IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

A REVIEW: QUALITY ASSURANCE IN HERBAL DRUG FORMULATIONS

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Abstract:

The current work is an effort to summarise the numerous quality guarantees of herbal formulations as well as their parameters. The quality assurance parameters that must be strictly followed for the herbal formulations during and after the manufacturing process, for the finished products in order to ensure their effectiveness, stability, and protection during the product's shelf life, have been briefly accounted for. Following a review of the introduction and history of herbal formulation use, the distinction between quality assurance and quality control is presented, as well as the general definition of quality assurance of herbal formulations such as macroscopic and microscopic characterization.

Index Terms- **Herbal drug, Quality, GMP**

INTRODUCTION:

Herbal drugs have been used since earliest times as medicines for the treatment of a range of diseases. Medicinal plants have played a important role in world health. In spite of the important advances observed in modern medicine in recent decades, plants still make an important contribution to health care. Over the past decades, attentiveness in drugs procured from higher plants, chiefly the therapeutic ones, has increased expressively.[1] Herbs have created in interest among the people by its clinically determine the effects like immunomodulation, adaptogenic and antimutagenic etc.[2] it is evaluate that about 25% of all modern medicines are directly or indirectly derived from higher plant.

According to the World Health Organization (WHO), due to indigence and lack of access to modern medicine, about 65-80% of the world's population which lives in developing countries depends necessary on plants for primary health care.[1] Also the overuse of synthetic drugs which end in higher incidence of adverse drug reactions, have motivated the humans to travel back to nature for safer remedies.[2] India is that the 8th largest country having a complete of around 47,000 plant species, out of which over 7,500 species have medicinal values. Among these medicinal plants only 800 species are claimed to be in use and around 120 species are employed in large quantities.[3] Currently the key pharmaceutical companies have demonstrated renewed interest in analysing higher plants as a source for brand new lead structures and also for the event of standardized phytotherapeutic agents with proved efficacy, safety and quality.[1] It is now increasingly accepted worldwide that screening natural products could be more practical strategies for locating new chemical entities as natural product libraries have a broader distribution of molecular properties as compared to synthetic and combinatorial equivalents, such as molecular mass, octanol-water coefficient, and ring system diversity.[3]

The expanded use of herbal medicines worldwide has led to concerns regarding to its safety, quality and effectiveness. The quality control of herbal drugs and their formulations is of paramount significance in justifying their acceptability in modern system of drug. One of the vital problems faced by user industry is non- availability of rigid quality control profiles and evaluation parameters for herbal formulations.[4]

HISTORY:

Home grown medication is the most seasoned type of medical care in the world. Spices had been utilized by all societies since the beginning. It was an indispensable piece of the improvement of present day development. The plants gave food, dress, asylum, and medication. A large part of the restorative utilization of plants appears to have been created through perceptions of wild creatures, and by experimentation. They deliberately gathered data on spices and grew very much characterized natural pharmacopeias. For sure, well into the 20thcentury a large part of the pharmacopeia of logical medication was gotten from the home-grown legend of local people groups. Numerous medications usually utilized today are of natural birthplace. In reality, about 25% of the physician

recommended drugs apportioned in the United States contain in any event one dynamic fixing got from plant material. Some are produced using plant removes; others are integrated to imitate a characteristic plant compound.

The utilization of plants as medication is more seasoned than written history. As quiet observer to this reality marshmallow root, hyacinth, and yarrow have been found painstakingly tucked around the bones of a Stone Age man in Iraq. These three therapeutic spices keep on being utilized today. Marshmallow root is a demulcent spice, mitigating to excited or aggravated mucous layers, for example, a sensitive throat or bothered stomach related lot. Hyacinth is a diuretic that urges tissues to surrender abundance water.

