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Review Article

A Review Article of Equipment and Raw Material

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ABSTRACT

Dual-energy CT, the object is scanned at two different energies, makes it possible to identify the characteristics of materials that cannot be evaluated on conventional single-energy CT images. This imaging method can be used to perform material decomposition based on differences in the material- attenuation coefficients at different energies. Dual-energy analyses can be classified as image data- based- and raw data- based analysis. the beam- hardening effect is lower with raw data based analysis, resulting in more accurate daul- energy analysis. on virtual monachromatic images, the iodine contrast increases as the energy level decreases; this improves visualization of contrast-enhanced lesions. Also the application of material decomposition, such as iodine and edema images, increases the detectability of lesions due to diseases encountered in daily clinical practice in this review, the minimal essentials of dual-energy CT scanning are presented and its usefulness in daily clinical practice is discussed.

INTRODUCTION

Equipment may be defined as any piece of plant, machinery, instrument etc. which is used for carrying out a specific activity or operation. E.g.- mixers, granulators etc. Equipment may be-single system or piece, or integrated system. The pharmaceutical industry makes use of different equipment at each stage of the manufacturing of drug products.

Selection of equipment:

selection of equipment has both strategic and financial impact on the company i.e. It has an essential for any company because it has direct influence on the success of the product facilities by optimum cost, improving quality, safety, and reducing environmental hazards Selection of an equipment therefore depends on the following factors:

- Operating criteria
- Availability of spares and servicing
- Maintenance
- Environmental issues

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- Availability of designs and maintenance manuals
- Cost

Design:

Should meet the requirements of the user and answer the following

- What operation should be performed with the equipment?
- Capacity of holding and the output?
- How the equipment should be cleaned?
- Do we have trained operators for the operating?
- How many personnel required for operating the equipment?
- Starting and stopping time of the equipment?
- Level of technology used?

Size:

- Decided based on the volume of the materials which we are going to handle
- Physical dimensions on the machinery, size of the room where the equipment should be placed
- Holding and output capacity

Location:

Decision of the location of placing the equipment should be based on

- location of the equipment
- Utility services required
- Material handling and movement

If the equipment discharges gas, fumes, then this factor should be considered while selecting the location of the equipment

Construction:

- Equipment shall be constructed so that surfaces that contact components and drug products shall not be reactive or absorptive as it alters the safety, identity, quality or purity of the drug product
- Construction material may be stainless steel or borosilicate glass and tubing should be capable of being washed and autoclaved.

Equipment identification:

- All equipment used shall be properly identified at all times to indicate their content, and when necessary, the phase of processing of the batch.
- Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment was used in the manufacture of each batch of drug product.
- SOP should be provided to describe how the number or code given to the equipment

Equipment Log:

- Manufactures must maintain a register or log of the various operations carried out on various operations
- Log should have the following: serial number, name of equipment used and its identification number, date and time of activities carried out, name of operators and supervisors, product

Equipment cleaning:

- Schedules and procedures of cleaning should be established.
- Cleaning procedures should contain details to enable operators to clean each type of equipment in an effective manner
- Cleaning and washing manual and automatic
- Operator doing cleaning must be so trained that their activities will not affect the product
- Equipment and utensils should be cleaned, stored, sanitized, or sterilised to prevent contamination
- Acceptance criteria for residues and choice of cleaning procedures and cleaning agents should be defined and justified
- Records of all the cleaning activities should be maintained

Equipment calibration and qualification:

- Control, weighing, measuring, monitoring, and test equipment that is critical for assuring

the quality of drug products should be calibrated according to written procedures

- Record of these calibrations should be maintained
- Equipment that does not meet the calibration criteria should not be used
- Deviations form approved standards of calibration should be investigated to determine if these could have had an impact on the quality
- Computerized systems should also be validated.
- Steps of all qualifications (DQ, IQ, OQ, PQ, MQ) must be carried out to ensure the equipment is designed, installed, operated and performed as expected to give a quality product
- Records of all performed qualifications must be maintained

Purchase specification of equipment:

Some of the important purchase specifications that should be considered are:

