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**Preliminary physicochemical analysis of a higher order
siddha formulation “*Kaalamega Narayana Chendhooram*”
(KMNC)**

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Abstract

Siddha system of medicine is one of the ancient medical system which had its origin in South India especially dravidan speaking Tamil people. This system of medicine comprises mooligai (plants), thadhu (metals and minerals), animal products in their medicinal preparations. In this system of medicine the purification process (suthi) is not as much easier, it requires multi steps to attain de toxic form and splits the metals and minerals into finer particles. Thus the Siddha formulation KMNC which was the metallo-mineral formulation undergoes various steps to attain purify form and plays a major role in treating life threatening diseases and chronic diseases in small doses. This system of medicine contains wonderful secretes specially in the field of chemistry. This system of medicine had a rich and unique treasure of knowledge in which metals and minerals are used. According Indian system of medicine *chendhooram* is a red colour powder composed of herbs, metals, minerals. The major bottle neck for the wider acceptance of siddha medicine to the World is due to lack of standardisation. Standardisation of traditional medicines is an important for establishing a constant biological activity. In recent decades the people from all over the World preferred to take natural medicines because of its easy availability, less toxic effects. Thus it is the best time to explore siddha system of medicine to make the healthy World without any adverse effect.

Keywords: Siddha, Physicochemical, Traditional system, Metals, Minerals, *Chendhooram*, *KMNC*, *Kaala Mega Narayana Chendhooram*.

Introduction

Siddha system of medicine is a part and parcel of the earliest Tamil medicine. It provides a cheap and efficient service to the people. The aim of this system is to keep the body and mind in a good condition. *Siddhars* had completely investigated the exact cause,

effect of diseases, all kinds of drugs and thereby came to realize what was beneficial and what was not, to their existence in life. The word *Siddha* comes from the word *Siddhi* which means an object to be attained or perfection, or heavenly bliss.

The importance and fundamental principles of siddha system of medicine were embedded in *Thirukkural*, and it clearly shows the longevity of the system not less than two thousand years. *Thiruvalluvar* in his monumental work *Thirukkural* had devoted a chapter for medicine. A deep study of those couplets threw more light on the social and medical area of those ages in Tamilnadu which gave rise to these pithy sayings, Disease is a state in which the body is not allowed to move about and the mind to think about or a state which makes the mind static and fastens the body as if every thing in a dominant state. It is pointed by *Thollkappiyar*, that the disease means suffering and depression^[1].

Healing is a matter of time, but it is sometimes also a matter of opportunity.

– Hippocrates

The unique preparations of siddha system of medicines like *parpam*, *chendhooram*, *kattu*, and *padhangam* are like “life saving” and “miracle”. Which were prepared by the siddhars on the basis of nano medicine. Recent advances in science explored that the nano particles, which finds the potential usage in bio-medical field especially in cancer and many degenerative diseases^[2].

Medicine is a science of uncertainly and an art of probability.

- Hippocrates

With the effects of nano partical , *chendhooram* is a category of medicines made from metals or minerals (arsenicals or mercurials or salts) by grinding them with specified juices or distillates or extractives and subjecting them to a process of sublimation or calcination or burning or frying or exposing to insolation till the characteristic reddening of the product takes place. The *chendhooram* are said to retain their potency for 75 years^[3]

The chemical findings of the prepared medicines shows the pharmacological effects of medicine. Thus an attempt was made in this study to standardise the siddha formation KMNC through physico-chemical analysis. This medicine was indicated for Cancer in siddhar classical literature.

Materials and Methods

Selection of the drug:

For this present study, the metallo-mineral formulation “**KAALAMEGA NARAYANA CHENDHOORAM**” was taken as the compound drug preparation for oral cancer mentioned in the classical Siddha literature “*Athmarakshamirtham Ennum Vaithiya Saara*

Sangeraham” written by *Kandhasamy Mudhaliyaar*, pg no:493, First Edition 1931^[4].

