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Role Of Experimental & Analytical Research In Validation For Ayurvedic Formulation

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ABSTRACT:

Standardization is measurement for ensuring the quality and is used to describe all measures which are taken during the manufacturing process & quality control leading to a reproducible quality, safety and efficacy. Ayurveda medicines are serving the needs of ailing humanity since many centuries. There is a need of systematic and well-organized coordination of allied sciences along with adequate infrastructure and facilities to solve various problems related to Ayurvedic formulation. Use of formulation when prepared in improper and short cut ways, can prove injurious effect to health. Earlier medicines were prepared by physician themselves for their patients. The physicians were well qualified to identify the materials. They were trained in various processing. They were following guidelines of Shastra & experienced teachers. According to the immediate need of patients they were modifying the formulation as per their occupied understanding. Today physicians are more involved with diagnosis and treatment. The drug manufacturing has gone into the hands of pharmacy. In large scale production manufacturers compromised with quality and quantity of material. Compromised with longer and lengthy procedures. Equivalent substitutes are added in the compounds are not validated. The extract important procedures either altered or made shortcut. The led to the decline in the quality of Ayurvedic drugs. So for justification of Ayurvedic formulation action there need to prove the analytical and experimental studies.

Keywords: Experimental, Analytical research validation , Ayurveda

Introduction: Analysis is important in every product, but in drug it is very important as it involves life. In comparison to general consumer products, in drugs there is and there can be only quality/standard product and no other products. Quality of the product comes from series of tests for quality control, starting from raw materials, in process during manufacturing, finished product etc.¹

Experimental study: The most recent development in experimental pharmacology is the sophisticated computational simulations of animal experiments, both in vitro and in vivo, referred to as in silico test. It is simplified ecological model that reduces a lot of animal testing, and considered to be more predictable regarding the success of the developing drugs in clinical trial.

Aims & Objective:-

1. **Aim:** Role of Experimental & Analytical research in validation for Ayurvedic formulation.

2. **Objectives:-**

Role of Analytical research in validation for Ayurvedic formulation

Role of Experimental research in validation for Ayurvedic formulation

Role of Analysis in Ayurvedic formulation:-

Standardization is measurement for ensuring the quality and is used to describe all measures which are taken during the manufacturing process & quality control leading to a reproducible quality, safety and efficacy.

Ayurveda medicines are serving the needs of ailing humanity since many centuries.

There is a need of systematic and well-organized coordination of allied sciences along with adequate infrastructure and facilities to solve various problems related to Ayurvedic formulation.

HERBAL DRUGS

QUALITY EVALUATION

A systematic examination of the extent to which an entity (part or product) is capable of meeting specified requirements.

The result of quality evaluation may be used for qualification, approval and registration or accreditation purposes.

A quality evaluation may be used to determine manufacturing quality capability.²

HERBAL DRUGS – QUALITY EVALUATION

- Absolutely required for
 - Authenticity
 - Purity
 - Safety
 - Quality evaluation
 - Quality control
 - Quality assurance
- The who and number of countries dealing with herbal drugs formulated various protocols for standardisation and quality evaluation
- The triple ‘p’ based protocols
 - Pharmacognostical
 - Physico – chemical
 - Phytochemical
 - Residual Analysis

HERBAL DRUGS – STANDARDISATION

- Taxonomical
- Morphological
- Anatomical
- Biological
- Biochemical
- Biotechnological

Physico-chemical:

Ash Values

pH

Optical Rotation

Specific gravity

Hardness

Disintegration time

Elemental Composition

Phytochemical

Extractive values

Chemical profiling

Markers- Bioactive, Biologically, Chemical, HPTLC/HPLC Based quantification.

Residual Analysis:⁴

1. Heavy Metals 2.Pesticides 3.Toxins 4.Radio-actives 5.Fumigants 6.Pathogens 7.Fungicides

Role of Experimental research in Ayurvedic formulation:³

- Ayurveda, the traditional system of medicine, is regarded as the most methodical and efficient among all such systems practiced in different parts of the world.
- Because of the complexity and the adverse effects associated with the use of chemical drugs, much of the world's

population is turning toward alternative systems of medicine.

