Limitless are the scriptures; since, short is the life and obstacles are numerous; therefore what is the best should be performed, just as the swan extracts milk mixed with water.

-Panchatantra.
CHAPTER V - Discussion and Conclusion

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DISCUSSION

At present, approximately 64% of total world population is almost dependent on traditional therapies for their health care, a fact that has been substantiated by the WHO recommendation to include traditional medicines in the primary health-care. It is well known that the prevalence of type 2 Diabetes Mellitus (DM) is rising globally but its impact is most marked in developing countries like India. India there is increasing urbanization and industrialization, which has led to physical inactivity, sedentary lifestyle, psychosocial stress and obesity leading to progressive increase in prevalence of DM. The features of Diabetes exhibit the characteristics like Prameha, especially Madhumeha. The use of many indigenous drugs has been described in classics and in practice for the treatment of Diabetes. In spite of that there is a need of more effective remedy, which can cure or control the disease promptly. In the country like India, many people are below the poverty line and they cannot afford the expensive treatment for diabetes. In such a condition there is need of a drug that will be effective, cost effective, abundantly and easily available to a common person. Kakamachi is also quoted as Mehajit and so consider as action on different factors of diabetes. Kakamachi is available abundantly, cheap and easily approachable to a common being. Hence the selection of Kakamachi was undertaken for the study entitled “Study of the Antidiabetic effect of whole plant of Kakamachi (Solanum nigrum Linn.)”. The present study was designed according to GCP Guidelines to screen the antidiabetic effect of Kakamachi with the following aims:

➢ To assess the clinical efficacy of Kakamachi in Diabetes Mellitus (NIDDM-Type-2).
➢ To specify the mode of action of Kakamachi in Prameha and Diabetes mellitus (NIDDM-Type-2).
➢ To assess the adverse effect of the drug if any in Kakamachi.

Plan of Study:

The entire study was conducted in following stages:

➢ Collection of authentic sample and standardization of Solanum nigrum as per API guidelines.
Preparation of Churna as per GMP norms
A controlled, randomized parallel single blind clinical trial.

The study was designed to validate the antidiabetic effect of Kakamachi in 90 cases of NIDDM (Type II).

After through review of literature on Kakamachi, review of Diabetes Mellitus (NIDDM Type II) as well as concepts of Prameha was taken. The sample of Kakamachi was collected from non contaminated area in Hyderabad in the month of November at its full maturity period. The drug was standardized according to API as well as WHO norms. The Controlled Randomized Parallel Single Blind Clinical Trial was conducted as per GCP guidelines on the subjects of Diabetes Mellitus Type II in the age group of 25-60 years to screen the antidiabetic effect. Statistical analysis was done by applying the ANOVA and Student’s t test to the observations and results of the study. The observations and results generated in every stage during the entire study are discussed in detail hereafter.

Discussion of Literature Review:

Exclusive review right from the Vedic period to till date was taken. The review shows that the description of Kakamachi found is found first time in Vedic literature of Koushikasutra. This is the plant amongst the few plants which are used widely for purposes like Shaka Dravya and Oushadha Dravya. In Samhita Granthas and later texts Kakamachi was incorporated under the category of Viruddha Anna. This is because it has incompatibility when it is used with milk, Guda, Mareecha and Pippali. Considering this aspect the precaution was taken while administering it to the subjects in clinical trial of the present study. In Bhavaprakasha Nighantu its use as Mehajeeta is mentioned. Other Nighantu also mentioned its Pramehaghna property. Kakamachi also used extensively for Kushtha, Shwash, Kasa and as Rasayana Dravya. It has also been observed through review that Kakamachi is also screened for its various activities such as Hepato-protective, Anti-pyretic, Anti-Inflammatory, Antibacterial, Anti-hypertensive, Anti-fungal, etc. these review indicate that the drug possesses broad spectrum of actions which attracted researchers to work upon it.

The detail review of Prameha and Diabetes Mellitus including its aetio-pathogenesis, diagnosis, symptomatology from Ayurveda and Modern literature has also
been taken. In the present study the attempt has been made to correlates find out between two diseases i.e. Prameha with Diabetes Mellitus. Review Diabetes Mellitus is considered as one of the type of Prameha. However antidiabetic action of any drug can not be just correlated with Pramehaghna action. The Pramehaghna action is a broad spectrum and provides the scope for further research.

