

The existing therapies as described earlier have many limitations and disadvantages. In the present formulation, attempts have been made to remove most of these disadvantages to a greater extent. This has been done by making the formulation a poly component product in which the plants viz. *Psoralea corylifolia*, *Ammi majus*, *Calotropis gigantea*, *Aloe vera*, *Ocimum basilicum*, *Arnebia benthamii*, petroleum ether extract of *Sesamum indicum*, *Jasmine arborescense*, ash of *Ammi majus* and *Psoralea corylifolia* have been used. The first two plants are the source of the active ingredient 'Furano-coumarins', providing the necessary amino acids for pigmentation, and the adequate amounts of copper, zinc and iron needed for tyrosinase activity and autoimmune modulation. For oral formulation plants viz. *Ocimum basilicum*, *Centella asiatica*, *Ammi majus*, *Psoralea corylifolia*, *Mucuna puriens* and *Aloe vera* along with ash of *Psoralea Corylifolia*; *Ammi majus* and *Mucuna pruriens* have been used. This anti-leucoderma herbal formulation has a two-component ointment and oral dose. The brief information of ointment and oral formulation is as follows:

3.6.1.1 Ointment

In the ointment ingredients, two plants *Psoralea corylifolia* and *Ammi majus*, which are rich in furano-coumarins, have been used as skin photosensitizer for initiation of erythema on the spots of leucoderma by the exposure to UVA radiation. This reaction is a free radical mechanism which creates heat sensation and blister formation. This activity has been subsided by the addition of two plants, *Calotropis gigantea* and *Ocimum basilicum*, ingredients which have anti-blister formation and anti-irritation properties. The fifth plant, *Aloe vera*, has antiseptic properties and checks the hyper pigmentation of skin. The ash of the first two plants is rich in copper, which has been added to make up the deficiency of copper needed for tyrosinase activity. The sixth plant has been added to impart the colour to the ointment and also to synergize the wound-healing activity. The ingredients of seventh plant impart the odor to the ointment and also improve the texture of skin.

3.6.1.2 Oral Dose

To check the emergence of new spots, an oral dose has been formulated, which contains the ingredients of six plants. The first two plants, *Psoralea corylifolia* and *Ammi majus*, have furano-coumarins, as in the case of the ointment. The third plant *Centella asiatica* has CNS-stimulating activity, which also helps in improving the psychological and emotional trauma of the patients. The fourth plant, *Aloe vera*, has properties to remove skin disorder of parasitic origin. Both the third and fourth plants have liver restorative properties which gradually improve the autoimmune system. The oral dose has been augmented with ash of first two plants, which are rich in copper, and ingredients of the fifth plant, *Mucuna puriens*, is rich in dihydroxy-phenylalanine, which makes up the deficiency of copper and DOPA.

3.7 TOXICOLOGICAL STUDIES

The toxicological studies of this herbal formulation have been carried out at Industrial Toxicological Research Centre (ITRC), Lucknow, for acute oral toxicity, subacute oral toxicity, the mucous membrane irritation test, the skin sensitization test etc. and