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Pharmaceutical and Analytical Study of *Tryushanadya Lauha* & Modified Form as *Tryushanadya Mandura* and their Comparative Evaluation for Antidiabetic Activity in Wistar Rats

Harlin Swer [a], Anita Wanjari [a*], Bharat Rathi [a], Mujahid khan [a], Makarand Sonare [a], Shweta Kamble [a] and Devyani Awari [b]

[a] Department of Rasashastra and B.K, Mahatma Gandhi Ayurved College Hospital Research Centre, Salod (H), Wardha. Datta Meghe Institute of Medical Sciences, Wardha, India.
[b] Department of Pharmacology, Datta Meghe college of Pharmacy, Datta Meghe Institute of Medical Sciences, Wardha, India.

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Background: *Loha*is a metal that is used in many preparations after transforming it into non-metallic form by purification and incineration method uses to treat different kinds of diseases. Mandura is the rusting of iron.*Tryushanadyalauha(TL)* is one among the *Ayurvedic*herbo-mineral formulations described in BhaishajyaRatnavalliand as modified dosage form as Tryushanadyamandura(TM).The herbal contents are *tryushana (i.epippali(Piper longum* Linn),*maricha (Piper nigrum Linn)and shunti (Zingiber Officinale* Roscoe)*, cavya (Piper chaba*Hunter)*, bakuchi (Psoralea Corylifolia*Linn)*,bhang (cannabis sativum* Linn),and*lavana* like *saindhava*,*aubhida,vida* and *sauvarchala* ,and*lohabhasma* is the main ingredient.
Aim: Pharmaceutical and Analytical study of *TryushanadyaLauha*& modified form as *TryushanadyaMandura* and comparative evaluation for antidiabetic activity in Wistar rats.
Materials and Methods: All herbal drugs will be collected, verified, and primarily authenticated by the Department of *Dravyaguna*. *Loha*and *Mandura* will be procured from the vendor and

**Corresponding author: E-mail: wanjarias@rediffmail.com, anita.wanjari@dmimsu.edu.in;*

authenticated by the Department of Rasashastra and BhaishajyaKalpana, Mahatma Gandhi Ayurved College Hospital Research Centre, Salod(H), Wardha, and they will be prepared as per reference. Organoleptic, *bhasmapariksha*, Physico-chemical,XRD and FEG-SEM parameters will be evaluated. To assess *Tryushanadya Lauha* (TL) and *Tryushanadya Mandura* (TM)antidiabetic action will be conducted in 30 Wistar rats in 5 groups and will be compared.

Observation and Results: The study will be assessed *Tryushanadya lauha* (TL) and *TryushanadyaMandura (TM)*antidiabetic action in 30 Wistar rats by using one-way ANOVA.

Conclusion: Pharmaceutical and Analytical study of *TryushanadyaLauha (TL)* & modified form as *TryushanadyaMandura (TM)* will provide the standard parameters.

Keywords: Tryushanadyalauha; Tryushanadya Mandura; organoleptic; XRD; antidiabetic; wistar rats.

1. INTRODUCTION

Ayurveda is one of the oldest systems of medicine that contain different classical text where different variety of formulations explains different diseases. Whatever was mentioned in *the Ayurvedic* classical texts are authentic and had undergone a lot of *tests* by *Acharya* and came to conclusion [1].

As Rasashastra and BhaishajyaKalpana is one of the branches of Ayurveda that deal with the preparation of herbo-mineral, metal, etc. where they will be processed in such a way where it will be fit for consumption and give action at proper dose without any harm to the body which is readily absorbed and assimilated.

According to the world health organization, Diabetes is a chronic, metabolic disease characterized by elevated levels of blood glucose, which lead over time to serious damage to the eyes, kidneys, heart, nerves, and blood vessels [2].

TryushanadyaLauha (TL) is one of the *Ayurvedic*herbo-mineral formulations described in BhaishajyaRatnavali.The herbal contents are *Tryushanai.epippali (Piper longum* Linn),*Maricha (Piper nigrum Linn)and Sunti (Zingiber Officinale* Roscoe*), cavya (Piper chaba*Hunter*), Bakuchi (Psoralea Corylifolia*Linn*), Bhang (cannabis sativum* Linn), and *Lavana* like *Saindhava*, *Audbhida, Vida, Sauvarchala ,*and*Lohabhasma* is the main ingredient. TL is indicated in *sthaulya* (obesity) *prameha* (diabetes),*kustha* (skin disorder), and many others diseases. It acts as *Rasayana*(immunomodulator) [3].