The main U.S. Pharmacopoeia was distributed in 1820. This volume incorporated a definitive posting of home grown medications, with depictions of their properties, uses, doses, and trial of immaculateness. It was intermittently changed and turned into the lawful norm for clinical mixes in 1906. However, as Western medication developed from a workmanship to a science in the nineteenth century, data that had at one time been widely accessible turned into the space of similarly few. When logical strategies were created to remove and orchestrate the dynamic fixings in plants, drug research centers took over from suppliers of restorative spices as the makers of medications. The utilization of spices, which for the majority of history had been standard clinical practice, started to be viewed as informal, or possibly offbeat, and to fall into relative obscurity.[4]

Numerous medications, including strychnine, anti-inflammatory medicine, vincristine, taxol, curare, and ergot, are of natural source. Around one-fourth of the physician recommended drugs administered by local area drug stores in the United States contain at any rate one dynamic fixing got from plant material. [5]

East India. India, situated among China and the West, went through a comparable cycle in the advancement of its medication. The recuperating that occurred before India's Ayurvedic clinical corpus was like that of antiquated Egypt or China (i.e., infection was seen as a discipline from the divine beings for a specific sin). Ayurvedic medication arose during the ascent of the methods of reasoning of the Upanishads, Buddhism, and different ways of thinking in India. Spices assumed a significant part in Ayurvedic medication. The primary Ayurvedic book on inner medication, the Charaka Samhita, depicts 582 herbs.[6]

QUALITY ASSURANCE:

Nature of an item is an exceptionally interesting issue these days, and particularly in the drug business. For sure, the administrative specialists have given exceptional consideration to quality in this specific industry, because of the high danger of harm of life and strength of patients conceivable, and created numerous rules to safeguard an adequate degree of value. Quality isn't any more considered accomplish capable by severe adherence to, and check of, determinations of quantifiable boundaries yet must be produced by a deliberately arranged and guided cycle. Quality isn't any more the sole duty of a focal quality office yet requires the drew in interest of the whole work force.[7]

It is characterized as the satisfaction all the necessities, lawful and experience based, associated with all parts of assembling of top notch natural restorative items. It begins from the earliest starting point, the determination, handling and acquisition of natural beginning material, follows the strategy and quality contemplation encompassing the intermediates and finishes with contriving and checking the last creation ventures towards the last restorative product.[7]

Quality affirmation is subsequently characterized as an organization. It envelops the control and documentation system, which protect, that the huge number of guidelines relating to and utilized in act of the drug business.

Assurance of product high-satisfactory relies upon on greater than simply right sampling and ok checking out of numerous additives and the completed dosage form. Prime obligation of retaining product high-satisfactory all through manufacturing rests with the producing department. Removal of obligation from production for generating a high-satisfactory product can bring about imperfect composition, consisting of substances missing , sub strong or brilliant strong addition of substances , or blend up of substances ; errors in packaging or filling , consisting of product contamination , mislabelling , or poor package ; and absence of conformance to product registration .Quality warranty employees ought to set up manage or checkpoints to screen the high-satisfactory of the product as it's far processed and upon crowning glory of the manufacture .These start with uncooked substances and the factor checking out and consist of in-process , packaging ,labelling , and completed product checking out in addition to batch auditing and balance monitoring.[8]

In context with pharmaceutical enterprise excellent warranty may be represented as:

Quality Assurance = GAP + GHP + GMP + GLP + different measures

GAP = Good agriculture practices.

GHP = Good harvesting practices.

GMP = Good production practices.

GLP = Good laboratory practices.

Good agriculture practices:

The recommendations for GAP of medicinal herbs is meant to use to the developing and number one processing of such plant life traded and utilized in therapy. Hence, it applies to the manufacturing of all plant life substances used withinside the food, feed, medicinal, flavouring and fragrance industries.

The principal purpose on this GAP is to make certain that the plant uncooked fabric meets the call for of the patron and the requirements of the very best excellent.

Good harvesting practices:

The beginning substances for all Phyto drug treatments are plant drugs. Mostly components or plant organs of medicinally used species and commonly withinside the dried form. According to WHO, there are 21,000 plant species as being therapeutically used as plant drugs. Between 70%-90% of those are commercially received with the aid of using accumulating the medicine withinside the herbal habit. Among those most effective approximately 50 – a hundred species are cultured with the aid of using PTC technique.[9]

Good Manufacturing practices:

To supply to the general public existence saving capsules of the best first-class and purity , the pharmaceutical enterprise conventional has cooperate with FDA, even in current years, whilst the regulatory companies have end up an increasing number of restrictive.