Desired output capacity- equipment purchased must be capable of processing desired quantity of product at the desired speed of operation. Product characteristics- the nature of the product, its reactivity, any special conditions necessary to ensure retention of its safety, efficacy and quality are all important Ease of operation-equipment operation must be simple and not involve complex skills. the equipment must be easy for the operator to operate after receiving proper training Ease of cleaning and maintenance- equipment will require cleaning and special, more thorough cleaning between batches of different products. The time used for cleaning is the time loss from manufacturing.so equipment must be easy to clean and maintain. Equipment supplier-price is often considered as an important criterion, but it is also important to consider quality before purchase of an equipment also the reputation of supplier should be considered [1]

[2] Maintenance of equipment:

Equipment maintenance is defined as facilities maintain to some desired level of efficiency to keep assets in a satisfactory condition.

Breakdown maintenance:

Means that people waits until equipment fails and repair it. Such a thing could be used when the generate any significant loss.

Corrective maintenance:

Improves equipment and its components so that preventive maintenance can be carried out reliably. equipment with design weakness must be redesigned to improve reliability

Maintenance prevention:

indicates the design of a new equipment. Weakness of current machines are sufficiently studied and incorporated before commissioning a new equipment

preventive maintenance:

Is daily maintenance, design to retain the healthy condition of equipment and prevent failure through diagnosis, to measure deterioration, periodic inspection or equipment diagnosis, to measure deterioration, it is further divided into

- Periodic maintenance: Time based maintenance consist of periodically inspecting, servicing and cleaning equipment and replacing parts to prevent sudden failure and process problems.
- Predictive maintenance: Is a method in which the service life of the important is predicted based on inspection or diagnosis, in order to use the parts to the limit of their service life. [2]

[3] HPLC [High- performance liquid chromatography]

Chromatography describes the use of high-performance liquid chromatography for qualitative and quantitative analyses.

This is done by comparing the chromatogram with the reference peak.

Discrepancies between the expected and experimental chromatograms may indicate sources of impurity within the lot.

Mass spectrometry:

LC-MS [liquid chromatography mass spectrometry] is an accurate and reliable method of chemical analysis that combines the advantages of liquid chromatography and mass spectrometry.

Mass to charge ratios derived from this analytical technique can reveal molecular weight of each compound and therefore help with the identification of the analytes and impurities.

UV-vis [ultraviolet-visible spectroscopy]

Spectrophotometric tests are critical for the identification of many chemical substances. These tests yield absorption spectra that demonstrates rough identification of the formulation and any contamination.

FTIR [**Fourier transform infrared spectroscopy**]

Infrared spectroscopy is notably the most powerful test in confirming the identity of small molecules and pharmaceuticals.

FTIR results may be used to compare multiple specific peaks in the IR spectrum with those of a reference standard, establishing a robust acceptance criterion.

Identity and purity- large molecules:

Large molecule- identity and purity testing

When manufacturing biological products [large molecules], it is imperative that each lot produced conforms to predetermined specifications.

Testing services for identity and purity

HPLC

Mass spectrometry

Western blot

ELISA

Mass spectrometry:

Mass spectrometry is a technique that can be employed to detect impurities in biological products and inform the manufacturer. When it comes to SDS-PAGE, it is procedure that segregates proteins in a polyacrylamide gel depending on their size.

Western blot:

To perform a western blot, start by running an SDS-PAGE gel and subsequently transferring the proteins onto a membrane. This technique allows for the

ELISA [**Enzyme- linked immunosorbent assay]** the protein of interest. indirect, direct and sandwich ELISA are the most common variations of ELISA.

The absorbance readings from each well are compared with the standard curve to determine the concentration of the protein of interest from each sample. [3]

[4] Materials and methods:

System elements:

1.Responsibility:

-usage and operation of medical equipment: medical staff including the head of the department, doctors and nurses

-Calibration, testing, repairing and preventive maintenance applied to the medical equipment:

The technical manager has primary responsibility for the content and accuracy of testing and calibration of the medical equipment; the technical manager has authority to edit and modify procedure for testing the medical equipment and has authority to assign the biomedical engineer to make preventive maintenance to the medical equipment.