*Loha*is a metal that is used in many preparations after transforming it into a non-metallic form by purification and incineration method. It will be in *bhasma* form and non-toxic which helps to cure many diseases. As *Lohabhasma* is one of the ingredients which is having properties like *lekhana*(scraping), *balya*(improves the physical strength)*,vrushya*(aphrodisiac), *varnya*(good complexion), and *medhya*(promote intellectual) etc. It cures *kaphapitta* diseases, *medo*, and *prameharoga*(correlated to obesity, metabolic syndrome, and diabetes mellitus) and is also useful in many diseases. *Mandura*is the rust of iron that forms by the reaction of iron and oxygen in the presence of water or air moisture. It has synonyms like *Kitta, Lohabhava*,*Lohakitta*, *Lohamala,* and *Lohacchista* [4].

Diabetes is a chronic and incurable disease. Hyperglycaemia is one of the diabetic symptoms, which in turn damages many of the body system leading to complications that further exacerbate the condition and affects the quality of life. In Adults, there is an increasing worldwide incidence of diabetes mellitus which constitutes a global public health burden [5].

According to WHO, worldwide 422 million people have diabetes, and 1.6 million deaths are directly attributed to diabetes each year [6].

In *Ayurvedic* classic diabetes can be correlated with *Prameha* later stage is *Madhumeha*. It is one of the critical diseases that can be treated in the early stage and by following the *guided regimen of food and code of conduct*. To contribute a safe and effective antidiabetic *Ayurvedic* formulation,TL is taken as it is a herbo-mineral formulation which is indicated in *Prameha .*

Mandura is derived from *Loha*. The previous study of *Lohabhasma* and *Mandurabhasma* on haematinic evaluation indicates the significant effect of *Mandurabhasma* than *Lohabhasma* on hemoglobin level*. Mandurabhasma* had better haematinic property as compared to *Lohabhasma* [7,8]. The process of preparation of *Lohabhasma* consumes a lot of time when

compared to the preparation of *Mandurabhasma* [9]. The pharmaceutical preparation of *Lohabhasma*is a tedious process involving many steps in the conversion of *Lohabhasma* from *Loha*. It is very costly and time-consuming also.*Lohabhasma* causes constipation, while in *Mandurabhasma* it is not observed [10]. The properties which *Manda Lohabhasma* have the same properties will be there in *Manda Mandura* in minute form, so to treat the disease *Mandura bhasma* can be used [11]. From all the above studies*, Lohabhasma and Mandurabhasma* were compared to assess different therapeutic potentials and indicate better therapeutic efficacy of *Mandurabhasma*.Considering this TL will be prepared by adding *Mandurabhasma* instead of *Loha bhasma*.If *TryushanadyaMandura*(TM) is having the same or better efficacy as compared to TL, a cost-effective, less time-consuming but efficacious product can be used in clinical studies.

1.1 Aim

Pharmaceutical-Analytical study of *TryushanadyaLauha* and modified form as *TryushanadyaMandura* and their comparative evaluation for antidiabetes activities in Wistar rats.

1.2 Objectives

1. To prepare TL*.*
2. To prepare TM.
3. To Analyse and compare TL&TM on different parameters.
4. To evaluation of TL&TM for anti-diabetic study.
5. To Compare and assess TL&TM for anti-diabetic study.

1.3 Hypothesis

a. Null hypothesis [H_0]:
TM *and* TL do not have any antidiabetic action.

b. Alternate hypothesis [H_1]:
BothTM and TL have antidiabetic action.

2. MATERIALS

The reference of TL is taken from *BhashajyaRatnavali* from 38 chapters of *Medovikara* 26-28 *shloka.*

2.1 Drugs Review

Trushana-i.ePippali (Piper longum Linn), *Maricha (Piper nigrum Linn), and Sunti (Zingiber Officinale* Roscoe).

***Trikatu*:** They are having *katu*(pungent) taste and *tishna*(sharp) property which penetrate the deeper *dhatu* (tissue) and sub-side the *kaphadosha*.

Vijaya: Having the *vikasi* property without undergoing the process of digestion will reach faster to the deeper tissue and stimulate the muscle which helps to increase its strength.