Ingredients of the drug:

1. Purified *Vediuppu* [*Potassium nitrate*] – 840 gm
2. Purified *Thurusu* [*Copper sulphate*] – 210 gm
3. Purified *Padikaaram* [*Aluminium potassium sulphate (Alum)*] – 840 gm
4. Purified *Vengaram* [*Sodium bicarbonate (Borax)*] – 210 gm
5. Purified *Navacharam* [*Ammonium Chloride*] – 210 gm
6. Purified *Pooneeru* [*Impure Sodium Carbonate (Fullers Earth)*] – 105 gm
7. Purified *Jaathilingam* [Red sulphate of mercury] – 525 gm
8. Purified *Gandhagam* [*Sulphur*] – 420 gm
9. Purified *Kalluppu* [*Sodium chloride*] – 210 gm
10. Purified *Rasam* [*Hydragyrum*] – 1050 gm
11. Purified *Aritharam* [*Tri sulphate of Arsenic (Yellow Orpiment)*] – 350 gm
12. Purified *Manosilai* [*Di sulphate of Mercury (Red Orpiment)*] – 140 gm

Collection of the raw materials:

All the raw materials were purchased from R.N. Rajan country drug store, Parrys corner, Chennai.

Identification and Authentication of the drug:

The raw materials were identified and authenticated by the experts of *Gunapadam*, Government Siddha Medical College, Arumbakkam, Chennai- 106.

The specimen sample of each raw material has been kept in the PG *Gunapadam* department individually for future reference.

Purification of the drugs:

Purification process was done as per the classical Siddha literature .

1. Purification of Pottasium Nitrate (*Vediuppu*) :

Materials Required:

1. Salt – 100gm
2. Water – 400gm
3. Fermented butter milk – 100gm
4. Lime juice – 100 gm

Procedure:

Water was added to the pottasium nitrate and boiled on a hearth with mild flames. The white yolk of eggs (4 nos) were added to every 1400gm of salt and

the bubbles thus appeared with impure substances were removed with wooden spoon.

The ingredients were then transferred to another pot, sealed with mud pasted cloth, filtered and transferred to another pot, sealed with mud pasted cloth, filtered and kept in places without aeration. Next day the water was filtered and salt was sun shade. This process was repeated for seven times to get it purified.

2. Purification of *Padikaaram* (Aluminium potassium sulphate (Alum)

The alum was dissolved in water and it was filtered, boiled. Then it was cooled to get purified form.

3. Purification of *Thurusu* (Copper sulphate):

The copper sulphate was fried, till it turns to whitish.

4. Purification of *Vengaram* (Sodium baborate):

Borax was bundled and hanged in the buffalo's dung solution and boiled. The bundle was cleaned with fresh water and insolated to get it in purified form.

5. Purification of *Navacharam* (Ammonium chloride):

Navacharam (Ammonium chloride) was dissolved in hot water and filtered. After it was cooled, it was poured in a broad mouthed vessel and insolated; the salt was formed in a purified form. It was preserved with small quantity of the root of jequirity in a bottle.

6. Purification of *Kalluppu* (Sodium chloride):

Kalluppu was dissolved in vinegar and clean with a cloth, dried in a sunshade.

7. Purification of *Pooneeru* (Impure Sodium Carbonate) :

Fuller's earth 1.3 litre was soaked in dew's water 5.2 litres and allowed to settle. Next morning it was churned well and the outer cream layer was removed. The remaining mixture was in procelin plates and insolated to obtain purified form. This process was repeated for ten times and stored in a bottle.

8. Purification of *Rasam* (Mercury)

Materials Required:

Mercury	– 35 gm
Brick powder	– 100 gm
Turmeric powder	– 100 gm
<i>Acalypha</i> juice (<i>Acalypha indica</i>)	– 1.3 litre

Procedure:

Mercury was triturated with brick powder and turmeric powder for one hour respectively and washed with water. Then the Mercury was boiled with the juice of Indian *Acalypha* till the juice completely evaporates. And thus mercury was purified.

9. Purification of *Lingam* (Cinnabar):

Lime juice, cow's milk and the *Acalypha indica* juice were mixed together in equal proportion and allowed to fuse Cinnabar so as to get it in a purified potent form.