2.Accommodation and environmental conditions:

The clinical engineer must be aware of the environment in which the equipment will operate and must be aware of any potential restrictions that the environment places on the include space, power, temperature range, vibration and shock, electric and magnetic fields, humidity and moisture, explosive and flammable environment.

The department should ensure that the environmental conditions do not invalidate the results or adversely affect the requirements of any measurement. All factors that affect in the equipment's environment must be known. All requirements that the department needs such as

electrical sources, oxygen connections, vide connections, air connections, etc. must be known.

3.Equipment:

The equipment data contain:

1.The name and address of the medical department,

2.Equipment identification and contact information as follows: equipment name, manufacturer name, location of equipment, model and serial number of equipment, contact person [his telephone and his name].

3.Required dates: equipment purchase date, equipment operating date, dates of previous calibration, date of the next calibration, date of previous repairs, date of previous test.

4.Category of the medical equipment: biomedical equipment is classified as follows: equipment that contain Electronic and mechanical systems, Equipment that contain electronic, mechanical and fluid systems.

5.Classification of the medical equipment according to its function to patient: if it is electrical, electronic, mechanical, radiation, acoustic, optics, chemical or magnetic.

4. -stages that medical equipment passes through during its lifetime at the hospital:

Any medical equipment at hospital must pass through necessary stages from beginning to think in buying it until it is scrapped from work at high efficiency and effectively at the hospital.

These stages are:

[Note: At each step into each stage, it must be mentioned the date of the step and who is responsible for doing it.]

1.-clinical request for purchasing new equipment

2.- product committee [they put the description of the New Equipment, including technical specification and medical description].

3.- financing department.

4.- purchasing department.

5.- offers studying and evaluation committee including medical evaluation and technical evaluation.

6.- sending purchasing order.

7.- pre- installation

8.-personnel training.

9.-equipment handling and inspection committee including evaluation of equipment according to technical view [test and experiment the equipment] and evaluation of equipment according to medical view.

10.- Installation.

11.- operation.

12.- Repair and repair request.

13.- calibration.

14.- Maintenance.

15.- scrapping.

16.- evaluation of the medical equipment

DISCUSSION:

Shows the medical equipment life cycle which demonstrates the stages that the medical equipment passes through during its lifetime at the hospital. In each stage the job of the person who is responsible for doing it must be mentioned. In our work data will be entered to medical equipment system form that was designed by using software package visual basic 6 [vB6] to measure parameters, calculate parameters, add new data for any medical equipment, save data in database and make evaluation for the medical equipment. Data will be entered to database by relations between VB6 and access program which was used for data structure. The quality improvement of the medical equipment will increase when performance efficiency, availability, quality rate overall equipment effectiveness, reliability and uptime increase. Also, the quality improvement of the medical equipment will increase when defect time downtime, failures decrease. Monitoring will verify that the quality improvement is stable and that efforts invested to improve the system were justified. If during the monitoring stage, the

system revealed no significant improvements, technical evaluation procedures should be re-evaluated to identify factors that prevented the system from responding to the methodology.

The system was applied on the data of medical equipment at the neonatal ICU department, Ahmed Maher teaching hospital, Cairo, Egypt. This equipment includes baby incubator, pulse oximeter, ventilator, syringe pump, infusion pump, and monitor

CONCLUSION:

This paper represents a medical equipment quality assurance system by building a systematic approach through software package for quality control and assurance of medical equipment performance within the health care quality system. The goal is to have a highly effective and accurate device that provides patient with required treatment. The biomedical engineer has the full support from technical manager and division director to provide and arrange high quality calibration and testing for medical equipment passes through it during its lifetime.

The study includes building monitoring and evaluating the system to modify it when needed

Future works are gathering all input parameters in one equation to make evaluation for the medical equipment, choosing threshold values for the output parameters and applying the system on more medical equipment. [4]

[5] **Raw Materials**

Raw Materials

Raw materials are materials or substances used in the primary production or manufacturing of goods. Raw materials are commodities that are bought and sold on commodities exchanges worldwide. Businesses buy and sell raw materials in the factor market because raw materials are factors of production.