Chavya: By its hot potency it will counteract the *Kapha dosha.*

***Bakuchi*:** It also has the property of *Rasayana* which helps to rejuvenate the body.

***Lavana*:** It can enter the minute channels of the body and help in mobilizing the *Kapha* from the upper part of the body*.* It cures constipation and increases taste.

***Loha*:** It possesses scraping property that sub-sides *Medadhatu* and *Kaphadosha*.It improves physical strength and is an aphrodisiac. It is also beneficial in reinstating physical strength after suffering from any chronic or acute ailments.

Mandura: It will increase the digestive capacity and taste. It is aphrodisiac and will improve the haematological parameters in the body. It may have the same property as that of *Loha*.

2.2 Drugs Collection and Authentication

a. All herbal drugs will be collected, verified, and primarily authenticated by the Department of *Dravyaguna*.

b. *Loha* and *Mandura* will be procured from the vendor and authenticated by the Department of *Rasashastra.*

c. Raw drugs will be standardized as per API.

d. Animals will be selected as per inclusion and exclusion criteria given in section

Table 1. Drugs review

Dravya	Latin name/ Family	Part use	Rasa	Guna	Veerya	Vipaka	Karma
Pippali	*Piper longum* Linn *Piparaceae*	Fruit	*Katu*	*Laghu Snigdha Tikshna*	*Usna*	*Madhura*	*Dipana,vrisya Rasayana Prameha&gulmaghna*
Maricha	*Piper nigrum Linn Piparaceae*	Fruit	*Katu*	*Laghu Tiksna*	*Usna*	*Katu*	*Kaphavatahara Dipana Pramathi*
Shunti[]	*Zingiber Officinale* Roscoe *Zingeberaceae*	Rhizome	*Katu*	*Guru Ruksha Tikshna*	*Usna*	*Madhura*	*Vatakaphahara Dipana Bhedana*
Vijaya	*Cannabis Sativa* Linn *Cannabaceae*	Leaves,seed	*Tikta*	*Laghu Tikshna Vyavayi*	*Usna*	*Katu*	*Vatakaphahara*
Cavya[12]	*Piper chaba* Hunter *Piperaceae*	Roots	*Katu*	*Laghu, Ruksha*	*Usna*	*Katu*	*Kaphavatahara Dipana Pacana*
Vida lavana	Black salt	Whole	*Lavana*	*Ruksha*	*Ushna*	*katu*	*Dipana,vibanda Urdhvaadha Kaphvatanulomana Anaha, vistambha*
Aubhidha Lavana	Reha salt	Whole	*Tikta, katu kshara*	*Tikshna Utkedi*	*ushna*	*katu*	*Utkedi*
Bakuchi	*Psoralea Corylifolia* Linn *Fabaceae*	Fruits	*Katu Tikta*	*Laghu Ruksha*	*Sheeta*	*Katu*	*Kaphavatahara Rasayana Twachya*
Saindhava Lavana	*Rock salt*	Whole	*Madura*	*Laghu*	*Anusna*	-	*Vrusya,hrudya tridoshahara dipana,avidaha*

Dravya	Latin name/ Family	Part use	Rasa	Guna	Veerya	Vipaka	Karma
Sauvarchala Lavana[13]	*Sochal salt (unaqua Sodium chloride)*	Whole	*Lavana*	*Laghu*	*ushna*	*Katu*	*Hrudya,ruchikara Sugandhya,dipana Udgarashodhana Vibandaghna*
Ayaschoorna (Iron)	*Ferrum (Fe)*	*Bhasma*	*Kashaya*	*Ruksha Guru Lekhana*	*Sheeta*	-	*Balya,vrushya Kaphapittahara Mehahara Varnya,medhya Sarvarogahara*
Mandura[14]	*Rubrum (Fe2O3)*	*Bhasma*	-	*Sheeta*	-	-	*Ruchikaraka Agnidipaka Pittashamaka Raktavruddhikara Pandukamalarogahara*

3. PREPARATION OF *LOHA bhasma* AND *MANDURA bhasma*

3.1 *Shodhana* of *Loha [15]*

- *Lohachurna* will be taken in a pan &heated over high flame till red hot
- Then it will be dipped into a vessel containing *Triphalakwatha(decoction)*
- Iron powder from *triphlakwatha* will be collected back
- Again will be heated till red hot and will be dipped in *triphalakwatha*
- This process will be repeated seven times.

