CHAPTER 8
SUMMARY

The physiochemical analysis of polyherbal formulations reveals the presence of flavonoids, phenolic compounds which could attribute to the medicinal efficacy. Heavy metals are present within the permissible limits and can be preferred to consume by mankind for various medicinal purpose. All the quality control parameters are within the limits according to the Indian Pharmacopeia for the regulatory purposes. The quality control study is likely to help the QA of polyherbal formulations in Ayurveda and in development of standard parameters. For the modernization of herbal medicine, study of the pharmacokinetics was an important aspect. The bio analytical methods were developed for the quantification of the bio-active components present in the polyherbal formulations and in the plasma sample, were highly sensitive and selective. The high recovery and precision values indicate that, the developed methods were accurate for the extraction of Mangiferin, Quercetin and Rutin from the plasma.

Pharmacokinetic results showed that Mangiferin was rapidly absorbed in to the portal vein after oral administration of Mangiferin alone with greater rate of absorption constant and higher volume of distribution. When it was administered in the form of formulation, there was an increase in AUC, which indicated that higher amount of the Mangiferin was absorbed from the formulation. Also tissue distribution studies showed that, Mangiferin could be rapidly and widely distributed into tissues and unable to cross the blood brain barrier in rats.

The bioavailability of Quercetin was lowered from the polyherbal formulation when compared with the co-administration, whereas the Rutin bioavailability was increased from the polyherbal formulation when compared with the co-administration. Therefore, it may be concluded that, the oral dose of mixed compounds in herb extracts could gain a significant biopharmaceutical advantage, when compared to the single compound. Consequently inter and intra herb interaction of the Quercetin and Rutin was elucidated.
The relative bioavailability of Mangiferin was investigated at a particular dose. It was found that, Mangiferin from the formulation was slowly absorbed into the blood after oral administration when compared with intraperitoneal administration at a dose of 30mg/kg equivalent weight of formulation. It was observed that, the relative bioavailability was only 41.5% of administered amount. While other parameters like $T_{\text{max}}$ was about 0.5hrs for i.p route whereas 3.0hrs for oral administration. It explains that Mangiferin is having better absorption at the gastrointestinal site from this formulation when it was administered orally.

Also an effective pharmacokinetic (PK) and pharmacodynamic (PD) model was established to determine the relationship between drug concentration and efficacy. PK-PD correlation allows understanding of the meaning of blood toxicant concentration and thus improve its clinical use. PD of diabetic formulation was investigated by streptozotocin (STZ) induced experimental diabetes. There is a correlation between plasma concentration of Mangiferin concentrations and effects of plasma containing Mangiferin of this polyherbal formulation, which means that Mangiferin plays an important role in antidiabetic effects of this polyherbal formulation. The investigation of dose-effect relationships has displayed a feasible method to clarify mechanisms of combination for this patented polyherbal formulation.

An open label and single dose pharmacokinetic study of Mangiferin present in the polyherbal formulation was carried out. Clinical pharmacokinetics of Mangiferin from the polyherbal formulation reveals that effective pharmaceutical dosage forms are required to enhance the bioavailability of the bio-active components from the polyherbal formulations.