**Discussion on Standardization and Safety Study:**

In the present study standardization of Kakamachi was done by Ayurvedic guidelines given in Charaka (Ch. Vi. 8/87). Likewise the interpretation of synonyms and homonyms explained in Nighantus was done for authentication for correct species to be used as Kakamachi. Based upon synonyms it was confirmed that *Solanum nigrum* is to be selected as Kakamachi. However *Solanum nigrum* was selected for standardization. The botanical identity and microscopic section was also carried out which resembles with the standard description in Pharmacopoeia.

It was also standardized by comprehensive guidelines given by WHO and Ayurvedic Pharmacopoeia. Some new methods for standardization were developed for Kakamachi with the help of phytochemical studies including HPLC, HPTLC, Herboprint™ with PDA detector and Fluorescence Study. Some of these studies are first of its kind which would be helpful in future as fingerprints for standardization of Kakamachi, which may be in term consider as novel parameters.

Study confirms that the drug taken for the study followed the standard parameters, decided by the Ayurvedic Pharmacopoeial committee of India. The Physiochemical standards like ash value, alcohol soluble extracts, water soluble extracts etc, were also with the limits of the values mentioned in Pharmacopoeia. The HPTLC analysis exhibits that all the samples have one common peak observed at the range of 772.9 to 865.7 heights. It is observed that this is the major compound present in all the vegetative parts of Kakamachi and could be considered as the marker. This needs further isolation and characterization. The qualitative study shows the presence of Saponins, Tannins and Alkaloids in Kakamachi.

The fingerprinting study was carried out using Herboprint™ method with HPLC-PDA detector. The study indicated Kashaya, Tikta and Madhura Rasa along with Tridosahara, Pittakaphahara and Vatahara property. With this technique the dose
comparison study was also performed and it was observed that the drug had Pittakaphahara and Vatahara action. The report obtained by the technology is correlating maximum with the references of Kakamachi mentioned in the traditional texts. The variation of the other parameter may be due to ecological and geological factors. These finding also correlated with finding of the clinical trial in the present study. This shows that Herboprint™ study with the help of HPLC-PDA detector may be a useful technique in future to validate the Ayurvedic action of a drug.

The heavy metals analysis of Kakamachi was carried out for Cadmium, Lead, Arsenic, etc., shows that the drug is free from the abnormal levels of heavy metals. Hence it is considered as safe to administer in the human beings.

To ensure the safety of the drug, acute and sub-acute toxicity study was carried out on Swiss Albino Rats. It showed that the LD₅₀ of Kakamachi is 1525 mg/kg and there was no general gross behavioral change in the animals during the course of the study. The sub-acute study provided that during the course of treatment the animals did not exhibit any mortality and no significant change in the organ weight or in the biochemical parameters. The overall observations of standardization and safety studies show that the drug Kakamachi used in clinical trial is of good quality and safe for administration in human beings.

Preparation of Trial drug:

The whole plant was used for clinical trial. Individual doses form in the classics is not mentioned clearly. Churna is indicated in Prameha. Hence, Churna of Kakamachi was selected as a doses form and it was also standardized. Kakamachi was dried under shade and the whole raw material were subjected to powder by pulverizer through mesh no. 85 and fine powered was obtained. The same drug was used for clinical trial. The drug of Sulphonylurea group were advised from the standard commercial brand of good quality with due recommendation of an expert as control drug to compare the result.

Discussion on Clinical Trial:

To validate the antidiabetic effect in Type II Diabetes Mellitus a controlled randomized parallel single blind clinical trial was conducted on 109 patients of Diabetes Mellitus (NIDDM Type II). The clinical trial protocol was designed as per Good Clinical Practice (GCP) guidelines. The detailed report of literature, standardization and chemical
analysis were put before the Institutional Ethical committee (IEC). The No Objection Certificate (NOC) was taken from the Institutional Ethical Committee (IEC) of Tilak Ayurveda Mahavidyalaya, Pune and Indian Institute of Chemical Technology (CSIR), Hyderabad. All of the patients were given the complete information about the clinical trial and after collecting Informed Consent Form (ICF), the patients were recruited for the study. This shows that the study was conducted in accordance with to accepted ethical guidelines of Biomedical Research.

The Case Record Form (CRF) was prepared incorporating thorough physical examination. An objective and subjective parameters were also incorporated in the CRF. Since no specific guidelines are given to assess the symptoms of Prameha, a Grading Analog Scale (GAS) was prepared, in which gradation was given according to severity of each symptom (0-3). This GAS is the first of its kind which would be useful to assess the severity of the symptom as well as the efficacy of the drug. Since this scale was prepared with the consultation of experts, it is hopped that this would be useful for further research.