10. Purification of *Thaalagam* (Yellow Orpiment):

Materials required:

Arsenic trisulphate	– 35 gm
Cow's urine	– 1 litre
Indian <i>Acalypha</i> juice	– 300 ml
Lime stone	– 300 gm

Procedure:

Arsenic trisulphide was bundled and kept immersed in the mixture of limestone, *Acalypha indica* juice and cow's urine and heated to get purified.

11. Purification of *Gandhagam* (sulfur):

Materials Required:

Sulphur	-	35 gm
Butter	-	35gm
Cow's milk	-	150ml

Procedure:

Sulphur was placed in an iron spoon. Butter was added and the spoon was heated till the butter melts, this mixture was immersed in inclined position in cow's milk. The procedure was repeated for about 7 times and thus sulphur was purified. Fresh milk was used each time.

12. Purification of *Manosilai* (Red orpiment)

Materials required:

Red orpiment	-	35gm
Cow's butter milk	-	125ml

Procedure:

Red orpiment was triturated with cow's butter milk for 3 hours. It was dried to get purified form^[5].

Preparation of the trial drug – “Kaalamega Narayana Chendhooram”

1. Purified *Vediuppu* [*Potassium nitrate*] – 840 gm
2. Purified *Thurusu* [*Copper sulphate*] – 210 gm
3. Purified *Padigaram* [Aluminium potassium sulphate (Alum)] – 840 gm
4. Purified *Vengaram* [*Sodium bicarbonate* (Borax)] – 210 gm
5. Purified *Navacharam* [*Ammonium Chloride*] – 210gm
6. Purified *Pooneeru* [*Impure Sodium Carbonate (Fullers Earth)*] – 105 gm
7. Purified *Jaathilingam* [Red sulphate of mercury] – 525gm
8. Purified *Gandhagam* [*Sulphur*] – 420 gm
9. Purified *Kalluppu* [*Sodium chloride*] – 210 gm
10. Purified *Rasam* [*Hydragyrum(Mercury)*] – 1050 gm
11. Purified *Aritharam* [*Tri sulphate of Arsenic* (Yellow Orpiment)] – 350 gm
12. Purified *Manosilai* [*Di sulphate of Mercury* (Red Orpiment)] – 140gm.

Procedure:

- 840 gm of 8th solution of *Vediuppu* [*Potassium nitrate*] and *Padigaram* [Aluminium potassium sulphate (*Alum*)] were taken.
- Along with that, 210 gm of *Thurusu* [*Copper sulphate*], *Vengaram* [*Sodium bicarbonate* (Borax)], *Navacharam* [*Ammonium Chloride*], *Kalluppu* [*Sodium chloride Impura*] were taken and then mixed with 105 gm of *Pooneeru* [*Impure Sodium Carbonate (Fullers Earth)*].
- Above ingredients were ground into fine powder and divided into 3 parts.
- First part of the powder was underwent distillation process, the end product was mixed with 2nd part of powder and dried.
- Second part of the powder was underwent distillation process, the end product was mixed with 3rd part of powder and dried.
- Third part of the powder was undergoes distillation process, the final end product was taken and kept in a sealed bottle.
- The *Jaathilingam* [Red sulphate of mercury]- 525 gm, *Aritharam* [Tri sulphate of Arsenic (Yellow orpiment)]-350 gm, *Gandhagam* [*Sulphur*] 420 gm, *Manosilai* [Di sulphate of mercury (Red Orpiment)] 140 gm were

ground, along with the end product of distillation for 12 hours (4 *saamam*) and made into fine powder and dried.

- Dried powder was kept in a mud pot which was sealed with 7 mud pasted plaster.
- Another mud pot with small quantity of sand was taken and above preparation was kept into it and sealed the lid with mud pasted plaster.
- The mud pot was ignited by using *Aavarai* stick for 30 hours (10 *saamam*), after 30 hours “*Chendhooram*” was obtained.