- Although the traditional and complimentary method of treatment may have health benefits and are normally practiced safely, over recent years there have been several concerns raised over the safety of some forms of complementary medicine.
- Description of very few therapeutic potent metals is available in Ayurveda.
- Their detoxifying procedures without altering its therapeutic potency, transferring the metal fit for oral administration as well as eliminating various disorders and maintaining health are also explained.
- In the classical explained formulation with wide range of therapeutic efficacy, using practically also.
- There are various methods explained to prepare bhasmas & herbal formulation, so to continue its long term uses, it is need to prove its safety before efficacy.

Herbs are not without disadvantages, and herbal medicine is not appropriate in all situations. These are a few of the disadvantages to consider:

- Inappropriate for many conditions: Modern medicine treats sudden and serious illnesses and accidents much more effectively than herbal or alternative treatments. An herbalist would not be able

to treat serious trauma, such as a broken leg, nor would he be able to heal an appendicitis or a heart attack as effectively as a conventional doctor using modern diagnostic tests, surgery, and drugs.

- **Lack of dosage instructions:** Another disadvantage of herbal medicine is the very real risks of doing yourself harm through self-dosing with herbs. While you can argue that the same thing can happen with medications, such as accidentally overdosing on cold remedies, many herbs do not come with instructions or package inserts. There's a very real risk of overdose.
- **Poison risk associated with wild herbs:** Harvesting herbs in the wild is risky, if not foolhardy, yet some people try to identify and pick wild herbs. They run a very real risk of poisoning themselves if they don't correctly identify the herb, or if they use the wrong part of the plant.
- **Medication interactions:** Herbal treatments can interact with medications. Nearly all herbs come with some warning, and many, like the herbs used for anxiety such as Valerian and St. John's Wort, can interact with prescription medication like antidepressants. It's important to discuss your medications and herbal supplements with your doctor to avoid dangerous interactions.

- **Lack of regulation:** Because herbal products are not tightly regulated, consumers also run the risk of buying inferior quality herbs. The quality of herbal products may vary among batches, brands or manufacturers. This can make it much more difficult to prescribe the proper dose of an herb.

Classical point of view in Analysis & Experimental study in Ayurvedic formulation

- In ancient Ayurveda acharyas are not having the analysis and experimental techniques.
- But they also analysis the herbal & herbo-mineral formulation.
- they used in analytical techniques are like:-
 - Bhasma pariksha
 - Sneha sidhi lakshana
 - Burning candle test in fermentation
- Lime water test in fermentation
- Avaleha paka lakshana are:
 - Confirmatory test
 - In pakakalina are:
 - Tantumattva (thready consistency)
 - Apsumajjati (sinks in water)
- 2. In pakanantara are:
 - Kharatva/sthiratva (rough and stable)

- Anguli mudra (finger prints are imparted)
- Gandha, varna and rasodbhava (color, odor and taste)

Experimental study in Ayurvedic formulation

- Drug can produce toxic effects in addition to pharmacological actions.
- Toxicology is the science that deals with the study of potential harmful effects of chemical and drugs on living organisms.
- In Ayurveda some formulation are having herbo-mineral drugs like Parada & gandhaka.
- Sometime this herbo-mineral formulation is creates Toxicity, if Proper shodhana is not done.
- It is obviously unethical to test for toxicity in humans.
- However some information can be gained from investigating accidental human exposures (e.g. Factory accidents).
- Otherwise most acute & chronic toxicity data come from animal testing or more recently in vitro testing methods and inference from data on similar substances.⁵

Conclusion

- An Ayurvedic formulation widely used by the rural and ethnic people in India for the treatment of *vata roga (neurological disorder)*.
- The trial drugs have a definite demonstrable anticonvulsant action as

ascribed by the experimental study conducted on albino mice.

- अल्पमात्रो प्रयोगित्वदरुचेरप्रसंगतः।
क्षिप्रमारोग्यदायित्वादैषदेभ्योऽधिको रसः॥
(र.सा.स.)
- To gets these properties from rasaoushadhis/ bhasmas SOP & SMP should be followed as mentioned in Ayurvedic literature followed by modern techniques.

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