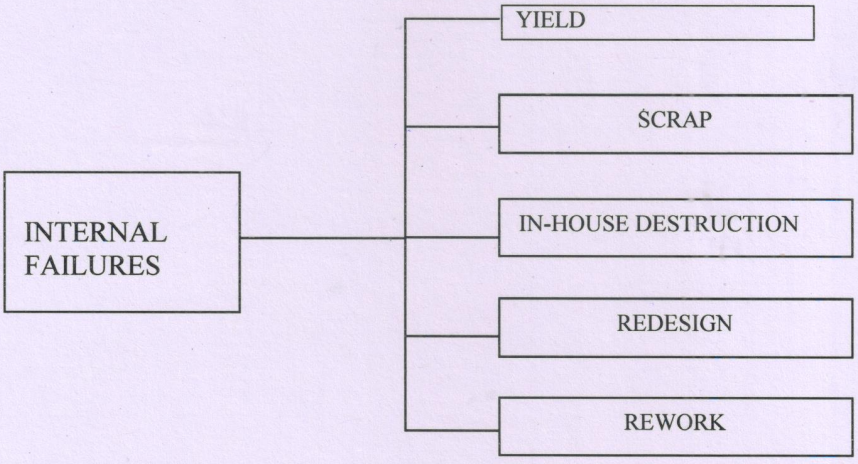
19.1 Internal Failures:

Due attention is given to the Internal Quality failures.



19.1.1 YIELDS:

Loss of yield or productivity is investigated and appropriate measures are taken to avoid recurrence.

19.1.2 SCRAP:

Wastage like excess overprinted packaging materials is minimized.

19.1.3 IN-HOUSE DESTRUCTION:

Materials and finished products, which are rejected and visual inspected not passed items, are well segregated and destroyed as per SOP.

19.1.4 REDESIGN:

Existing specification, systems and procedures are redesigned or updated based on regulatory requirements or other benefits like better process, better customer appeal, etc.

19.1.5 REWORK AND REPROCESS:

Reprocessing:

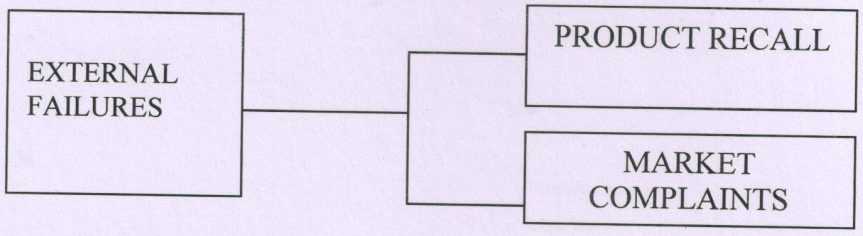
It is subjecting an intermediate stage product or final product that does not conform to standards or specifications to one or more processing step that are part of established manufacturing process in order to obtain acceptable quality intermediate stage or final product.

Reworking: It is subjecting an intermediate stage product or final product that does not conform to standards or specifications to one or more processing step that are different from

established manufacturing process in order to obtain acceptable quality intermediate stage or final product.

19.2 EXTERNAL FAILURES:

A great emphasis is given to minimizing External Quality Failures which have direct relation with customer's satisfaction.



19.2.1 **Product Recall**:

These are two types:

19.2.1.1 FDA initiated recall.

19.2.1.2 Voluntary recall

19.2.1.1 FDA INITIATED RECALL:

FDA collects the finished product sample at random from company or from market and analyzed in their laboratories for compliance with label claim & also other physical parameters. In case of any non-compliance, FDA asks for explanation and instructs the manufacturer to withdraw the particular batch of the product immediately, it is the responsibility of QA Department to eliminate such recalls by giving proper explanations to authorities if occasion arises.

19.2.1.2 VOLUNTARY RECALL:

Voluntary recall is initiated by the Company due to any quality problem, which has cropped up during the shelf life of a product. Whenever sufficient data is collected indicating the unsuitability (chemical or physical) of a product or a particular batch of a product for remaining in the market or the consumer's use the stocks are recalled from all locations wherever distributed by Quality Assurance Department with the help of

Distribution Department. This action originates from the quality review data or persistent consumer complaints. The stocks thus received are checked and destroyed after suitable documentation.