3.2 *Marana* of *loha*

- Purified *lohachurna* will be taken in a mortar and pestle &triturated with lemon juice.
- After obtaining the semisolid consistency of the slurry, small pellets will be prepare
- Pellets will be dried properly.
- Dried pellets will be enclosed in the saucer of earthen pots.
- These enclosed saucers will be subjected to *Gajaputa* (unit of heat).

3.3 *Shodhana* of *mandura*

- *Mandura* will be heated red hot over glowing charcoal
- Then it will be dipped in the vessel containing *gomutra(cow urine)*
- This process will be repeated 7 times.

*3.4 Marana*of*Mandura*

- Purified *Mandura* will be triturated by alovera juice in mortar and pestle.
- Pellets will be prepared from the slurry and dried properly.
- Dried pellets will be enclosed in the saucer of earthen pots.
- These enclosed saucers will be subjected to *Gajaputa*.

3.5 Preparation of TL and TM *[16]*

- All the drugs mentioned above (1-7) will be taken and made into powder
- *Loha Bhasma* will be added to the above powders.
- Similarly, in another preparation, *Mandura Bhasma* will be added.
- All the materials will be mixed together and will be store.

3.6 Standardization Parameters

3.6.1 Organoleptic parameters

- Colour
- Odor
- Taste
- Touch
- Appearance

Table 2. Preparation of tryushanadyaloha/mandura

Sl.No	Drugs	Part use	Dose
1	*Tryushana (Piper longum* Linn, *Piper nigrum Linn, Zingiber Officinale*Roscoe*)*	Fruit	1 part
2	*Bhanga (cannabis sativum*Linn*)*	Leaves/seed	1 part
3	*Cavya(Piper chaba* Hunter)	Root	1 part
4	*Vida lavana(*black salt*)*	Whole	1 part
5	*Aubhidhalavana*	Whole	1 part
6	*Bakuchi(Psoralea Corylifolia*Linn)	Fruits	1 part
7	*Saindhavalavana(*rock salt*)*	Whole	1 part
8	*Sauvarchalalavana (*sochal salt*)*	Whole	1 part
9	*Loha*	Bhasma	12 part
10	*Mandura bhasma*	Bhasma	12 part

3.7 Bhasmapariksha [17]

1. ***Rekhapurnatva***(fine enough to enter the crevices of finger).

- To ascertain the fineness of prepared *bhasma*,when *bhasma* is rubbed in between the thumb and index finger *bhasma* enter and embed in fingerprints which consider enough fine and accepted as standard.

2. ***Nirdhooma*** (smokeless)

- *Bhasma* is properly prepared.

3. ***Niswadu*** (tasteless)

- *Bhasma* shouldn't have any taste.

4. ***Dantagrekachkachabhava*** *(*it should not produce sound while chewing).

- To check any other particles in *bhasma*.

3.8 Physico-chemical analysis [18,19]

1. Moisture analysis

- To ensure and control the quality of the product as the moisture content will affect the process ability,shelf-life,usability, and quality of the product.

3.9 Total Ash

- To detect inorganic substances and alsogives an estimation about purity and quality of drugs.

3.10 pH

- To know the pH value, whether it is acidity or alkalinity.

3.11 Acid –insoluble Ash

- To determine the concentration of siliceous compound in the sample.

4. Modern Sophisticated Analysis [20]

4.1 XRD

- For identification of crystalline material and analysis of unit cell dimensions and also identify the chemical composition information of metals.

4.2 FEG-SEM

- To observe the surface of the sample.

4.3 Methods

4.3.1 Study centres

1. Department of *Rasashastra* and *BhaishajyaKalpana*, MGACH&RC, Salod (H) Wardha.
2. Analytical study will be carried out at *Dattatraya Ayurved Rasashala*, MGACH&RC, Salod(H) Wardha.
3. Experimental study will be carried out at the animal house, DMCP, DMIMS (DU), Wardha.
4. According to the need for study, analysis or experiments will be carried out in laboratory or research institute of national repute as listed in DMIMS (DU) profile.

4.4 Study Design

An experimental study will be done in five groups containing 6 Wistar rats (3 males and 3 females), a total of 30 Wistar rats.