This is a huge ranging idea regarding all depend that in my view or together have an effect on the first-class of product. It is the definitely of the association made with the item of making sure that product are of the first-class required for his or her meant use.

The gadget first-class warranty suitable to the producer of the pharmaceutical product shall make certain that:

- The pharmaceutical are designed and evolved in a manner that takes account of the necessities of GMP and different related codes including the ones of GLP and GCP.
- Adequate preparations are made for producer, deliver and use of accurate beginning and packaging materials.
- Adequate manage on beginning materials, intermediate merchandise and bulk merchandise and different in system controls, calibration and validation are carried out.
- The completed product is successfully processed and checked according with hooked up procedure.
- The pharmaceutical merchandise aren't launched on the market product provided earlier than legal individuals have licensed that every manufacturing batch had been produced and managed according with the necessities of the label declare and another provisions applicable to manufacturing, managed and launch of the pharmaceutical merchandise.[10]

QUALITY ASSURANCE OF HERBAL DRUGS:

Quality confirmation of home-grown items might be guaranteed by appropriate control of the natural fixings and by methods for GMP. Some natural items have numerous natural fixings with just modest quantity of individual spices being available. Compound and chromatographic tests are helpful for creating completed items particulars. Steadiness and timeframe of realistic usability of homegrown items ought to be set up by the production. There ought to be no distinction in standard set for the nature of various dose structures, for example, tablet and case of home grown cures just as from those of other drug readiness.

In UK, for the authorized home grown cures the European logical agreeable for phytotherapy monographs are a significant turn of events. In India most of the home grown cures accessible are being advertised for quite a while, indeed, for some items it could be before D and C act 1948.The condition, in other non-industrial nations for the deal and creation of natural items are like UK.

Quality, security and viability of homegrown medications need to guarantee to give sound logical balance to upgrade purchaser certainty and to improve business possibilities for natural medicines.[9]

Quality assurance and quality control confusion

Quality Assurance: A set of activities produced to assure that the development or maintenance process is adequate to ensure a system will meet its objectives.

Quality Control: A set of activities produced to evaluate a developed work product.

QA activities assure that the process is defined and appropriate. Methodology and standards advancement are examples of QA activities. A QA review would target on the process elements of a project - e.g., are requirements being defined at the proper level of detail.

QC activities focus on identifying defects in specific output - e.g., are the defined requirements the right requirements

Quality Assurance makes confirms you are doing the right things, the right way. Quality Control makes assure the results of what you have done are what you expected.

testing is one example of a QC activity, but there is other examination difference is that QA is process dependent and QC is product dependent. Testing therefore is product dependent and thus is in the QC domain. Testing for quality of product is not assuring quality, it is managing it.

The term “quality assurance” and “quality control” is sometimes used vice-versa, but there is an important difference. Quality control generally refers to analysing of raw material, packaging components, and final product for conformance to established requirements. quality assurance is a term that involve quality control, but has broader meaning to include procedures, personnel training, record keeping and facility design and monitoring. The philosophy of a quality assurance program is to build quality into the product, rather than to rely only on final product testing to cull out defective product.[11]

GENERAL CONCEPT:

The following general concepts are crucial in the development and setting of specifications. They are not all applicable, but each should be considered in specific situations.

1) Characterization: -

Consistent quality for herbal products can only be guaranteed if the starting plant materials are defined rigorously and precisely. Characterization of a herbal substance/preparation or herbal medicinal product is thus required in order to establish specifications that are both comprehensive and relevant.

a) Macroscopic/microscopic characterization:

The shape, size, colour, surface characteristics, texture, fracture, and appearance of medicinal plant material are used for macroscopic characterization.

Colour:

The colour is useful in indicating the general origin of the drug; for example, material derived from the aerial part of the plant is usually green, whereas material derived from the underground part of the plant is usually devoid of green colour.

Size:

When evaluating a crude drug, the length, width, and thickness of the raw materials are extremely important. For this measurement, a millimetre graduated ruler will suffice.