- **Key Takeaways**

Raw materials are the input goods or inventory that a company needs to manufacture its products. Examples of raw materials include steel, oil, corn, grain, gasoline, lumber, forest resources, plastic, natural gas, coal, and minerals.

Raw materials can be direct raw materials are used in a multitude of products and can take many different forms. Raw materials are the input goods or inventory that a company needs to manufacture its products. For example, the steel used to manufacture vehicles would be a raw material for an automobile manufacturer. For manufacturing companies, raw materials inventory requires detailed budgeting and a special framework for accounting on the balance sheet and income statement. Raw materials are often related to natural resources. For this reason, manufacturing companies may be at the disposal of mother nature regarding the availability to secure raw materials. In the same light, manufacturing companies may not want to directly invest in extracting the raw materials. For example, consider how a company relies on oil or plastics often does not own the

drilling rig that extracts the raw materials from the group materials, which are directly used in the manufacturing process, such as wood for a chair. Indirect raw materials are not part of the final product but are instead used comprehensively in the production process. The value of direct raw materials inventory appears as a current asset on the balance sheet.

Accounting for Raw Materials:

Manufacturing companies take special steps to account for raw materials inventory. This includes three distinct inventory classifications on their balance sheet compared to just one for non-manufacturers. The current assets portion of the balance sheet represents the assets that are likely to be used up in less than one year and include :

- Raw materials inventory
- Work-in-process
- Finished goods

All inventory, including raw materials inventory, should be valued at its comprehensive cost. This means its value includes shipping, storage, and preparation. The typical journal entries in an accrual accounting system for the initial purchases of raw materials inventory include a credit to cash and a debit to inventory. Debiting inventory increases current assets, and crediting cash will reduce cash assets by the inventory amount. When a company uses raw materials inventory in production, it transfers them from the raw materials inventory to the work-in-process inventory. When a company completes its work-in-process items, it adds the finished items to the finished goods inventory, making them ready for sale. In some cases, raw materials may be divided into two categories: direct and indirect. Whether a raw material is direct or indirect will influence where it reported on the balance sheet and how it is expensed on the income statement. [5]

[6] **Direct Raw Materials:**

Direct raw materials are materials that companies directly use in the manufacturing of a finished product, such as wood for a chair. Direct raw materials are placed in current assets and are expensed on the income statement within cost of goods sold. Manufacturing companies must also take added steps over non-manufacturing companies to create more detailed expense reporting on costs of goods sold. Direct raw materials are typically considered variable costs since the amount used depends on the quantities being produced.

Direct Raw Materials Budget:

A manufacturer calculates the amount of direct raw materials it needs for specific periods to ensure there are no shortages. By closely tracking the amount of direct raw materials bought and used, an entity can reduce unnecessary inventory stock, potentially lower ordering costs, and reduce the risk of material obsolescence. Raw materials may degrade in storage or become unusable in a product for various reasons. In this case, the company declares them obsolete. If this occurs, the company expenses the inventory as a debit to write-offs and credits the obsolete inventory to decrease assets.

Indirect Raw Materials:

Indirect raw materials are not part of the final product but are instead used comprehensively in the production process. Indirect raw materials will be recorded as long-term a ssets. They can fall under several categories within long-term assets, including selling, general, and administrative (SG&A) or property, plant, and equipment (PP&E).Long-term assets usually follow a depreciation schedule that allows them to be expensed over time and matched with revenue they help produce. For indirect raw materials, depreciation timing will usually be shorter than other long-term assets like a building expensed over several years.

Types of raw materials:

Raw materials can be classified in several ways, but one common classification is the nature of how the good is extracted. These types include:

- Mined raw materials extracted from the earth, such as ores, stones, metals, minerals, lime, sand, soil, oil, and coal.
- Plant-based raw materials come from trees or plants, including fruits, nuts, flowers, vegetables, resins, wood, cotton, and latex.
- Animal-based raw materials are extracted from animals such as milk, meat, furs, leather, and wool.