Animals will be divided into five groups:

- Group I-Normal Control(NC)
- Group II-Standard Control(SC)
- Group III-Vehicle Control(VC)
- Group IV-Test group 1 TL
- Group V-Test group 2 TM

4.5 Dose calculation [21,22]

The calculation of dose will be by using rat conversion factor (Paget & Barnes).

Human dose x 0.018/250g of rats

=500x0.018/250g of rats
=9mg/g.

4.6 Oral Glucose Tolerance Test [23]

It will be performed in the same group of rats. Glucose (4 g/kg) will be fed orally for 1 day.One hour after the administration of the drug. Blood will be withdrawn after glucose administration and fasting plasma glucose levels will be estimated at 0,30,60 &120 minutes.

Table 3. Grouping of study animals, the dose of drugs, and Vehicle

Groups	Name of groups	Drugs	No.of Animals	Dose	Vehicle	Study duration
Group 1	Normal control (NC)	-	6	-	-	15 days
Group II	Standard group	Metformin	6	9mg/g	Water	15 days
Group III	Vehicle group	*Honey &grita*	6	18mg 36mg	-	15 days
Group IV	*Test group1*	TL	6	9mg/g	18 mg Honey 36 mg ghrita	15 days
Group V	*Test group 2*	TM	6	9mg/g	18 mg Honey 36 mg ghrita	15 days

Glucose tolerance measures the body's response to sugar (glucose). The glucose tolerance test can be used to screen for diabetes. The glucose tolerance test identifies abnormalities in the way of body handles glucose after a meal –often before fasting blood glucose level becomes abnormal.The glucose tolerance test is performed to show how well the body handles sugar from foods and the risk for diabetes [24].

4.7 Sample Size

- 30 (5x6) 3 males and 3 females of Wistar rats will be used as an animal models.
- Thirty Wistar rats will be used as animal models.
- The sample in animals study is 6 is the smaller sample for any experimental study in each group so according to IEAC the reduced the number use of animals in the study as much as possible.

4.8 Inclusion and Exclusion Criteria

4.8.1 Inclusion criteria

- Rats weighing 200-250 grams of either sex.

4.8.2 Exclusion criteria

- Diseases and pregnant rats.
- Less than 200 grams of weight.
- Weight above 250 grams

4.8.3 Withdrawal criteria

The rats will be withdrawn from the study if any platform of the disease arises in wistar rats.

4.8.4 Randomization

The animals will be taken randomly.

4.9 Analytical and Experimental Study

- Blood glucose level
- OGTT(oral glucose tolerance test)

4.10 Outcome Measures

- Blood glucose levels will be estimated at the intervals.

4.11 Statistical Methods

- Statistical analysis will be done by applying suitable tests (one way ANOVA).

4.12 Experimental Animals

- Healthy adult Wistar rats weigh of 200-250 grams of either sex between 2 and 3 months 0f age will be used for the study.
- 30 (5x6) 3 males and 3 females of Wistar rats will be used as an animal models.

4.13 Housing and Husbandry

- All the rats will be healthy and will be kept in a standard environment.
- They will be housed in the group in polypropylene cages and maintained under standard conditions.

- Food will be fed with rat pellet diet.

4.14 Animal Care and Monitoring

- All animals will be acclimatized before the study.
- While withdrawing the blood from the animal's care will be taken not to cause pain and blood will be withdrawn at 0.5-1ml
- To reduce pain anaesthesia can be used
- Side effects may be seen during the study but all the standardization will be taken before giving the medicine to animals.

4.15 Interpretation/ Scientific Implications

If the result comes out are as follow

1. TL is having more antidiabetic action when compare to TM than what is explained in BhaishajyaRatnavalli stand right.
2. TM and TL have both antidiabetic actions but TM is more effective thanTM can be used instead of TL for preparation and further study.
3. As *Rasa Ratna Samucchaya* stated that *Mandura* is the extract of *loha* expected to have its quality so can be used to treat disease as *loha* instead.

4.16 Limitation

- The study is an experimental study in 30 Wistar rats as it is a pre-clinical study to obtain preliminary efficacy, toxicity, and pharmacokinetic information the sample size is less.
- For the safety of human beings, it has to be studied in animals and later clinically in humans.
- If this Antidiabetic study is successful then this data will be used in another clinical study for the intervention of the Antidiabetic study.