Drug profile:

Drug Name : Kaalamega Narayana Chendhooram
 Dosage : 244 mg of Chendhooram (1/2 Panavedai)
 Route : Enteral (Oral)
 Adjuvant : Thipili chooranam with honey (bd for 48 days – 1 mandalam)
 Indications : *Kannaputru* [ORAL CANCER], *Elaippu* [Tuberculosis], *Kuttam18* [Hansen’s Disease]
 Reference : “*Athmaraksha Mirutham Ennum Vaithiya Saara Sangeeraham*”^[4].

Fig no: 1. Ingredients of Kaalamega Narayana Chendhooram:



Purified *Vediuppu* [*Potassium nitrate*]



Purified *Thurusu* [*Copper sulphate*]



Purified *Padigaram* [Aluminium potassium sulphate (Alum)]



Purified *Vengaram* [*Sodium bicarbonate(Borax)*]



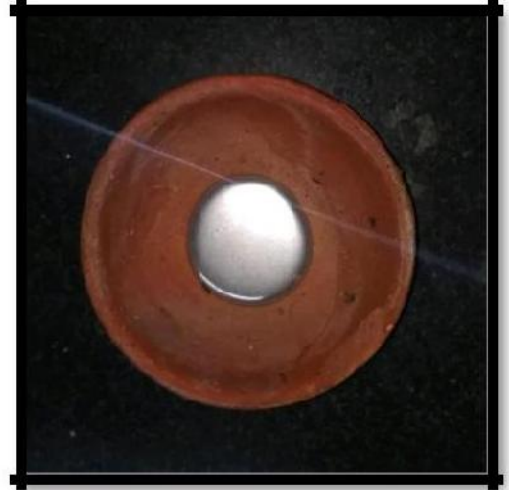
Purified Navacharam [Ammonium Chloride]



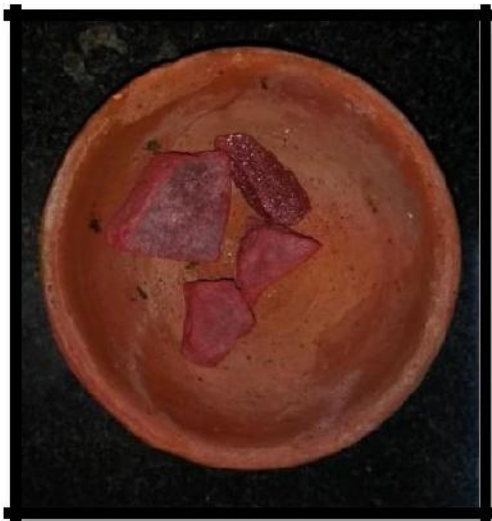
Purified Kalluppu [Sodium chloride Impura]



Purified Pooneeru [Impure Sodium Carbonate (Fullers Earth)]



Purified Rasam [Hydragyrum]



Purified Jaathilingam [Red sulphate of mercury]



Purified Aritharam [Tri sulphate of Arsenic (Yellow orpiment)]



Purified Gandhagam [Sulphur]



Purified Manosilai [Red Orpiment]

Fig No:2: Preparation of *Kaalamega Narayana Chendhooram*:

Process 1:



Preparing for *Thravagam*

Process 2.



Process 3.



1st part undergoes distillation process



Collection of *Thravag*

Process 4.



The obtained *Thravagam* was used to grind the second part



Again the second part underwent distillation to process

Process 5.



The obtained *Thravagam* is used distillation to grind the third part



Again the third part underwent process

Process 6.



The end product of distillation was sealed in a bottle.

Process 7.



Grinding of prepared medicine

Process 8.



Final product was sealed with mud pasted cloth

Process 9.



Ignition of final *Chendhooram*



Final end product of *Chendhooram*



***Chendhooram*^[4]**

Chendooram:

Definition:

Chendooram is a category of medicines made from metals or minerals (arsenicals or mercurial's or salts) by grinding them with specified juices or distillates or extractives and subjecting them to a process of sublimation or calcinations or burning or frying or exposing to insolation till the characteristic reddening of the product takes place. The *Chendooram* are said to retain their potency for 75 years

Method of preparation:

Usually two method of preparation are adopted in their processing, with some exceptions and variants. Such as:

1. Sublimation by the sand – bath process
2. Calcination.

Other method of preparations:

1. Prepared without heating (*Araippu Chendooram*)
2. Prepared by open heating (*Erippu or Varuppu Chendooram*)
3. Prepared by applying heat in the range close to 100 c (*LaguPuda Chendooram*).