Raw materials are often segregated into these three categories as each type often entails very different investments to procure the raw materials. For example, the operations of a farm are substantially different from an oil drilling rig; companies that require both raw materials must be mindful of how to most efficiently source the materials.

Example of Raw Materials:-

Consider a company manufactures tables and chairs. Below are the materials used in production:

- Direct raw materials: timber, wood, cushions, padding for the chairs, cloth fabric to cover the chairs
- Indirect raw materials: fittings, nails, wood glue, equipment for workers

Since the wood, padding, and fabric can be directly tied to the production of the tables and chairs, they are considered direct raw materials. When calculating the cost on a per-unit basis, the direct raw materials could be traced to each unit. The glue, nails, and worker equipment would likely be considered indirect materials since the quantities used would not be significant, nor would they be directly tied to each unit produced. These types of costs would likely be allocated

What are raw materials in food :

Raw materials in food can be standalone items like meats, milk, fruits, and vegetables. They can also refer to the ingredients that go into a food item or recipe. For instance, milk is a raw material used in the production of cheese and yogurt.

What is the difference between inventory and raw materials:

In many cases, raw materials are a type of inventory. It represents goods on a balance sheet that have not yet been converted to work-in-progress or a finished product. Companies often buy, acquire, or extract raw materials for use, then report raw materials as an asset. Then, as the company uses raw materials in the production of finished goods, it converts the raw materials into products it can sell to consum [6]

[7] Raw materials

What are raw materials?

All materials that are used into the manufacturing of a finished bulk (even though it may not be

present in final product) and which are consumed by person using it are called as raw materials, raw materials can be either active drug or inactive substance.

Purchase specification of raw materials:

Written guidelines that precisely define the operational, physical, and /or chemical characteristics, as well as the quality and quantity of a particular item to be required.

Regarding purchasing of pharmaceutical materials following points should be considered:

- All materials should be purchased against an approved and adequate specification which defines not only the grade and quality of the materials, but also the nature of the packaging and container used.
- The quality material should clearly specify the physical, chemical, and microbiological specifications as specified in PHARMACOPOEIAL or in-house specifications.
- The quality parameter should also specify characteristics like, bulk density, particle size etc.
- Material should be purchased and sourced only from approved suppliers and manufactures
- Choice of vendor should be primarily based on quality considerations and when these are met other commercial considerations should play their role, like, price, delivery period.
- Consistency in quality, delivery and price should be given importance
- Raw and packing materials should only be purchased by buyers who are trained and poses sufficient technical knowledge.
- Material managers who have sufficient exposure on raw and packing material should be appropriate persons for this; alternatively industrial pharmacist with training in material management can do a much a better job.
- All materials while purchasing should be checked for the following: name of the manufacturer or supplier, name of the product, batch number, date of manufacture and expiry, quantity received and number of packages, and condition of containers and materials.
- Enter into contracts with specific vendors after performing a vendor audit that provides an assurance of raw materials and packaging materials of the desired level of safety and meeting quality standardisation.

Steps of purchasing raw materials:

- Purchase requisition
- Selection of vendors
- Inviting quotation
- Placing the order
- Receiving materials
- Sampling and testing of incoming materials
- Checking of invoice/bill, recording of bill in books
- Releasing the payment to the supplier

Purchase requisition:

Purchasing is an activity directed towards procuring the material supplies, equipment and services required in the operations of an enterprise. The organisation setup of a purchase manager is responsible for the size of the effective, efficient and economic operation of the department.

Types of purchasing: -

- Centralised – when different branches of company require similar type of raw materials.
- Decentralised – when different of company require similar type of raw materials.

Selection of vendors:

Selection of vendors is carried out in 4 stages: -

- First stage – survey stage – identify potential sources through trade directories, wed browsing trade journals, supplier's catalogue etc.

