Literature Review, Research Envisaged and Plan of Work

2.1 Literature Review

➢ Jain, V, et al 2011; Developed TLC densitometric methods for quantification of standard marker compound in Triphala Churna for routine quality control.

➢ Shukla, S.S, et al. 2011; Reported the various fundamental aspects and basic concept of siddha medicines.

➢ Jain, V, et al 2011; Reported the HPLC determination of ‘Trikatu Churna’ a potent Ayurvedic Formulation for routine quality control.


➢ Shukla, et al. 2010; Developed and validate the TLC densitometric fingerprinting method by using Berberine as marker compound in poly-herbal Unani formulations named Habb-e-Bukhar.

➢ Shukla, et al. 2009; Reported various approaches towards standardization and quality assessment of herbals.

➢ Pandey, et al. 2009; Developed the UV spectrophotometric fingerprint method for evaluation of sitopaladi churna using piperine as marker compound.
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- Wei. X, et al. 2009; Determined the oleuropein in stem of *Syringa oblata* from different districts by HPLC.

- Musthaba. S. Mohamed, et al. 2009; Summarizes various novel drug delivery technology technologies for herbal actives, which are gaining more attention for better therapeutic response.


- Jain. V, et al. 2007; Reported the various Standardization parameters of Triphala Churna by different spectrophotometric approach.

- Shukla, K, et al. 2007; Developed the quality control parameters of Bhaskar Lavan Churna: A Traditional Ayurvedic formulation.


- Govindarajan, et al. 2007; Developed High-performance liquid chromatographic method for the quantification of phenolics viz. gallic acid, catechin, syringic acid and rutin in Chyavanprash.
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- Lijuan, et al. 2006; Developed the fingerprint of *Salvia miltiorrhiza* Bunge by high-performance liquid chromatography with a coulometric electrode array system.

- Biringanine, et al. 2006; developed the validation protocol for the HPTLC standardization of the determination of acteoside in leaves of *Plantago palmata* Hook.

- Wadekar, et al. 2006; Studied a systematic characterization of the drug samples after various calcination stages by XRD, SEM and EDS analysis in Vanga bhasma.

- Saleem, et al. 2006; Determined content of iron and nitrogen by volumetric analysis while content of magnesium, aluminium and calcium by inductively coupled plasma emission spectroscopy for Karpura shilajit bhasma.

- Kasar, et al. 2006; Determined bio-efficacy by various biological methods like antioxidant study, microbial contamination study and finally stability study of Chyavanprash according to ICH guidelines.

- Bagul, et al. 2005; Performed phytochemical evaluation of PrabhakaraVati using HPLC method by quantifying Gallic acid in the formulation and compared it with marketed formulations.

- Elamthuruthy, et al. 2005; Reported the standardization and determination of percentage of Aloin in Kumariasava by HPTLC method.

- Bagul, et al. 2005; Developed HPLC method for quantification of Gallic acid in the PrabhakaraVati formulation and compared it with marketed formulations.

- Scartezzini, et al. 2005; Developed reliable and feasible HPLC method with diode array detection for the determination of ascorbic acid in Svaras Bhavana.
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➢ Bhagwat, et al. 2004; Reported the characterization of Kapardika bhasm in raw material, intermediate obtained during the process and final product by using powder XRD and IR techniques.

➢ Rastogi, et al. 2004; Performed high performance thin layer chromatography for quantitative analyses of different amino acids viz. alanine, valine and lysine in Chyavanprash.


➢ Francis, et al. 2003; Performed simultaneous HPLC method for determination of Vasicine and Glycyrrhizin from herbal preparation.

➢ Bhagwat, et al. 2003; Characterization of Zinc oxide in raw material, intermediate obtained during the process and final product of Kapardika bhasm by using powder XRD.

➢ Jain, et al., 2003; Analyzed extractive values of three batches of chyavanprash in different solvent by spectrophotometrically for spectrum, overlain spectrum and linearity studies.

➢ Eapen. et al. 2002; Performed standardization for estimation of piperine and embelin content by HPTLC and iron content was estimated by U.V. Spectroscopic method for Navayasa Churna.
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- Lalla et al., 2002; Determined physico-chemical characters of Calcium Carbonate and studied safety and efficacy of the Shantha Bhasma.

- Bhavsar et al., 2001; Evaluated quantitatively and qualitatively by employing TLC and titrimetric methods for detection of alkaloid in Kurchi bark and Ativish root in formulation.

- Lalla, et al., 2001; Evaluated extractive values, ash value, phytoconstituent and some physical constants and compared it with similar formulations of Triphala churna.

- Mitra, et al., 2001; Determined microelements and metal content in the swarna bhasma by Infrared spectroscopy and atomic absorption spectrometry.

- Padiyar, et al., 2000; Reported stability studies and physico-chemical protocols of churna as per ICH guidelines.

- Sheth, et al., 2000; Determined percentage of piperine in Trikatu churna by UV spectrophotometric method.

- Agrawal, et al., 2000; Presented standardization, quality control and quality assurance of Ayurvedic formulations.

- Dwivedi, et al., 1999; Developed techniques for Ayurvedic preparation (Vajraka Taila) and standardization of their, pharmaceutical / manufacturing technique, physico-chemical parameters individually applicable, self-life of the product.

- Giri, et al., 1999; Reported Ayurvedic properties of Angya vardhani vati individual constituents, its medicinal properties, diseases for which used doses and type of vehicle to be used for various cases.
Alam, et al. 1998; Analyzed oil for determination of its pharmacopoeial parameters in Ksirabala tailam.