Only confirmed cases of NIDDM and symptoms of Prameha were recruited in the study. The patients were divided in three groups by Random sampling Method.

- Group A: Kakamachi powder
- Group B: Sulphonylurea group medicines.
- Group C: Kakamachi along with Sulphonylurea drug in combination

Since the use of the placebo is not ethical, the control drug like Sulphonylurea was selected. The combination group was designed to know the compatibility of the drug with modern medicine along with efficacy.

The dose was decided by dose variation study which was 3 gm two times a day with water before meal. Prameha is due to vitiation of Apanavayu and Vyanvayu and has Roga Adhishthana in Basti. In such condition the time of administration of the drug must be Pragbhakta i.e. before meal. Hence the drug was administered before both the meals.

The doses of Sulphonylurea and combination group were also before meal as decided by the experts.

The duration of treatment in all the groups was 12 weeks and follow-up was taken for another 4-week. This trial duration period was decided which was analogous with the
standard of New Millennium Indian Technology Leadership Initiation (NMITLI) project of Government of India.

The screening of the patients was carried out in following manner:

Initially 0 day screening was done based upon CRF which incorporated the signs and symptoms of Prameha and Diabetes Mellitus along with objective parameters. For the assessment of Subjective parameters GAS was used. The objective parameters included efficacy parameters like Blood Glucose Level, Glycosylated Hb and Glucose Tolerance Test. The Human safety parameters like Liver function, Renal Function Test and Lipid profile were also investigated. Overall, all these parameters fulfilled complete ethics of safety and efficacy assessment in the clinical trial. The diet and restrictions was kept same to achieve an un-biased data and to assess the exact mode of action of a drug in unique format.

The Blood Glucose level was considered as the acceptance, rejection and withdrawal parameters for continuation and discontinuation of the therapy. The Fasting blood glucose level >130 mg/dl and post load glucose level >224 mg/dl with successive investigations were considered as non-responding parameters. The patient who didn’t follow the advice of the investigators and unable to perform the investigations for assessment was considered as dropped out. In case of hyperglycemia or hypoglycemia, all the possible therapy including insulin therapy was considered as a rescue medicine. This step was taken to follow the ethical guidelines into consideration. However, there was no need of rescue medicine in the trial period. This suggests that the drug was safe to administer. To know the adverse drug reaction of Kakamachi an ADR protocol was prepared incorporating mild, moderate and severe reactions. There was no such reactions observed in the trial period.

The data obtained in the trial was analyzed by various statistical methods. All the methods were internationally accepted and regularly used in the Biomedical clinical Research. For that, standard software named “MINITAB” was used to calculate the statistical values. The subjects were classified by the scoring pattern as well as percentage reduction method under improved, marked improved, moderate improved, mild improved and no improved category. This was done to specify the exact action of drug on the
disease. The inference obtained by statistical analysis suggests that this software can be used in Ayurvedic clinical trial for accurate and fast results.

**Observations:**

In the present study maximum number of patients belonged to the age group 49 to 60 yrs. This particular age period comes under the Proudha Avastha of life. In this age group there is natural aggravation of Vata which hinders the normal digestion / metabolism. These findings are concordant to the recent published survey data (Shera A.S, Jawad F et al), which shows that the onset of type II diabetes mellitus is in the forties.

**Majority of the patients in the present study 62.38% were male and 37.61% patients were females.** These findings also co-relate with the survey data for diabetes (Basavanagovadappa H, Prabhakara AK et al).

In the present study, the majority of patients had education up to graduation, while the higher secondary educated patients were less. The Primary educated and postgraduates were also very less. No specific co-relation could be established with respect to the disease and education.

In the present study the maximum patients were of household occupation. This finding supports with the Ayurvedic texts which highlights that comparative sedentary lifestyle leads to conditions like Prameha and also contributing factor in Type 2 diabetes in Modern Medicine.

In this study, maximum subjects belonged from urban area. The finding supports to the recent WHO's Annual Report (2000), that the prevalence of Diabetes Mellitus is twice in the urban than in rural.

In the present study, maximum subjects were suffered to diabetes from last 3 to 7 year. It indicated that the patients diverted towards Complimentary and Alternative Medical (CAM) therapy after using modern medicine.