Specifications for Chendooram

1. *Chendooram* is red in nature, well fine in particle size and tasteless.
2. With suitable adjuvant they possess therapeutic values.
3. They are said to retain their potency for 75years^[3].
4. Thus the prepared medicine KMNC was subjected to Sublimation by the sand – bath process

Analytical specifications of chendooram

1. Description
 - Colour
 - Odour
2. Identification –chemical
3. Particle size mesh size – 200 – 300
4. Loss on drying at 105 °C
5. Total –ash
6. Acid – insoluble ash, Water soluble ash
7. Assay of element (s)
8. Ayurvedic specifications
9. Lustreless

10. Fine enough to enter the crevices of finger
11. Floats on water
12. Smokeless
13. Tasteless
14. Irreversible

Analysis as per AYUSH guidelines^[7]

1. Floating on Water:

A pinch of *Chendooram* gently placed on the still surface of water in a vessel, did not sink immediately. It was found that the *Kaalamega Narayana Chendooram* particles floated over the surface of water indicated lightness of the trial drug.

2. Lines on fingers:

Chendooram in well prepared form should be as fine powder. When taken between thumb and index finger, the fine powder will fill up the lines of the finger print. A pinch of *Kaalamega Narayana Chendooram* was taken in between the thumb and index finger and rubbed. It was found that the *Kaalamega Narayana Chendooram* entered into the lines of the finger and was not easily washed out from the lines, confirmed its fineness.

3. Irreversible reaction:

The well prepared *Chendooram* does not get reversible to its metallic state when heated with a mixture of cane jaggery, hemp powder, ghee and honey. A pinch of *Kaalamega Narayana Chendooram* was taken and mixed with cane jaggery, ghee and honey. It was observed that *Kaalamega Narayana Chendooram* did not reverse to its metallic state.

4. Tasteless:

The well prepared *Chendooram* should be completely tasteless. Presence of any taste like sweet or bitter indicate incomplete preparation which needed another Calcination process. When a small amount of *Kaalamega Narayana Chendooram* was kept on the tip of the tongue, no specific taste was found.

5. Lusterless:

If any shining particle is present in *Chendooram*, it indicates that the *Chendooram* is not manufactured properly and contains unchanged substances like minerals, metals and other toxic substances. There should be no shining particles present in the well manufactured *Chendooram*. *Kaalamega Narayana Chendooram* was taken in a petri bowl and observed for any lustre in daylight through magnifying glass. No lustre was observed in the *Chendooram*.

Organoleptic character of the *Chendhooram* :

The organoleptic characters of the sample were evaluated which include evaluation of the formulation by its colour, odour, taste, texture etc.

Colour:

A sample of *Chendhooram* were taken in watch glasses and placed against white back ground in white tube light. The *Chendhooram* were observed for its color by naked eye.

Odour:

Chendhooram were smelled, the time intermission between two smelling was kept 2 minutes to nullify the effect of previous smelling.

Taste:

A sample of about *Chendhooram* was tasted and the taste was reported.

Size:

The *chendhooram* was completely sieved through mesh size 120.

Physico-Chemical Investigations^[8]:

Physico-chemical investigations like pH value, Loss on drying at 105°C, Ash test have been done at The Tamilnadu Dr M.G.R Medical University, Anna salai, Guindy, as per the guide lines of WHO.

Solubility Test

A pinch of sample (*KMNC*) was taken in a dry test tube and to it 2 ml of the solvent was added and shaken well for about a minute and the results are observed. The test was done for solvents like distilled water, Ethanol, Petroleum ether, Propylene glycol, Toluene, Benzene, Chloroform, Ethyl alcohol, Xylene, Carbon tetra chloride and the results are observed individually.

pH value:

Potentiometrically, pH value is determined by a glass electrode and a suitable pH meter. The pH of the *KMNC* was written in results column.