Odour and Taste:

The odour and taste of a crude material are extremely sensitive criteria that are based on individual perceptions. The strength of the odour, such as weak, distinct, or strong, is first determined, and then the odour sensation, such as musty, mouldy, rancid, fruity, aromatic, and so on, is determined.

Surface characteristic:

The texture is best examined by taking a small amount of material and rubbing it between the thumb and forefinger; it is typically represented as ‘smooth,' ‘rough,' or ‘gritty.' The softness or hardness of a material is determined by its contact. Bending and rupturing the sample reveals the brittleness and appearance of the broken plane as fibrous, smooth, rough, granular, and so on. All of these characteristics are useful in determining the general form of material and the existence of multiple components. [9]

The microscopic characterization of plants is primarily dependent on plant parts such as leaves, roots, bulbs, fruits, seeds, barks, woods, underground drugs, whole species, and unorganised drugs. [12]

Leaf Constants:

Palisade Ratio: The number of palisade cells under each epidermal cell on average. It is possible to evaluate it using powdered drugs.

Number of veins and islets: It is known as the number of veins – islets per square mm on the leaf surface halfway between the midrib and the margin. In 1929, Levin counted the number of veins and islets in many dicot leaves..

Vein-termination number: This is defined as the number of vein determinations per square mm of leaf surface halfway between the midrib and the margin.

Stomatal number: It is the total number of stomata per square millimetre of the leaf's epidermis. [13]

Stomatal index: This is the ratio of the number of stomata to the total number of epidermal cells, with each stoma counted as one cell. It is calculated using the following formula: -

$$\textbf{S.I. = S / E + S x 100}$$

Where, S.I. = Stomatal index

S = Number of stomata per unit area

E = Number of epidermal cells in the same unit area [12]

Trichomes:

These are additional essential diagnostic features that aid in the identification of drugs and the detection of adulterants. Trichomes (fig1) are tubular elongated or glandular epidermal cell outgrowths. Trichomes were also known as plant hairs. Trichomes are graded as follows based on their structure and number of cells:[12]

- Covering trichomes, non-globular trichomes and Clothing trichomes
- Glandular trichomes
- Hydathodes or special type of trichomes.

Fig.1 Trichomes

Stomata:

Stomata's main and most essential function is gas exchange, and their secondary function is transpiration. Stomata, on the other hand, are widely found to be abundant in dicot leaves. Stomata in dicotyledons are categorised into the following groups based on the shape and arrangement of subsidiary cells. [12]

- Paracytic or rubiaceos or parallel- celled stomata
- Diacytic or caryophyllaceous or cross-celled stomata
- Anisocytic or cruciferous or unequal-celled stomata
- Anomocytic or ranunculaceous or irregular-celled stomata

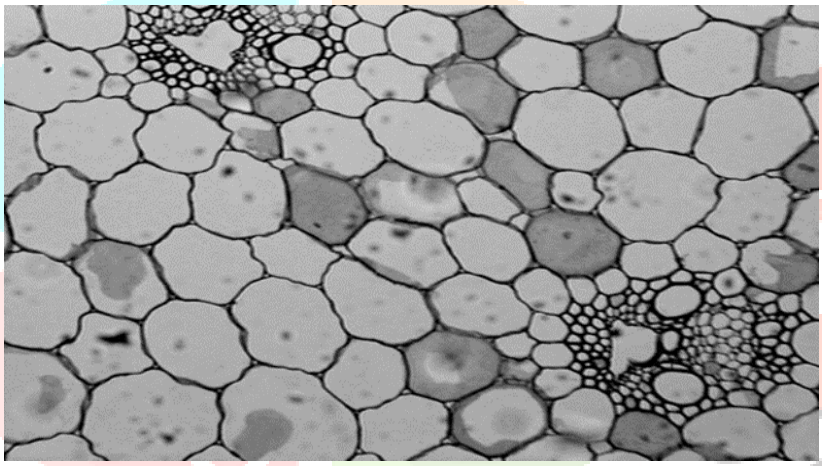

Fig.2 Stomata

b) Phytochemical characterization:

