

Transformational Dosage form Can Change the Scenario of Herbal Medicine in the World: A Research Based Scientific Approach

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Introduction

Traditional medicine has been empirically used for different health ailments from primitive to till now. Ancient philosophers and scientist were conducted experiment to claim the safety and efficacy of herbal medicine and formulated different hypothesis. Some of the hypotheses are already proven by scientific justification and technological adaptation. Some are not proved by clinical trials or other interventional studies. But it has been claimed that herbal or traditional medicine has huge prospect to prove, to establish new formulation and can play great role in health disorders. Peoples are used to take such medicines which are easily accessible, feasible and affordable. Some formulations are not used to take by consumers because semisolid or powder forms are so bitter or pungent that these are difficult to consume. By transforming the dosage form and gather huge clinical data or result regarding safety and efficacy of herbal medicine, the medicine will become more popular medicine to the peoples and can play pivotal role in economy. That's why; transformational dosage form can change the scenario of herbal or traditional medicine in the world.

Existing dosage form and their physico-chemical analysis

Majority formulations of the traditional or herbal medicine are semisolid, powder, incinerated and liquid form. There phytochemical, qualitative and quantitative analysis and reach a unique conclusion are very difficult task. Compound formulation is the prime drawback to conclude or claim the efficacy. So, scientific justification, identify the active and potent ingredients, isolate the potent metabolites, preclinical and clinical trials are needed to generalize the herbal medicine in the world.

From primitive to till now, a lot of semi-solid and powder forms have been using to cure different health ailments. But due to some reasons, these dosage form become very difficult to prescribe, consume and marketing. Modern civilized communities are seeking lucrative, palatable, age-appropriate dosage form, patient's centric formulations and Minitab's. Adaptation of old pharmaceutical dosage form are very difficult task due to high sugar containing, large dose and lack of evidence based preclinical and clinical trials. Technology platforms are required to aid the development of age-appropriate medicine to maximize patient acceptability and affordability. A collaborative approach will benefit not only pediatrics but also other patient populations such as geriatrics from an accelerated patient-centric approach to drug delivery [1].

Appropriate dose, quantitative and qualitative analysis of semisolid preparations are very difficult to ensure. Technological adaptation and the dose specific formulation are needed for accessible, affordable, safe and effective herbal medicine in the world. It is also important to give

the attention on affordable price, packaging and administration devices and vehicle for improving the overall quality and acceptability of the medications. Ideal formulation have to follow the factors related to efficacy and ease of use, safety and influencing factors of access of patients medicines based on benefit-risk approach.

Solid dosage forms are having long term stability, easy supply chain and low cost. Conventional solid dosage form may not be suitable for patient with swallowing difficulties especially for pediatric population. Pill swallowing cups have been used to increase the suitability of tablets and capsules of relatively large size to a broader population range. Multi particular products have been reported to provide a more reproducible distribution in the GI tract with lower risk of local irritation, although knowledge in the field is still limited and subjected to a high degree of inter and intra individual variability. The manufacturing process of multiparticulate products usually include a polymorphic coating step as downstream processing for improved aesthetical properties or taste masking or controlled release formulations can be adopted for transformational dosage form [2].

Safety and efficacy of herbal medicine

It has been claimed that traditional medicine or herbal medicines were having very few clinical trials and lack of evidence to comply with modern medicine. But last 10 years of scientific advancement and technological adaptation and different studies proved that herbal medicines are safe and effective in large extend by preclinical and clinical trials. Preclinical and clinical trial on garlic proved that garlic is very safe and effective herbal medicine for dyslipidemia. Majority of the listed (attached) nutritive foods or drugs have clinically proved as a safe and effective. Suggested new dosage form can be used for preclinical and clinical trials.

Side effects or adverse effects of herbal medicine

It has been well established that herbal medicines have few or negligible or unwanted side effects/adverse effects. It may be due to inappropriate purification method or procedure, adulteration, inappropriate formulation or lack of understanding of plants or drug interaction, high or heavy metal toxicity and pesticides or insecticides [3].

Powder form can be transformed into tablet or capsule form

From one of the oldest profession of mankind, powder technology has now transformed itself form an art into science with its principal applicability in food, chemical and pharmaceutical industry. Apart from the basic conventional process like grinding, mixing and formulating pharmaceutical manufacturing processes involve modification of powder and particle properties to great a novel drug

formulation, with enhanced solubility and dissolution properties. Pharmaceutical powder technology also deals with areas of surface engineering usually explore through the application of surface chemistry and surface morphology. Overall, the properties like particle size, shape, adhesiveness, morphology, roughness, wet-ability, density, surface chemistry, plasticity, hardness, brittleness and hygroscopicity are important for successful dosage form design and development [4].