In the present study maximum numbers of patients i.e. 74.31% were having positive family history. This data shows that Type 2 Diabetes Mellitus has a strong genetic component. Charaka also described the prognosis of the Madhumeha, where he has explained that Kulaja Vikara is resulted due to defect in the Beija. Chakrapani too, opines that it may be inherited from father, mother or grand parents. It means that the
disease is inherited from generation to generation (Hirofumi Shegeta, Masako Shigeta et al.).

In the present study, maximum patients were found to be habitual to tea and coffee. The tea, which contains milk and sugar, might account for Madhumeha. Tea is also aggravating factor for Vata and may hamper the Agni leading to metabolic disturbances.

In the present study, total 109 patients were recruited in three groups out of which 45 in Group A, 32 in B and C each. The responded cases were further divided equally in two categories by continuing and dis-continuing the same trial drug. This was done to understand the long-term effect of the drug and reappearance of rise in Blood Sugar level. It had given the nature of drug action after withdrawal. In Group A, 56% patients were not responded and only 44% had responded well to the drug. In Group B also the dropped cases were due to unwillingness to perform the investigations, in which 21.73% patients did not responded and 78.26% patient had responded well to the drug. In Group C, 31.81% patients did not respond and 68.18% had responded well to the drug. In all the groups the dropped out cases were due to unwillingness to perform GTT due to its time consuming method.

ASSESSMENT OF SUBJECTIVE PARAMETERS-

Highly Significant Relief: (p<0.001)

Kakamachi had shown highly significant results in subjective parameters like Prabhoota Mutrata, Mukhatalu Shosha, Karapadatala Daha, Pipasa. The only objective parameters Post prandial BSL showed highly significant result with Kakamachi.

The results were positive step towards curing the disease. The results give support to the textual reference of Gayadasa about Prameha, where he opines that, excess urine quantity is because of liquification of the Dushyas and their amalgamation. Vagbhata too explained that, Prameha is Mutraatipavruttiya Vikara and the excessive urination helps in the elimination of excessive accumulation of Ama. Prabhuta Mutrata is also related with Kleda as it has seen in Mutrasya Kledavahanam. So the Kakamachi proves to be considered as Pramehaghna according to the text due to its Kledanashana and Amapachana action in the present study.
Highly significant result in Mukha-Talu Shosha and Pipasa indicated that the drug is acting on the Rasavaha and Udakavaha Srotasa. Mukha-Talu-Kantha-Shosha is due to Rukshaguna of Vata and also due to loss of coldness and unctuousness caused by Udakakshaya.

Kara-Padatal Daha is due to Ashayapkarsha Gati of Pitta. Karapadatal Daha is due to the loss of Ambu, which is Sheeta in nature and required for Preenanam. Failing to this mechanism leads to Daha. Kakamachi was mentioned to be Tridoshaghna in nature and Rasayana but mainly as Pittaghna. These properties might have contributed to improve the parameter. The highly significant relief in Post prandial BSL indicates that the drug can act on metabolic improvement. This is also a supporting to the Ayurvedic textual concept of Tikta Katu Rasa, Ushna Veerya and Katu Vipaka of the drug.

In comparison with Kakamachi, Sulphonylurea drug didn't show the positive result in the above mentioned subjective parameters. This may be due to the targeted action of the compound. Sulphonylurea had given highly significant relief in Post Prandial BSL. It is a proof for the targeted action.

The combination group showed highly significant relief in Prabhoota Mutrata, Shrama, Mukhatalu Shosha, and Karapadatala Daha. The objective parameter like Post Prandial BSL. It indicates that the combination group was influenced by Kakamachi with special reference to subjective parameters.

**Significant Relief:**

Kakamachi had given significant relief in Shrama, and Pindikodwestana along with the objective parameters like S. Creatinine and Glucose tolerance test.

Relief in Shrama and Pindikodwestana parameter might be due Tridoshaghna nature and Rasayana properties of Kakamachi, which helped to form Dhatusamya in the body. It can be attributed the relief was due to improvement at microcirculation and antioxidative property of the drug. The significant relief in S. Creatinine shows improvement in glomerular function of Kidney. This result also supports to the textual reference where Kakamachi was indicated for Shotha and Meha. In both the condition the pathology is related with Kidney functions. The improvement in GTT indicates the metabolic improvement. This can be correlated with stimulation of Agni and Dhatvagni due to Kakamachi according to Ayurveda.
In relation with Sulphonylurea group significant decrease in results observed in S. creatinine, and Glucose tolerance test. The drug also shows positive result due to its specified action of *Solanum nigrum*.