Chromatographic fingerprinting is used to collect analytical data on constituents, which includes constituents with established therapeutic activity as well as compounds appropriate for use as active markers or analytical markers. A chromatographic finger print profile reflects the qualitative/quantitative determination of various components present in a complex plant extract, regardless of whether their precise identity is known. Thin layer chromatography, the easiest and least expensive method, offers a wealth of knowledge on the composition of medicinal plant drugs and their preparations, making it the technique of choice for positive identification of raw materials. The HPTLC technique blends selectivity and sensitivity, resulting in features that indicate stability. Non-chromatographic Assays (Gravimetric, Titrimetric, and Spectrophotometric) Simpler techniques that provide a more comprehensive picture of the various groups of compounds present in the herb or polyherbal product under consideration. This analytical procedure is then passed to the customer, who can then conduct subsequent tests at any other qualified and fitted lab of their choosing. [9]

c) Impurities:

Impurities are categorizable as follows:

-impurities originating in starting materials (active ingredients, excipients) and containers

-process impurities resulting from the production process

- Contaminants, which are impurities such as heavy metals, pesticides, mycotoxins, fumigants, and microbial waste, including extraneous sources and radioactive substances, if appropriate.
- Because of the unique nature of herbal medicinal products, degradation products should primarily resolve toxicologically related impurities resulting from the degradation of herbal substances/preparations.
- Residual solvents, which are byproducts of production processes.

2) Design and development considerations:

The experience and data gathered during the production of a herbal substance/preparation or herbal medicinal product should serve as the foundation for specification development. In general, the herbal medicinal product should only be tested for quality attributes that are specific to the dosage type and the herbal substance or herbal preparation present. For example, it may be possible to recommend removing or replacing such tests on this basis. Some examples include:

-reduced testing for pesticide residues when a herbal product is grown under strict organic cultivation without pesticides or other chemicals and potential contamination from neighbouring plantations has been removed.

-excluding or reducing microbial limit tests in herbal preparations such as extracts or tinctures based on ethanol content if scientific evidence supports it.

3) Pharmacopoeial tests and acceptance criteria:

The Indian Herbal Pharmacopoeia includes critical requirements for certain analytical procedures and approval conditions applicable to herbal substances, herbal preparations, and herbal medicinal items. Pharmacopoeial approaches should be used if they are appropriate.

Drying and Storage of Plant Drugs

Drying

Drying is the process of removing enough moisture from a crude drug to improve its consistency and make it resistant to microorganism growth. One of the parameters influencing the final quality of the drug is the drying phase. Slow drying at a moderate temperature is needed to promote enzyme action. If enzymatic activity is not required, drying should occur as soon as possible after selection. Drugs containing volatile oils are prone to losing their fragrance if not dried or distilled immediately, and all moist drugs are prone to mould growth. As a result, drying equipment and stills should be placed as close to the developing plants as possible.

This has the added benefit of lowering freight costs, as many fresh medicines require a significant amount of water.

The drying process can take anywhere from a few hours to several weeks, and it is heavily influenced by the weather in the case of open-air drying.

Artificial heat drying is faster than open-air drying and is often needed in areas with high humidity. Artificial heating may be accomplished with continuous belt driers, open fires, stoves, or hot-water pipes. There must be at least 15 cm of space between superimposed trays in all drying sheds, and air must circulate freely.[14,15,16]

HERBAL SUBSTANCES:

These are primarily whole, scattered, or cut plants, plant parts, algae, fungi, and lichen in their natural state, typically dried but sometimes new. Exudates that have not been subjected to a specific procedure are often regarded as herbal substances. According to the binomial scheme, herbal substances are correctly identified by the plant component used and the botanical name (genus, species, variety and author).

Leaves, spices, roots, bulbs, seeds, bark, and other botanical materials are examples of herbal substances. Even if the herbal substance is the starting material for the herbal preparation, a broad specification must be established for it. Unless otherwise justified, a specification for the herbal is needed when fatty or essential oils are used as active ingredients in herbal medicinal preparations. [17]

Identification Tests:

1. Foreign matter:

In herbal products, foreign matter can be any organism, element, or product that isn't named with a specific limit, or it can be any organism, part, or product that isn't named with a specific limit. Mineral admixtures that do not adhere to the medicinal plant content, such as dirt, stones, and dust, are examples. Medicinal plant content should be free of any visible signs of contamination.[9]

Sampling:

It's difficult to prepare a pooled sample for herbal drugs because most of the foreign matter is piled on top of the medicinal plant content, which is naturally non-uniform. As a result, it's important that the sample size be large enough to be considered representative. A weighed quantity (50-500gm) of the whole substance is taken as a sample, depending on the type of drug.