- Second stage – enquiry stage – analysis of information in standard enquiry format. Enquiry stage is done to ensure internal facilities of vendors, financial adequacy and stability, reputation of vendor, location of vendor's factory and industrial relations.
- Third stage – negotiation and selection stage – quality control specifications, clarification, credit, quantity discounts.
- Fourth stage – experience and evaluation stage – the buyer evaluates and appraises the performance of the vendor. The objective is to improve the performance of vendors in which they are deficient. Evaluation is done especially on two counts – quality and delivery.

Receiving materials:

- Visual examination for all incoming materials, containers, lids and seals.
- Check for physical damage to the containers, rodent or insect infestation, proper labelling in specified manner.
- Materials should be quarantined until they have been sampled, examined, and released for use.
- Before incoming materials are mixed with existing stocks, they should be identified as correct, tested and released.

Sampling and testing of incoming materials:

- At least one test to verify the identity of each batch of material should be conducted.
- a supplier approval should include an evaluation that provides adequate evidence that the manufacturer can consistently provide material meeting specifications.
- Samples should be representative of the batch of material from which they are taken.
- Sampling methods should specify the number of containers to be sampled and the amount of material to be taken from each container.
- Sampling should be conducted at defined locations and by procedures designed to prevent contamination of material sampled.
- Containers from which sampled are should be opened and reclosed carefully.
- Cleaned dried, and sanitized utensils should be used for sampling.
- Sampling room should have specific temperature, relative humidity, and air pressure.
- There should be specific requirements for specialised products like – sterile products, poisons, patent drugs, beta LACTUM products, hormones, and steroids.
- Sampled containers and sample collection containers should have the following details

Name of the material
Batch no. for manufacture
Date of sampling
Name and sing of sampler [7]

[8] Purchase records:

Points to be checked and recorded: -

- Date of product
- Batch no.
- Control no. assigned by the manufacture
- Quantity received
- Name of supplier
- Purchase of order no.
- Excise gate pass
- Date of manufacture and expiry

Maintenance of store for raw materials:

- Materials should be handled and stored in a manner to prevent degradation, contamination, and cross contamination
- Materials stored in fibre drums, bags, or boxes should be stored off the floor
- Suitably spaced to permit cleaning and inspection

- Materials should be stored under conditions and for a period that have no adverse effect on their quality
- Oldest stock should be used first
- Rejected materials should be identified and controlled under a quarantine system designed to prevent their unauthorised use in manufacturing.

Location of storage area:

- Store should be located adjacent to the manufacturing area.
- Location depends upon the nature and value of items to be stored and the frequency which items are received and issued.
- Minimum wastage of space, handing costs and operating costs.
- Maximum ease of operations.

Facilities:

- Inspection centre.
- Space for storing retained samples for quality control
- Centralised weighing areas
- washing room
- quarantine room

Storage area conditions:

- Room temperature-30°c
- Relative humidity-60
- A.C storage – temperature-25±2°c, RH-55%
- Low temperature storage-2-8°c
- Light sensitive material in amber colour container.

Labelling of materials in storage area:

- Designated name of product
- Batch no given by supplier
- Status of content
- Expiry date or date beyond which retesting is necessary

Approved materials must be stored properly and issued for use in a way such that earliest approved stock is used first before more recently approved stock. If materials have been stored for very long period without usage, they must be retested.

Importance:

Raw materials are crucially important for ensuring safety, quality and efficacy of pharmaceutical products. There are many things to be considered that could impact the way raw materials need to be blended, such as polymorphism, the particle of raw materials and other properties

Hence, raw material analysis is essential to determine the purity, identity and quality of the raw materials before they go into the manufacturing process. [8]

[9] Need:

As hundreds of raw materials and ingredients are used in the process of formulating the final pharmaceutical product, it is quite tough to check every in gradient for quality Unless the ingredients have undergone quality testing, beginning the manufacturing process won't be possible. Moreover, if low-quality raw materials are used, it will result in a low-quality finished product which could face product recall.

This can cause significant damage to materials cost as well as reputation. Therefore, raw materials testing in pharmaceuticals is necessary

[a]. Ensuring a quality product:

Pharmaceutical raw materials testing is carried out to establish that all the incoming raw materials match the right specifications and requirements. needless to say, incorrect supply of raw materials will lead to a compromise in safety and quality of the end product. Besides, it will also cause manufacturing delays and significant wastage of time and costs. Therefore, testing labs help pharmaceutical companies lay down the specifications for the raw materials right from the initial stages of drug development.