20.0 MARKET COMPLAINTS

Market complaints normally originate from the consumer, trader or the stockiest. The nature of complaints varies from less quantity, physical defects, loss of efficacy, pack defects, side reactions, etc. On receipt of the complaint acknowledgement is given to the customer. The complaints are then investigated in detail by Quality Assurance Department with the help of Production Department. Suitable measures are taken / advised for avoiding recurrence of such complaints. Training is given to all the personnel involved in the work. A suitable reply is sent to the customer. A complete record of all the complaints & action taken is maintained by Quality Assurance Department.

21.0 TRAINING

Training is an important function of any organization. Training is must for each & every person in order to develop the required skills, general awareness and continuous increase in the overall efficiency. Training is a continuous process. The performance of each & every individual reflects directly or indirectly on the quality of the product manufactured which is very important for the health of the customer. Quality Assurance Department plays a very vital role in maintaining quality of the products; therefore training to Q.A. Personnel is very important.

Training is divided into three parts:

22.1. Training to new recruits.

22.2. Refresher training programs for all.

22.3. Training after adoption of any new system / equipment or change in any process.

2.1.1Training to new recruit:

Recruitment of new employee is done on the basis of his / her qualification & merits in accordance to the Job he / she is selected for Taking in view his / her qualification and experience he / she is trained by Senior Personnel for following :

22.1.1. Knowledge about the company and its functioning.

22.1.2. Rules and Regulations of the company.

22.1.3. Nature of Work and Job Responsibilities.

22.1.4. Quality Assurance System and Good Laboratory Practices.

22.1.5. Analysis of the materials /products.

22.1.6. Operation, Calibration and Maintenance of Instruments, etc.

21.2. Refresher Training Program for All:

Refresher Training is very important and is arranged periodically. Any one of the trained persons prepares for a specific topic and discuss with his colleagues. Lectures of faculties outside the department are also arranged.

21.3. Training after adoption of new system /equipment:

The concerned employee is being trained for the use of the system / equipment by authorized persons who install system / equipment. Training records of individual are being maintained separately.

22.0 VALIDATION

DEFINITION: Validation is the evaluating of process, product or analytical method to ensure compliance with product or method requirement. Validation is an action of proving in accordance with the principles of good manufacturing practice that any procedure, process equipment, material, activity or system actually leads to expected results. Validation is the evidence, which give high degree of assurance that the product meets the laid down specification.

Type of validation conducted at Maxwell Pharma.

22.1. Prospective Validation':

This Validation conducted prior to the distribution of a new product, or product made under revised manufacturing process, where the revisions may affect the product's characteristics.

22.2. Concurrent Validation:

Concurrent Validation is establishing documented evidence that a process does what it is supposed to do, based on data generated during actual implementation of the process.

22.3. Retrospective Validation:

System or processes are in place, which have not been previously validated but are functioning well and constantly producing good products, already in production. Establishing documented evidence that a process currently in use does what it purports to do. This may be based on review and analysis of historic information (i.e.) validation of a process for a product already in distribution based on accumulated production, testing and control data.

23.0 PROCESS VALIDATION:

Process is a unique combination of Raw Material, equipments and procedures that when brought together & exercise as a whole provides particular out come. Process validation is a documental program which provides a high degree of Assurance that a specific process will consistently produce a product meeting its predetermined specification and quality attributes. Before validating the process the equipments will be qualified. The validation of Facilities, equipments ands devices is commonly called Qualification. Qualification is divided in four elements. Design Qualification, Installation Qualification, Operational Qualification and Performance Qualification.

24.0 EQUIPMENT QUALIFICATION

All critical pieces of equipment used to produce, package or test the products will be qualified. Equipment qualification will be carried out as outlined in Equipments Qualification Protocol.

24.1 Installation Qualification:

Installation Qualification studies establish confidence that the process equipment and ancillary system are capable of consistently operating within the established limits and tolerance. This phase of validation includes examination of equipment design, determination of calibration, maintenance requirements, adjustment requirements, identification of critical elements that could affect the product etc. Information obtained with the above mentioned studies is useful to establish written procedures for calibration, maintenance, product manufacturing and control of equipments.

24.2 Operational Qualification:

The purpose of the operational qualification is to provide rigorous testing to demonstrate the effectiveness and reproducibility of the process. This phase of qualification includes visual checking of the equipment, checking the functioning of switches and indicator lights, cleaning procedures, actions resulting from installation qualification, re-qualification (time scales and triggering factors), and testing of processes specific for the equipment.