Procedure:

A thin layer of paper is spread with the specific amount of plant material mentioned below. To sort foreign matter into different categories, it must be examined visually or with magnifying lenses (6x or 10x), and the foreign matter must be picked out and the percentage registered. The rest of the herbal drug sample is sieved at 250 mesh to remove dust, which is considered a mineral admixture. The amount of foreign matter in each category should be calculated in grammes per 100 grammes of air-dried sample.

Unless otherwise stated, the following amounts of samples must be taken into account in order to classify the foreign matter of any herbal drug as described by WHO:

Leaves, flowers, seeds and fruits - 250 gm

Roots, rhizomes and barks - 500 gm

Cut medicinal plant material - 50 gm

2. Total ash:

The oxidation of the product's components is known as ashing. A high ash value indicates contamination, substitution, adulteration, or carelessness in the preparation of the crude drug for marketing. Total ash is used to measure the total amount of material formed after the ground drug is fully incinerated at a low temperature (around 450°C) to extract all carbons. The alkali chloride can become volatile at higher temperatures, and this procedure may be used to extract it. Carbonates, phosphates, silicates, and silica are commonly found in total ash, which includes both physiological ash derived from plant tissue and non-physiological ash, which is the result of the sticking material to the plant surface, such as sand and dirt.

3. Acid Insoluble ash:

Boil the total ash for 5 minutes in 25 ml of dilute hydrochloric acid, then gather the insoluble matter in ashless filter paper, wash with hot water, and ignite to constant weight. Calculate the amount of acid insoluble ash using the airdried drug as a guide.

4. Water Soluble Ash:

Boil the ash for 5 minutes in 25 ml of water, then collect the insoluble matter in a silica crucible or on ashless filter paper, after washing with hot water, ignite for 15 minutes at 450°C. Subtract the weight of the insoluble matter from the weight of the ash; the weight difference represents the ash that is water-soluble. Calculate the percentage of water-soluble ash in relation to the air dry. [9]

5.Assay:

Assays of the content of herbal substances containing constituents with known therapeutic activity or active markers are required, along with details of the analytical processes. A specific, stability-demonstrating procedure should, whenever possible, include determining the content of the herbal substance. Other supporting analytical processes may be used to achieve overall specificity if the use of non-specific assays is justified.[9]

6. Foaming Index: -

Saponins contain phytoconstituents with high molecular weight that have detergent activity. Saponins are mostly distinguished by their ability to foam. Saponins are found in medicinal plants of various groups, particularly those from the families Caryophyllaceae, Araliaceae, Sapindaceae, Primulaceae, and Dioscoreaceae. [9]

Recommended procedures for foaming index determination

1gm of plant material is to be reduced to coarse powder (sieve no. 1250), accurately weighed, and transferred to a 500ml conical flask containing 100ml of boiling water. Maintain a sufficient boil for 30 minutes. Cool and filter into a 100ml volumetric flask, then add enough water to dilute to volume through the filter. Fill ten stoppered test tubes (height 16cm, diameter 16mm) with the decoction in successive portions of 1ml, 2ml, and 3ml, and adjust the volume of the liquid in each tube with water to 10ml. Cap the tubes and shake them in a lengthwise motion for 15 seconds, at a rate of two shakes per second. Allows you to stand for 15 minutes and measure the height of the foam.

The foaming index can be calculated using the following formula: -

1000 / A

Where A is the amount of the decoction in millilitres used to prepare the dilution in the capping tube where foaming to a height of 1cm is observed.

HERBAL PREPARATIONS:

They are obtained by extracting, distilling, expressing, fractionating, purifying, concentrating, or fermenting herbal medicines. Tinctures, extracts, essential oils, transmitted juices, and distilled excludes, as well as comminated or powdered herbal substances, are examples of these.