4.17 Experimental Procedures

- Group I Non-diabetic healthy control group received normal saline intravenously
- The hyperglycaemia will be induced by alloxan monohydrate at a dose of 65 mg/kg.
- Group II vehicle group will be given with Honey 1ml (18mg) & *Ghrita* 2ml (36mg),
- Test drug treated group i.e Test group 1 will be give with *TL* 500mg/kg (9mg/kg) with Honey 1ml (18mg) &*Ghrita* 2ml (36mg) and
- Test group 2 with *TM* 500mg/kg (9mg/kg) with Honey 1ml (18mg) &*Ghrita* 2ml (36mg)
- While standard treated group received Metformin 500mg/kg (9mg/kg).
- The vehicle or drug treatments were given daily orally for 15 days.
- Blood will be withdrawn from fasted rats (10 h) on 0, 1, 3, 12 h, 72 h (3rd day),168 h (7th day), 264 h (11^{th} day), and 360 h (15th day), and fasting plasma glucose levels were estimated at all intervals.

4.18 Oral Glucose Tolerance Test

- On the 16^{th} day, Oral Glucose Tolerance Test will be performed in the same group of rats.
- Glucose (4g/kg) will be fed orally for 1 day. One hour after the administration of the drug.
- Blood will be withdrawn after glucose administration and fasting plasma glucose levels will be estimate at 0,30,60 &120 minutes.The glucose tolerance test is performed to shows how well the body handles sugar from foods and risk for diabetes [24].

4.19 Expected Outcome

If TL or TM shows expected & significant result as Antidiabetic will be helpful to conduct clinical trials in Human being. If TM is having same or better efficacy as compared to TL,a cost effective, less time consuming but efficacious product can be used in clinical studies.

5. DISCUSSION

TM is herbo-mineral formulation which is indicated in *prameha* and *mandura* is one of the *lohakitta* used as dosage form TM , with the question can it be compared and have the quality of *loha* comparative study is taken. *Mandurabhasma* have a more significant effect than *lohabhasma* on haemoglobin level and *mandurabhasma* had better haematinic compared to *lohabhasma* [25,26].

The process of preparation of *loha bhasma* consumes a lot of time when compared to the preparation of *mandura bhasma*. The pharmaceutical preparation of *loha bhasma* is a

tedious process involving many steps in the conversion of *loha bhasma* from *loha*.It is very costly and time-consuming also.*Loha bhasma* if not given the sufficient number of *puta* it causes constipation, while in *mandura bhasma* is not there. The properties which *mandalauhabhasma* have the same properties will be there in *suddha manda mandura* in minute form, so to treat the disease *mandura bhasma* can be used [27]. From all the above studies*, Loha bhasma and Mandura bhasma* were compared to assess different therapeutic potentials and indicating better therapeutic efficacy of *Mandura bhasma*.Considering this *TL* will be prepared by adding *Mandura bhasma* instead of *Loha bhasma*, as in *mandura* it will be less time consuming, less costly for preparation and it will not cause constipation. With the help of X-Ray Diffraction (XRD) the crystalline fraction of the molecule will be recognized in both the samples that is *TL and* TM [28]. Even in analytical study XRD and FEG-SEM may show the nano-particles size of *mandura* is less than *loha* as the number of *puta* is given more in loha [29,30]. If TM is having the same or better efficacy as compared to TL ,a cost effective, less time consuming but efficacious product can be used in clinical studies.In this study, TL and TM are the two formulation use to evaluate their antidiabetic action in induced hyperglycaemia by alloxan monohydrates. Later the interval blood glucose will be estimate and at last day of study oral glucose tolerance test will be done to check how much the rats can tolerate glucose after the medication. At last to conclude which of the two*, Lauha or Mandura*, has the better anti-diabetic action.

6. CONCLUSION

If this antidiabetic study is successful, then this data will be used in another clinical study for the intervention of antidiabetic study, as it is herbal-mineral medicine, so it may or may not show toxic effects in animal models. So after the pre-clinical study, it can be studied as a clinical trial in human beings.

NOTE

The study highlights the efficacy of "Ayurvedic" which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

CONSENT

It is not applicable.

ETHICAL APPROVAL

All animals experiment will be carried out by the guidelines of CPCSEA after the approval of the Institutional Animal Ethical Committee (IAEC). Protocol no: - DMIMS/IAEC/20-2021/16

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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