

## Pharmaceuticals

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## A STUDY OF QUALITY CONTROL TEST & EVALUATION PARAMETER FOR AYURVEDIC FORMULATION IN LIQUID, SEMI-SOLID & SOLID DOSAGE FORMS.



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**Abstract:-**

The use of ayurvedic drug as medicine is the ancient form of health care known to delicacy & it is used in all culture through history. The identification of purely active moiety is an important requirement for quality control & dose determination of plant related drugs. Standardization of ayurvedic drug means conformation of its identity, quality & purity. The present overview covers the evaluation parameter with their standard value of the same ayurvedic dosage form. The process of good quality control & assurance. Evaluation of ayurvedic dosage form at different stages were also discussed.

**Introduction:-**

Quality control & evaluation of ayurvedic formulations is essential in order to assess of quality drug. Based on the concentration of their active principle, physical, chemical, physiochemical quality evaluation & in-vitro, in-vivo parameters. Natural products have been our single most successful source of medicine dosage forms are the means by which drug molecules or plant parts are delivered to site of action within a body. The routes for which herbal dosage form may be administered include topical, oral, parenteral etc.

Definition of Ayurvedic formulation: -Ayurvedic medicine are all the medicine intended for internal or external for in the diagnosis treatment, migration, or prevention of disease or disorder in human being or animal.

Ayurveda has been defined as the "Knowledge of living" or "science of longevity"

**Classification of Ayurvedic dosage forms:-**

They are classified into four groups as below-

- A) Solid dosage form: - Pills, Ghutika, Vatika
- B) Semi-solid dosage form: - Avaleha, Pak, Lapa, Ghrita
- C) Liquid dosage form: - Asava, Arista, Ark, Taila, Drava Ka
- D) Powder dosage form: - Bhasma, Sattva, Pisti, Mardana, Lavana, Kshara, Churn

**Need of quality control for ayurvedic formulations:-**

- When traditional medicine was developed technology & concept of quality control was quite different.
- During past thousand-year dynamic process of evaluation may have changed the identity of plant material.
- Due to commercialization, supply of genuine raw material has become a changed.
- Properties of botanicals may have undergone change due to time & environmental factor.
- It is cardinal responsibility authorities to ensure that consumer

get the medication, which guarantee, purity, safety, potency & efficacy.

**WHO Guideline standardization of ayurvedic formulation:-**

Standardization & quality control parameter for ayurvedic dosage form are based on following fundamental parameters:-

- Quality control of crude drug material, plant preparation & finished products.
- Stability assessment & shelf life.
- Safety assessment, documentation of safety based on experience or toxicological studies.
- Assessment of efficacy by ethnomedical information & biological activity evaluation.

**Advantages of ayurvedic dosage form:-**

- Better health & better memory.
- Prevention of cold & flu.
- Ability to handle stress & anxiety. Improved sleep & concentration
- Better digestion
- Healthier skin & slows down aging.
- Stronger immune system.

**Common evaluation parameter for the ayurvedic dosage form:-**

- 1) Taxonomical estimation: - Authentication of drug material.
- 2) Organoleptic/sensory evaluation: - Color, odor, appearance, powder particle size distribution, powder flow, clarity.
- 3) Foreign matter: - Foreign plant, own plant, another animal, mineral.
- 4) Microscopic evaluation: - Qualitative: - palisade ratio, vein islet, vein termination, stomatal index, stomatal number. Qualitative: - lycopodium spore count method, starch grain, calcium oxalate crystals.
- 5) Chromatographic & other methods: - HPLC, TLC, HPTLC, UV-spectrometry, GC-MS.
- 6) Physiochemical parameters: - pH, Disintegration time, friability, hardness, sedimentation rate, solubility, viscosity, ash value, extractive value, volatility, oil related values, swelling index, foaming index, melting range, optical rotation, moisture content
- 7) Pharmacological parameter: - Bitterness, astringent activity, antimicrobial activity, hematological activity, antioxidant activity, nitric oxide scavenging activity.
- 8) Toxicological parameter: - Limit test, pesticide contain, heavy metals, aflatoxin, radioactive, bioburden.

**Aim & Objectives:-**

To describes the importance, concept, processes & parameters required for the standardization of Ayurvedic drug.

**1) Solid dosage form:-**

- Vatika & ghutika -

Evaluation parameter: - Color, odor, taste, total sugar, reducing sugar, particle size, identification, microscopy, HPTLC, TLC, heavy metal test, microbial contamination, pesticide residue.

Physical evaluation: - Ash value, PH, volatile oil, alcohol soluble extractive, melting point, loss of drying, hardness, uniformity of content, friability test, disintegration test.

## 2]Semi-solid dosage form:-

### • Avaleha:-

Evaluation parameter: -TLC, color, odor, taste, loss of drying, total ash value, acid insoluble as, alcohol soluble extractive value, water soluble extractive, PH, microbial limit, aflatoxin, storage.

### • Lapa:-

Evaluation parameter: - color, odor, taste, appearance, consistency, microscopic evaluation, loss of drying, ash value, HPTLC.

### • Prash:-

Evaluation parameter: -Color, odor, taste, appearance, consistency, PH, aqueous & methanol extract, water soluble extractive, alcohol soluble extractive value, loss of drying, total acid content, vitamin content, saponification value, acid value, total fat.

### • Ghritas:-

Evaluation parameter: -Color, odor, taste, appearance, weight/ml, viscosity, iodine value, saponification value, rancidity

## 3]Liquid dosage form:-

### • Asava & Arista:-

Evaluation parameter: - Color, odor, taste, appearance, PH, specific gravity 250c & total solid, alcohol content, non-reducing sugar, reducing sugar, test for methanol, shelf life, chromatography, viscosity.

### • Tails:-

Evaluation parameter: -Color, odor, taste, appearance, weight/ml, viscosity, iodine value, saponification value, acid value, rancidity

### • Ark:-

Evaluation parameter: - Color, odor, taste, appearance, PH, volatile matter, clarity test, sterility test, shelf life, chromatography.

## 4]Powder dosage form:-

### • Churn:-

Evaluation parameter: -Color, odor, taste, appearance, microscopic evaluation, particle size, loss of drying at 1050c, total ash, water soluble extractive value, PH, HPTLC, HPLC, TLC, microbial contamination, shelf life

### • Basma:-

Evaluation parameter: -Color, odor, taste, appearance, loss of drying, total ash, acid insoluble ash, water soluble ash, solubility, particle size, assay of element, specific gravity, Ph value, floating property.

## Conclusion:-

In Indian ayurvedic industry is growing in a tremendous rate with the tremendous increase in traditional ayurvedic therapy several concerns regarding the safety & quality of ayurvedic medicine have also been observed. There is need for more advanced technique of standardization. The advancement of analytical technique will serve as a rapid & specific tool in the herbal research, therapy allowing the manufacturer to set quality standard & specification so as to seek marketing approval from regulatory authorities for therapeutic efficacy, safety & shelf life of ayurvedic drug. Quality control of ayurvedic has not only to established reasonable analytical methods for analyzing the active constituents in ayurvedic medicine, but many factor should be concern such as pesticide residue, aflatoxin, heavy metal, GMP, etc. there is need for development of technique which include both traditional methods of evaluation & modern method of evaluation. This will improve the

quality of the drug & also motivate the practitioners to get more involved in the standardization process.

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