Identification tests:

- Water content
- Residual Solvents
- Inorganic impurities, toxic metals
- Microbial Limits
- Mycotoxins
- Pesticides, Fumigation agents, etc
- Assay

1. Tablet (Coated and uncoated) and hard capsules:

One or more of these tests may also be used on soft capsules and granules.

a) Disintegration:

The first critical step toward a solution is the disintegration of the tablet into smaller particles.

A rigid basket-rack assembly that houses six cylindrical glass tubes with lengths of 77.5+-2.5 mm, internal diameters of 21.5 mm, and wall thicknesses of 2mm. The tubes are held vertically by two superimposed transparent plastic plates, each 90mm in diameter and 6m thick, and perforated with six holes the same diameters as the tubes. The holes are equidistant from the centre of the plate and evenly spaced apart. A piece of woven gauze made of stainless-steel wire 635 micrometres in diameter with nominal mesh apertures of 2.00mm is attached to the underside of the lower plate. The upper plate is filled with a stainless-steel disc perforated with six 22mm-diameter holes that fits over the tubes and holds them between the plastic plates. The holes correspond to the top plastic plate and the upper open ends of the glass tubes. The plates are kept rigidly in place and 7705mm apart by vertical metal rods at the periphery and a metal allow the assembly to be connected to a mechanical system capable of raising and lowering it smoothly at a constant frequency of between 28&32 cycles per minute over a distance of 50&60 mm.

A cylindrical disc for each tube, each 20.7+- o.15mm in diameter and 9.5+-0.15mm in thickness, made of transparent plastic with a relative density of 1.18 to 1.20, and pierced with 5holes, each 2mm in diameter, 1 in the middle and the other 4 evenly spaced on a circle of radius 6mm from the centre of the disc.

In a suitable jar, ideally a 1000ml beaker, the assembly is suspended in the liquid medium.

A thermostatic arrangement for heating the liquid and keeping it at 37^{o} +- 2^{o}.

b) Dissolution:

A cylindrical vessel with a hemispherical bottom and a nominal capacity of 1000 ml was made of borosilicate glass or another appropriate transparent material. The vessel has a flanged upper rim and a lid with many holes, one of which is central A motor with a speed regulator capable of keeping the paddle's rotational speed within 4% of the speed specified in the individual monograph. The motor has a stirring component that consists of a drive shaft and a paddle-shaped blade B.

A water bath collection to keep the dissolution medium at 36.5^{o} to 37.5^{o} Fahrenheit. Throughout the test, the bath liquid is held in a steady and smooth motion. The vessel is firmly clamped in the water-bath, preventing displacement vibration from other devices.

c) Hardness:

Tablets must have a certain amount of strength, or hardness and resistance to friability, in order to withstand mechanical shocks during manufacturing, packaging, and shipping. The strength of a tablet was traditionally measured by splitting it between the second and third fingers, with the thumb serving as a fulcrum. If there was a sharp snap, the tablet was considered strong enough. Today, diametric compression experiments are performed with the following instruments: [18]

Monsanto tester

Strong-Cobb tester

Pfizer tester

The Monsanto hardness tester is made up of a barrel with a compressible spring between two plungers. The lower plunger is pressed against the tablet, and a zero reading is obtained. Turning a treaded bolt forces the upper plunger against a spring before the tablet breaks. The fracture force is measured, and the zero-force reading is subtracted.

About 20 years later, the Strong-Cobb tester was made. The original design used a plunger that was triggered by pumping a lever arm, which used hydraulic pressure to push an anvil against a stationary base. A hydraulic gauge measures the force needed to fracture the tablet.