Transform of semisolid (khamira, majun, looqe and etrifal) form to orodispersible, orodispersible films, capsule and chewable form

It is very difficult task to transform semisolid form to easily accessible form without compromising their therapeutic efficacy and establish a safety profile. Ancient philosophers were developed these types of semisolid forms or different formulation for different preventable and curable diseases. But alteration of disease pattern, host susceptibility and environmental diversification are leads to modify the dosage form. It has been observed that highest sugar content is found in the majun and khamira. These two formulations are not allowed to consume by diabetic patients. It can create negative effect among the consumers. Looqe preparations are also difficult to consume by consumers due to presence of high adhesiveness, bad odour, taste, unacceptable palatability, lack of stability data and dose titration. So, it is time taken issue to transform these form into another accessible, affordable, suitable and lucrative form to generalize the traditional medicine in the world for different health ailments. It has been proven that the semisolid form can transform into capsule or tablet form without changing their therapeutic efficacy such majune arde khurma, majun daul musk motadil jawaharwala, majun e dobidul ward, majune falasafa, majune jalali, majune salab, etrifal e ustukhudus, jawarishe kamuni, labub e kabir, jawarish e jarani sada, ark maku and syrup nilufor are transform into lucrative capsule form by Dehli's India .

Fine powder and incinerated form can transform to micronized capsule or minitab form

Traditional medicine has been enriched with different and diverse dosage form from ancient to till now. The fine and incinerated powder formulations can be easily transformed by using modern technology into micronized capsule form, polymorphic crystalline form, nano particular form for improve biocompatibility and versatility without changing the therapeutic efficacy. List of herbal medicines or dietary or food supplements can be transformed into suitable form (attached).

Lipid or water soluble nano particular drugs can be transformed into sterile injectable form

Lipid nano particulate drug delivery system is having size dependent and solubility dependent properties. The advantage of lipid based formulation protect active compound from biological degradation or transformation. There are so many form of lipid base formulation like nanoparticle, liposome, transferosome, ethosomes, niosome and phytosomes [5].

Pharmaceutical particle technology is employed to improve poor aqueous solubility of drug compounds that limits in vivo bioavailability owing to their low dissolution rate in the gastrointestinal fluids following oral administration. The particle technology involves several approaches from the conventional size reduction processes to the newer, novel particle. It has been well explained that solubility, dissolution and gastro intestinal permeability

are fundamental parameters that control rate and extent of drug absorption and its bioavailability. Oral bioavailability of a drug depends on aqueous solubility, drug permeability, dissolution rate, first pass metabolism and susceptibility to efflux mechanism [6].

Research based applicable strategies of herbal or traditional medicine: Verhoef and Van der Greef have recommended some methods for evaluation of efficacy of traditional medicine. According to them randomized controlled trials (RCT) have the highest status in biomedical research; observational studies, factorial designs, and preference trials, seem to be better alternatives for improving and testing traditional medicine treatments [7]. Observational studies are more suitable for the evaluation of traditional medicine. They are cheaper, have higher external validity, and are better equipped to accommodate the medical logics and therapeutic goals of traditional medicine. Some other alternatives to the RCT design are the retrospective treatment-outcome survey (RTO), the comparison of prognosis and outcome study (CPO)–an 'outcome method' in which biomedical physicians monitor traditional treatments and the dose escalating prospective study (PDE) which looks at the way experimental subjects respond to traditional single and compound drugs [7].

The dosage of drugs along with their dosage forms and duration of their usage during acute and chronic conditions need to be quantified and laid down through strict scientific procedures. The shelf life of both crude as well as compound formulations needs to be worked out on basis of various scientifically valid tests of potency. The manufacturing and expiry dates should be clearly mentioned on drug packs. Setting up of drug manufacturing facilities of international standards in compliance with the GMP should be encouraged via various government policies to attract big investors in the trade of drugs of herbal and mineral origin which will directly help in raising the standards of their quality [7].

Prospective approaches can be adopted to transform the herbal medicine in the world

Unani, ayurvedic, herbal or traditional medicine has been empirically used for remedies of different health disorders. Until, a lot of dosage form cannot be transformed into suitable dosage form or novel form. To develop and standardize the traditional form into suitable age-appropriate and patient centric form is the demand of the modern civilized consumer. Which part of the plant will be used for clinical or preclinical trials will depends on their phytochemical composition, clinical indications and applications. So, some prospective suggestions will help to transform the dosage form without altering the quality, quantitative analysis and fundamental concept of ancient philosopher.

- It is needed to set up a mind in a positive manner that development, validation and standardization are required to prove the efficacy and safety of the herbal medicine to the traditional personnel's.
- By avoiding poly pharmaceutical formulations and use of single drug for clinical trial and isolation of active metabolites, will help to achieve the desire goal.
- Technological adaptation, follow standard protocol and ensure skilled manpower in the appropriate place are mandatory to transform the dosage form herbal medicine in the scientific world.

- It is an utmost important step to prove the safety and efficacy of traditional medicine by Preclinical and clinical study in the multicentre environment, culture and race under one umbrella.
- To set up a standard parameters for testing the herbal product and should be followed by the manufacturer.
- Age appropriate oral drug delivery and the patient centric formulation development are prime approach to transform the herbal medicine.

Conclusion

By transforming the dosage form, ensure the quality and complies the ancient philosopher concept of herbal medicine, it will become most universal health system in the world.

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