The combination group shows significant relief in Avila Miutrata and Pindikodwestana of subjective parameters and S. Creatinine in objective parameters. In this group the relief in subjective parameters is more influenced by Kakamachi. This is considering as synergistic action and compatibility of the drug.

**Non Significant Result:**

Kakamachi could lower the values in Karapadatala Suptata, Atinidra, Swaduasyam along with the objective parameters like Fasting BSL, Glycosylated Hb, Lipid Profile, BUN and Liver function test after administration. However, their reduction was not statistically significant. In one of the studies carried out on mice, for detection of action of glycoprotein isolated from *Solanum nigrum* on plasma lipoprotein. It revealed that it reduces the plasma lipoproteins significantly. In the clinical trial of Kakamachi instead of isolated compound, the drug as a whole was taken for assessment. It can be said that either the dose has to be increased for significant result or dosage form like Ghana etc. has to modify or duration is to be increased. This will required major project on a larger sample size.

The Sulphonylurea group has no significant relief in almost all subjective parameters as well as in objective parameters like Lipid profile, Glycosylated Hb. Liver function test. However it lowers significantly BSL. The action of Sulphonylurea on lipid is still controversial, where as the drug was contraindicated in hepatic insufficiency. This may be the reason for getting the non-significant relief.

The combination group also showed non significant relief in Swadu asyam, Tandra, Atinidra and Karapadatala Suptata. The objective parameters like Fasting BSL, Glycosylated Hb, Lipid profile, Liver function etc had non significant relief. This may be due to drug interaction.

**Increase parameters:**

Kakamachi had shown rise in the parameter like Kesh- Nakha Vriddhi with the rise in S. Triglycerides and VLDL.
Kesh- Nakha Vriddhi is due to involvement of Meda a precursor Dhatu of Asthi and Majja. The no significant relief in lipid profile indicates that Kakamachi didn’t have action on Meda Dhatu. Hence the drug is not a better choice for hyperlipidimic cases.

The Sulphonylurea group had shown rise in the parameters like Shrama, Karapada Daha, Karapada Suptata, Dehe Schikkanata, Atinidra and Pindikodwestana. The objective parameters like BUN, Total Cholesterol, LDL, Triglycerides, VLDL were increased. This indicates that even though the BSL was controlled but the patient didn’t get relief in the symptoms.

In the subjective parameter no subjective parameter was increased except Kshudhadhikya. The objective parameters like BUN, Cholesterol, LDL, Triglycerides and VLDL were increased. This combination was also fails to restrict the lipid levels. This may be due to both Kakamachi and Sulphonylurea drug, to which themselves are not able to control the parameter individually. The rise in BUN was observed but it was under normal limit. It requires still more study in large sample and longer duration.

**Overall effect of the therapy**-

In Kakamachi Group the non responding cases were more (56%) as compare to Sulphonylurea group (21.73%). In the combination group there was 31.82% non response. In Kakamachi Group only 44 % patients were responded. However, in this group it gave complete relief. It shows that Kakamachi has individual specific action on Kaphavata dominant conditions. The overall inference can be drawn as follows:

The overall result of assessment of BSL and Grading Analog Scale Kakamachi gave mild to moderate improvement. The BSL was comparatively less improved than other two groups, but had shown better results in improving the symptoms of Prameha and diabetes. Sulphonylurea group has far better result in controlling the BSL than the symptomatic parameters. The combination group gave relief in both BSL as well as symptomatic parameters. The Overall inference can be stated that:

- Kakamachi gives better relief in early diagnosed, non complicated and less severe Diabetes Mellitus. The therapeutic application of Kakamachi can be done in the patient who has aggravated symptoms but less BSL.
- The use of Sulphonylurea group drug can be applicable in chronic as well as complicated cases of Diabetes mellitus.
The combination group drugs are suitable for the moderate condition where it is necessary to monitor both the BSL as well as symptomatic relief.

**PROBABLE MODE OF ACTION OF KAKAMACHI**

Kakamachi shows Relief in Prabhoota Mutrata, Avila Mutarta, Pipasa, etc symptoms. The action of Kakamachi is due to Rasa, Guna, Veerya, vipaka it possesses. In the present study its mechanism of action can be summarized as follows.

