8. SUMMARY

The study was divided into four schedules

I. Schedule:

Simple, specific and sensitive Bio-analytical method was developed in human plasma for the \textit{In vivo} estimation of allopathic anti-diabetic formulation GLB and GLM. The developed method was validated as per USFDA guidelines and \textit{in vivo} pharmacokinetic study was carried out by using the developed method.

II. Schedule:

Diabetic patients were screened and divided into three groups based on their case history. Allopathic (GLB and GLM) and poly-herbal (Mehagni) anti-diabetic formulation administered in individual Groups: GLB (Group A), poly-herbal (Mehagni) formulation (Group B) & GLM (Group C) as mentioned in the methodology. The baseline anthropometric and metabolic parameter were measured. The Group B diabetic patients show an anti-diabetic activity by decreasing blood glucose and lipid levels significantly.

III. Schedule:

Based on individual group study report, Group A and C patients were further subdivided into two groups respectively; Group A1 with the continuation of GLB therapy and Group A2 (GLB + Mehagni) receives combined therapy. Similarly in group C1 with the continuation of GLM therapy and Group C2 (GLM + Mehagni) receives combined therapy. The 3 months recorded data of blood glucose and lipid level in diabetic patients from Group A1 was compared with Group A2. Similarly Group C1 was compared with Group C2 and a significant decrease in blood glucose and lipid level was noted. The study showed that combining allopathic drug and poly-herbal formulation provides a better control over the blood glucose and lipid levels.

IV. Schedule:

90th day pharmacokinetic study was performed for Group A1, A2, C1 and C2 patients at 0, 0.5, 1, 2, 3, 4, 6, 8 and 12h. The results showed that poly-herbal formulation influenced the pharmacokinetic parameters of GLB and GLM in diabetic patients when co-administered. This could be useful for the diabetic patients with GLB and GLM therapy to obtain a better control over diabetic complications and might serve as an alternative medication for T2DM patients.