CHAPTER II. BRIEF RESUME OF THE INTENDED WORK

Scope of the work envisaged

As many as 65 million people, suffer from Vitiligo worldwide. Surprisingly India accommodates 0.46 - 8.8% vitiligo patients against 0.5-1% of the world Vitiligo population. While much emphasis is being given in the developed world, although India bears a soaring vitiligo statistics, no Vitiligo societies or organizations exists in the subcontinent to minimizes social stigma and facilitate public awareness, collaborations in Vitiligo research and services. When one is succumbed to vitiligo, he is not only affected physically but also physiologically and socially.

Conventional treatment of Vitiligo involves corticosteroids and UV radiation. But these has some side effects like Cushing’s syndrome, skin carcinoma etc. A team of scientists at King’s College London have discovered that Piperine the compound that gives black pepper its spicy, pungent flavor and its synthetic derivatives can stimulate pigmentation in the skin. Use of Piperine in Vitiligo not only reduces UV radiation but also avoids side effects. But unless a proper dosage form has not been developed, the piperine as API will not be able to localize in the dermis either by not able to penetrate the tough stratum corneum or entering into the blood stream and gets thwarted. It either does not cross the tough stratum corneum or majority of the drug trespass into the systemic circulation. This reveals the potentialities of developing not only conventional dosage forms for topical piperine formulation, but also novel drug delivery systems can be brought into account. This clearly shows ample scope for developing spectra of formulations and optimizes the dosage form based on tissue drug bioavailability.
Aim and objectives

The main interest of the investigations gathered here was in pursuit of developing a topical dosage form of a suitable antivitiligo agent. In the light of reported works on antivitiligo activity of piperine, this project was aimed to bring a ray of hope to the “down casted” by a dosage form incorporated with the bioactive compound piperine, as the API (active pharmaceutical ingredient) for antivitiligo. The formulation must be able to achieve the drug to penetrate the stratum corneum and get lodged in the dermal layers without further trespassing into the systemic circulation. Thus the tissue bioavailability of the drug in the dermal region must be maximized where the melanocytes proliferency and formation of melanocytic dendrites can be achieved.

1. Objectives of the work in accordance to the aim was to prepare, characterize and evaluate piperine incorporated topical formulations by which tailoring of the drug as near to the melanocytes has to be achieved.

2. The objectives were further alienated into formulation development of preliminary conventional formulations, later novel drug delivery system developments and further extension of nanotechnology products.

3. Formulation development of conventional topical preparations-cream and ointment incorporated with piperine.

4. Formulation development, characterization and evaluation of piperine phytosomes.

5. Formulation development, characterization and evaluation of ultra deformable vesicular drug delivery systems (transfersomes) incorporated with piperine.

6. Formulation development, characterization and evaluation of piperine-liquid crystalline nanoparticles (cubosomes) incorporated into hydrogel.

7. On the other hand, designing, fabrication and validation of analytical instruments like “modified diffusion cell” and “consistency tester”.
Project protocol (flow chart)

Literature review
Collection and authentication of dried fruit of black pepper
Standardization of black pepper
pilot scale extraction

Soxhelation [4.6%] Refluxation [4.2%]
Scale up extraction
Characterization, standardization
Sonication of piperine
Preformulation studies on piperine
fabrication of students diffusion c ell and consistency tester
Product Development of Topical Formulations

Conventional Novel DDS
Ointment Cream Phytosomes Transfersomes Cubosomes

Characterization and evaluation of dosage forms: Drug content, diffusion studies, partition coefficient, XRD, FTIR, SEM/TEM, Confocal microscopy, consistency test, exvivo-permeability
test, Physiochemical stability analysis, tape stripping, entrapment efficiency, In-ovo biocompatible studies, Skin irritation test and pharmacological studies on selected formulations.* = TLC, UV spectral analysis, SEM, microscopy and chemical test; ** = XRD, FTIR; = optimized formulation for pharmacological evaluation.