24.3 Performance Qualification:

The purpose of Performance Qualification is to check the ongoing performance of the equipment.

25.0 VALIDATION POLICY OF MAXWELL PHARMA

Maxwell Pharma is very particular about the quality of its products and

Believes that,

ii) Quality, safety and effectiveness must be designed & built into the product.

iii) Each step of the manufacturing process must be controlled to maximize the probability that the finished product meets all Quality and design specifications.

Maxwell Pharma is aware of the fact that many end product testing have limited sensitivity. Under such circumstances quality can be assured only through validation and proper in-process control.

To assure the quality of finished products manufactured throughout the process Maxwell Pharma have decided to implement concept of validation throughout the company, not restricting it to any single operation.

A written down validation procedure is designed and implemented before the procurement of equipment of facility or adoption of process. All validation protocols are prepared by involving persons from Quality Assurance, Production, Engineering, Maintenance, and Research & Development by taking into consideration the requirements of the process/equipment manufacturer's instructions and statutory requirements.

Validation procedures are designed and Protocol for Process validation is prepared which is applicable to each and every Product Manufactured. All validation protocols and records of validation are maintained by Quality Assurance Department.

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26.0 CLEANING VALIDATIONS

Cleaning validations will be performed on product contact surfaces to assess the effectiveness of the cleaning procedures in removing the chemical residues (drug substances, excipients and or dyes), cleaning agent(s) and reducing the microbiological bioburden from processing and packaging equipment to acceptable levels.

The acceptable storage time and condition of storage for clean pieces of equipment will also be verified to demonstrate that the equipment is free of any microbiological contamination prior to use. The following conditions/situations warrant cleaning of the equipment:

- Cleaning between batches of different products.
- Cleaning after maintenance.
- Cleaning after contamination. Extent of the clean is evaluated on a case by case basis.
- Cleaning prior to use, after equipment has been cleaned and stored for a prolonged period of Time. Duration time and storage condition will be verified as part of the cleaning procedure.

27.0 VALIDATION OF ANALYTICAL METHODS

Analytical methods used for the identification, or assaying the purity and or the impurity profiles for drug substances, packaging components and drug products and will be validated for reliability, accuracy and preciseness of its intended purposes.

All analytical methods used in a validation study will be validated. The analytical methods will be validated as outlined in the current USP and the ICH Guidelines on Analytical Method Validation.Compendial methods will be verified as per individual protocol.

The tests generally considered for a method validation are as follows:

- Accuracy
- Precision

  Repeatability

  Intermediate Precision
- Limit of Detection (LOD)
- Limit of Quantitation (LOQ)
- Specificity
- Selectivity

- Linearity
- Range
- Ruggedness and Robustness
- Stability of the standard and sample solutions

Each method validation will have a protocol, which will be approved prior to any validation activity, and a report at the completion of the tests will be issued.

Transfer of analytical methods from Pharmaceutical Development to Analytical Services laboratories of importing analytical methods from external laboratories (sister companies or analytical research and development Lab.) will be qualified with appropriate validation protocols.

Records of validation are maintained by Q.C. Department.

28.0 RE-VALIDATION:

Re-validation is the repeat of the initial process validation to provide assurance that changes in the equipment, process and/or in the process environment, whether intentional or unintentional, do not adversely affect process characteristics and product quality.

Re-validation will be done for processes and procedures for reasons stated below. It involves a repeat of the validation process. The validation committee shall decide the Extent of re-validation.

Re-validation will be done in the case of:

28.1 Changes of physical properties of starting materials that may affect the Process or product.

28.2 Transfer of processes to another site (change of facilities and installations that influence the process).

28.3 Changes of packaging material

28.4 Changes in the process.

28.5 Changes in the equipment, except when the replacement is of a "like-for-like" type. Production area and support system changes.

28.5 Appearance of negative trends, and appearance of new findings based on Current Updating of knowledge.

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QA MANAGER		04/06/2023

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28.7 Periodic re-valuation will be done on the basis of a review by the Validation Committee of the following:

28.7.1 Master formula and specifications.

28.7.2 Calibration records

28.7.3 Standard operating procedures

28.7.4 Cleaning records

28.7.5 Analytical methods and Records of planned preventive maintenance.

END OF DOCUMENT

APPROVED BY	SIGNATURE	DATE
QA MANAGER		04/06/2023

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