<table>
<thead>
<tr>
<th>Action of Kakamachi</th>
<th>Causative factor</th>
<th>Resulted action or Site of action</th>
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<tr>
<td>1. Kapha Dosha</td>
<td>Tikta Katu Rasa</td>
<td>Kaphanashana</td>
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<tr>
<td></td>
<td>Ushna Veerya</td>
<td>Tridoshaghna</td>
</tr>
<tr>
<td>2. Pitta Dosha</td>
<td>Tikta Rasa</td>
<td>Pittanashana</td>
</tr>
<tr>
<td></td>
<td>Ushna Veerya</td>
<td>Effect</td>
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<tr>
<td>3. Vata Dosha</td>
<td>Ushna Veerya</td>
<td>Vatanashana</td>
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<td>4. Bahu Abaddha Kapha</td>
<td>Katu Rasa, Ushna Veerya</td>
<td>Kledahara, Amahara</td>
</tr>
<tr>
<td>5. Ama</td>
<td>Tikta Rasa</td>
<td>Amapachana</td>
</tr>
<tr>
<td>6. Prabhoota Mutrata</td>
<td>Tikata Rasa</td>
<td>Mutravaha Srotasa</td>
</tr>
<tr>
<td></td>
<td>Amapachana</td>
<td></td>
</tr>
<tr>
<td>7. Avila Mutrata</td>
<td>Tikta Rasa, Ushna Veerya</td>
<td>Mutravaha Srotasa</td>
</tr>
<tr>
<td>8. Shrama</td>
<td>Amapachana, Rasayana</td>
<td>Rasavaha Srotasa</td>
</tr>
<tr>
<td>9. Mukha Talu Shosha</td>
<td>Tikta Rasa, Amapachana</td>
<td>Udakavaha Srotasa</td>
</tr>
<tr>
<td>10. Karapadatala Daha</td>
<td>Tikta Rasa, Rasayana</td>
<td>Udakavaha &amp; Rasavaha Srotasa</td>
</tr>
<tr>
<td>11. Karapadatala Suptata</td>
<td>Tikta Katu Rasa, Ushna Veerya</td>
<td>Raktavaha Srotasa</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Pindikodwestana</td>
<td>Amapachana, Rasayana</td>
<td>Mamsavaha Srotasa</td>
</tr>
<tr>
<td>13. Improve in quality life</td>
<td>Rasayana</td>
<td>Sarva Shreera</td>
</tr>
</tbody>
</table>

In the present study the relief supports indication the classical references of Kakamachi. Thus overall study suggests Kakamachi and its combination with Sulphonylurea helps in lowering the symptoms of Prameha.

Sulphonylureas cause hypoglycemia by stimulating insulin release from pancreatic cells. The exact action on organ is not yet been cleared. To understand and compare the specific action of Kakamachi with Sulphonylurea Pharmacokinetic study on animal is necessary.

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CONCLUSION

- Kakamachi is non controversial easy available and cheaper drug.
- Standardization of Solanum nigrum suggests that it is of good quality
- The standard monogram prepared concludes that these could be useful for future standard.
- The safety study concluded that the drug used for clinical study was safe for human beings.
- The grading Analog Scale prepared infers that it could be used to assess the severity of the symptoms and effect of the drug.
- Kakamachi gives better relief in early diagnosed, non complicated and less severe Diabetes Mellitus. The therapeutic application of Kakamachi can be done in the patient who has aggravated symptoms but less BSL.
- The use of Sulphonylurea group drug can be applicable in chronic as well as complicated cases of Diabetes mellitus.
- The combination group drugs are suitable for the moderate condition where it is necessary to monitor both the BSL as well as symptomatic relief.
- Nither Kakamachi nor Sulphonylurea Group is useful in lowering the lipid levels in hyperlipidemia.
- Assessment of Human safety parameters can be concluded as Kakamachi or Sulphonylurea Group drug or Combination Group are safe for long term administration up to 3 months.
cope for Future study:

➢ The present study can be conducted further to assess the specific action of Kakamachi only in newly diagnosed (Less than one year) and less complicated cases.

➢ The antidiabetic effect of Kakamachi can be confirmed on various diabetic animal models to know the exact mode of drug action.

➢ The Prameha assessment scale GAS is unique scale designed for the first time has proved to be effective in rating the severity of the symptoms. It is also used to decide appropriate mode of treatment for the patients. However its use for the screening and diagnosing purpose has to be still evaluated in a large sample group.

➢ The study with different doses and modified doses form is necessary to screen for confirming the antidiabetic action with respect to lower of BSL.