[**b**]. **Lab**: **standards and approvals needed**

Every pharmaceutical product or medical device has to be approved by the state FDA and the central drugs standards control organisation

[CDSCO] before it is rolled out for public use or commercialization. Testing laboratories can help carry out materials analysis DSC analysis, chemical tests, physical characterisation, NMR testing, FTIR testing and more, all according to the specifications and safety protocols established by the FDS and CDSCO. Traditionally, chemical testing laboratories perform the raw materials testing and prepare the reports to determine their quality and suitability to be used in pharmaceutical drug formulations. They are well equipped to carry out the sophisticated procedures in raw material tests.

Guidelines for handling raw materials:

When raw materials are received, it is important to visually inspect them for labels and any container damage. after inspection, the raw materials should be moved to a designated quarantine area where their labels are replaced with "under test" labels.

Quality control personnel are responsible for sampling, and they should take the samples from the quarantine area. During sampling, it is crucial to ensure that the sample is representative of the entire batch, that the sampling equipment is clean, and that the containers are resealed after sampling. Upon receiving approval or rejection for the raw materials, it must be moved to the designated areas for approved or rejected materials. The raw materials should be stored in a container that is clean. Storage should be at the optimal temperature and humidity. Regular intervals should be scheduled for inspection. The materials should in a way that ensures the first material received is the first one issued. [9]

[10] Quality control raw material testing:

Before manufacturing begins, all raw materials must be tested for purity. Identity and quality. Depending on the type of product [tablets and capsules vs. biotech products], as few as 15-20 to as many as 60 raw materials might be needed for product development. The extent of raw material testing is determined by the manufacturer. A conservative approach would be to perform complete analysis of each lot of raw material received. Pharmacopoeia provides monographs for the most commonly used raw materials in the pharmaceutical industry.

Thes monographs detail several different analytical techniques. Karl Fischer moisture analysis, PH, viscosity and titrations are common but more complex techniques such as HPLC, GC-MS and ICP-MS are sometimes required.

The analytical chemistry and microbiology teams can help you with the necessary testing for materials, APIs, finished products, packaging materials and medical devices.

Testing services for raw materials:

Physicochemical properties

Identity and purity- small molecules

Identity and purity-large molecules

Physicochemical properties testing services:

Physicochemical property tests are integral to the verification, manufacturing support, and lot release programs for pharmaceuticals and biologics. It is essential that certain physical and chemical properties do not vary between or within lost, as they can determine critical compound features like drug delivery and absorption of the product in vivo.

Appearance:

This guarantees that all the solutions that are tested do not contain any visible particulates.

- Physical state
- Colour
- odour

PH:

PH will determine whether the sample's acidity alkalinity meets the client's expected specifications. The PH of a small molecule pharmaceutical or biologic formulation can significantly affect its stability. Solubility, and in vivo delivery, making this a crucial element of any lot release program.

Moisture content:

Water is a component found in many pharmaceutical and biologic products either as hydrates or adsorbed water. The amount of water present can impact the effectiveness, these products, making it necessary to specific standards.

Osmolality:

Osmolality is another important factor of lot release for a developed drug and is defined as the total number of solute particles per kilogram of solvent. Freezing point technology to test the osmolality of prepared solutions to ensure correct isotonicity, consistency, formulation, and product stability.

Viscosity:

A fluid's resistance to flow, measured as viscosity, is a principal component of lot conformance. Viscosity is fundamental to a formulation's intended propagation and activity, and may be used as a benchmark for compound concentration or degradation.

Optical activity:

Many pharmaceutical compounds are chiral and hence optically active, given that they rotate plane polarized light. The measure of optical activity of the provided solution can then be used by the client for many different aspects of a lot release program. By comparing with predetermined target specifications, polarimetry may be used to detect impurities or to determine the concentration of the intended chiral drug product. [10].

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