The Pfizer tester was created and distributed to the industry. This tester works on the same mechanical principle as pliers. The tablet is squeezed between a holding anvil and a piston connected to a direct force reading gauge when the pliers' handles are squeezed. [18]

d) Friability:

The Roche friabilator can be used to assess the friability of tablets. The tablets are exposed to the combined effects of abrasion and shock by rotating a plastic chamber at 25 rpm and dropping the tablets 6 inches with each revolution. A preweighed tablet sample is normally put in the friabilator, which is then turned 100 times. After that, the tablets are dusted and reweighed. It is appropriate to lose less than 0.5 to 1.0 percent of the tablet weight. [18]

e) Weight Variation:

According to the USP weight variance test, 20 tablets are weighed individually; the average weight is determined, and the individual tablet weights are compared to the average. If no more than two tablets are beyond the percentage limit and no tablet varies by more than twice the percentage limit, the tablets pass the USP exam. [18]

Table: Weight variation tolerances for uncoated tablets:

Sr No	Average weight of tablets(mg)	Max. % difference allowed
1	130 or less	**10**
2	130- 324	**7.5**
3	More than 324	**5**

f) Moisture content:

Moisture is an unavoidable part of crude drugs that must be avoided to the greatest extent possible. Cleaning or garbling the harvested drug plants to extract soil or other extraneous material is accompanied by drying, which plays an important role in the consistency and purity of the material. The target of drying fresh material is: [9]

- To help in their preservation
- To "fix" their constituents, i.e., to prevent enzymatic or hydrolytic reactions that could change the chemical composition of the medication
- To promote subsequent comminution (grinding into a powder) and
- To lose weight and bulk

2. Oral Liquid:

Normally, one or more of the following basic tests will apply to oral liquids and powders intended for reconstitution as oral liquids. [19]

i. Uniformity of dosage units:

This concept encompasses both material and mass uniformity. In general, acceptance criteria for weight variation, fill volume, and/or fill uniformity should be defined. Pharmacopeial protocols must be followed.

Tests may be conducted as in-process controls if necessary; however, the approval requirements must be included in the specification. This definition can be extended to single-dose as well as multiple-dose packages. [18]

ii. pH:
Where appropriate, pH acceptance requirements should be given, and the proposed range should be justified.

iii. Alcohol content:
The alcohol content should be stated where it is declared quantitatively on the label in compliance with applicable regulations. [9]

iv. Dissolution:
In addition to the attributes mentioned above, it may be essential (for example, if the constituents of the herbal substance or herbal preparation are only sparingly soluble) to provide dissolution testing and acceptance requirements for oral suspensions and dry powder products for resuspension.
Dissolution testing may be done as an in-process test or as a release test, depending on its importance to product results. Dissolution of solid dosage types, as well as particle size distribution, should be discussed. [19]

v. Water Content:
If an oral product requires reconstitution, a test and approval criteria for water content should be suggested. Loss on drying is usually regarded as satisfactory if the effect of absorbed moisture vs. water of hydration has been adequately defined during product production. In certain cases (for example, essential-oil preparations), a more complex procedure (e.g., Karl Fischer titration) is needed. [9]

PHYSICAL QUALITY ASSURANCE:

Until now, quality assurance of phytopharmaceutical products has been addressed solely from a chemical and physiological standpoint. The physical quality of plant extracts, on the other hand, is just as critical for the producer and processor. Many plant extracts exist in a form that makes further processing even more difficult, if not impossible, without the addition of appropriate adjuvant substances. As a result, extracts of Crataegus fruits, Curcuma extracts, and many others cannot be dried into more manageable dry products using roller, belt, or spray drying. Male fern extract is one such example, which is produced as a solvent-free thin extract. Since the ratio of active substances to corresponding plant substances remains unchanged, the producer just has to declare the steps he has taken. [9]

CONCLUSION:

The quality of herbal products can be assured by careful monitoring of the herbal ingredients and the use of GMP. Quality assurance ensures that you are doing the right things in the right way. Quality Assurance is a process-oriented discipline. It includes the monitoring and reporting mechanisms that ensure the pharmaceutical industry's plethora of regulations are followed.

Since almost all formulations do not go through an effective quality control process, one cannot depend on their quality and efficacy. The key explanation for this is the lack of formal quality control protocols for herbal formulations.

As a result, pharmaceutical formulations of drug combinations have shown a growing trend to counteract other symptoms unique to one drug n formulation, and therefore analytical chemists would have to embrace the task of developing effective methods for drug analysis in such formulation.

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