Saraswathy, et al. 1998a; Prepared Civanar Vembuk Kulit Tailam for standardization and chemically analysis for identity and purity. The physico-chemical data, TLC and HPTLC finger printing profile were evolved for fixing standards and also identify the plant drugs used in the medicine.

Singh and Ramprakash, 1997; Developed identification parameters for some Ayurvedic drugs (Shatshakar churna Dashmularista) using IR spectrophotometry.

Rao, et. al. 1997; Developed standardization parameters of Arjuna bark (Terminalia arjuna), Mrividika fruits (Vitis vinifera) and Madhuka flowers (Madhuca indica).

Pandey, et al. 1997; Analyzed samples of Sinduraya taila according to textural references and standardized for their physico chemical constituents.


Thankamma, et al. 1996; Detection of Acorus callamus, Curcuma longa Allium sativum and Aegle marmelos in Vachalasunadi Bilvapatra taila by TLC methods.

Agrawal, et al. 1996; Developed TLC method for confirmation of the presence of main ingradient Vatsanantha (Aconitum chasmanthum) in Tribhuvanakirti formulation.

Hepsibah, et al. 1996; Detected the presence of drugs present in pinda Taila that was prepared using Rubia cordifolia, Hemidesmus indicus and vateria indica and beeswax by TLC.
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- Purohit, et al. 1995; Standardized some marketed polyherbal Ayurvedic antidiabetic formulations.

- Thankamm, et al. 1995; Detected *Acorus calamus* in Ayurvedic preparations (Vacadi taila) by TLC.

- Mahrotra, et al. 1995; Standardized popular Ayurvedic adaptogenic preparation and developed ethnobotany of its ingredients.

- Bhutani, et al. 1994; Developed protocols for the isolation and separation of the bioactive rich fraction from individual plants showing antistress, immunomodulatory and memory enhancing Ayurvedic drugs and their standardizations.

- Raina, et al. 1993; Developed macroscopic, microscopic evaluations, quantitative chemical testes and chemical finger printing by using UV/TLC/HPTLC/ techniques and fluorescence studies.

- Alam, et al. 1993; Standardized some Dashmula containing formulations viz. Dasmularistha, Dashmula kwath, Dashmula taila containing *Uncaria lagapodioides, Solanum xanthocarpum, Tribulus terristris, Gemlina asiatica, Aegle marmlos, Premna integrifolia* etc. and analyzed for total alkaloidal content.

- Saraswathy, et al. 1993a; Reported physico-chemical parameters of Tirikatu churanam consisting of *Zingiber officinalis, Piper nigrum, and Piper longum*.

- Tiwari, et al. 1993; Standardized Bhringaraja taila containing *Eclipta prostana, Rubia cardifolia, Santalum album, Sida cardifolia, Berberis aristata*.

- Dutta, et al. 1992; Analyzed specific gravity, alcohol content, pH value, total solid content and sugar content in Asavas and Aristas and R.I., Acid value, Iodine value and R.M. value in Ghrita and Taïla.
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- Katiyar, et al. 1992; Discussed standardization Problems, realities and rationale of Ayurvedic drugs.

- Tiwari, et al. 1992; Developed quality control parameters of indigenous pharmaceutical products and technique of preparation of bhasama, asavas, aristas and avaleha has been demonstrated.


- Siddiqui, et al. 1991; Developed physico-chemical data of traditional drug containing harda (Terminalia chebula), balhera (Terminalia belerica) and amla (Emblica officinalis).

- Shastry, et al. 1991; Developed quantitative and qualitative characters of Rasa along with the general parameters like L.O.D. Ash value, water and alcohol soluble extractive etc.


- Saxena and Dholikia, 1990; Identified and developed TLC & PC of Dasmula taila by using suitable solvents and spray reagents.

- Somanathan, et al. 1989; Developed methods for standardization of Dasamulum kasayam for the comparison of market samples with laboratory sample.

- Alam, et al. 1985; Studied standardization of Drakshadi Vati composed of Vitis vinifera (Draksha), Terminalia chebula (Pthya), and Sita (Sugar candy).

- Alam, et. al. 1983; Developed methods for standardization of Dhanvantra Ghrta.
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- Anand Kumar, et al. 1982; Developed methods for standardization and also determined physical and chemical characteristics of Chittiramoola thailam like refractive index, sp. gr., iodine value; acid value, saponification value and unsaponifiable matter.
2.2 Research envisaged

By standardization of the herbal drugs and development of modern dosage form for the herbal bioactive, we can achieve the global acceptance of traditional medicines. Further we will be able to quantify the active ingredients present in the crude drugs, as it is affected by variety of factors either by natural like different climatic conditions or by poor manufacturing and storage conditions. In addition to this we can also develop modern dosage forms like capsule of traditional indigenous formulations which can greatly increase the production rate, quality of packaging material, elegance of design and overall aesthetic appeal.

The present work is an approach to develop standardization parameters for some indigenous formulations and development of their capsule dosage form. These formulations includes two Ayurvedic formulations Balacaturbhadrika churna and Shringyadi churna, one Unani formulation named Safoof-E-Sana and one Siddha formulation called Thirikadu choornam which are official in their respective formularies of India and cited in standard traditional literature. These stated formulations manufactured on large scale and used frequently by the physician of the country. In order to establish the standardization parameters of these above stated formulations following studies have been undertaken.
2.3 Plan of work

- Literature survey for selection of formulations.
- Collection of raw materials.
- Identification of crude drug.
- Standardization of crude drug.
- Preparation of selected formulations according to official books.
- Standardization of formulations.
- Development of fingerprint method of lab and marketed formulation by
  - UV
  - HPLC
  - HPTLC
- Comparison of marketed and prepared formulations.
- Development of modern dosage form (Capsule) and its evaluation
- Compilation and presentation of data.