Loss on Drying:

An accurately weighed 2gm of *Kaalamega Narayana Chendhooram* formulation was taken in a tarred

glass bottle. The crude drug was heated 105⁰ c for 6 hours in an oven till a constant weight. The percentage moisture content of the sample was calculated with reference to the shade dried material.

Determination of total Ash:

Weighed accurately 2g of *Kaalamega Narayana Chendhooram* formulation was added in crucible at a temperature 600⁰c in a muffle furnace till carbon free ash was obtained. It was calculated with reference to the air dried drug.

Determination of acid insoluble ash:

Ash above obtained was boiled 5min with 25ml of 1M hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was burnt to a constant weight in a muffle furnace. The percentage of acid insoluble as was calculated with reference to the air dried drug.

Determination of water soluble ash:

Total Ash 1g was boiled for 5min with 25ml water and insoluble matter collected on an ash less filter paper was washed with water and ignited for 15 min at a temperature not exceeding 450⁰c in a muffle furnace. The amount of soluble ash is determined by drying the filtrate.

Determination of water soluble extractive:

5gm of air dried drug. Coarsely powdered *Kaalamega Narayana Chendhooram* was macerated with 100ml of distilled water in a closed flask for twenty-four hours, shaking frequently. The solution was filtered and 25 ml of filtered was evaporated in a tarred flat bottom shallow dish, further dried at 1000c and weighted. The percentage of water soluble extractive was calculated with reference to the air dried drugs.

Determination of alcohol soluble extractive:

2.5gm of air dried drugs coarsely powdered *Kaalamega Narayana Chendhooram* was macerated with 50ml. alcohol in closed flask for 24 hours. With frequent shaking, it was filtered rapidly taking precaution against loss of alcohol .10ml of filtrate was the evaporated in a tarred flat bottom shallow dish, dried at 1000 c and weighed. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

Results and Discussion

Table: 1 Physical Parameters of KMNC:

S.No	Parameters	Results for ideal <i>Chendhooram</i>	Results of <i>KMNC</i>	Interpretation
1	Colour	Reddish	Reddish brown	<i>Chendooram</i> colour.
2	Floating of Water	Floats on water	Floats on water	Lightness of drug.
3	Finger Print Test	Impinged in the furrows of finger	Impinged in the furrows of finger	Indicates fine particles of powder.
4	Luster	Lusterless	Lusterless	Change of specific metallic character of raw material After incineration
5	Taste	No specific taste	No specific taste	Change of specific metallic character of raw material After incineration

Colour:

It is reddish brown in colour. The absence of shining indicates there is no free form of metals.



Fig no: 3

Floating on water:

Kaalamega Narayana Chendhooram floats on water. It is due to its less specific gravity. So, it possesses the property of *Chendhooram*.



Fig no: 4

Finger print test:

Kaalamega Narayana Chendhooram impinged on the cervices of finger. This indicates the particles are fine and it is in micro size.



Fig no: 5.

Lusterless& tasteless:

It is lusterless and tasteless



Fig no: 6

Table-2 Physical characterization of *Kaalamega Narayana Chendhooram*

S.no.	Parameter	Result
1.	Colour	Reddish brown in colour
2.	State of the drug	Powder
3.	Consistency	Fine powder
4.	Solubility	Sparingly soluble in water, DMSO. Well soluble in acids (HCl and H ₂ SO ₄)
5.	Sense on touch	Fine
6.	Sense on taste	Tasteless
7.	Sense of smell	No significant smell is observed

Results of Physical Parameters

Table-3

S.No	Parameter	Result
1.	Specific gravity	0.956
2.	pH value	4.24
3.	Particle size	Completely passes through sieve no.120
4.	Loss on drying at 105 degree Celsius	0.61%
5.	Total ash value	97.78%
6.	Acid insoluble ash	0.23%
7.	Water soluble ash	4.76%

Discussion on Physico - Chemical parameters:

Solubility

- Solubility is the major factor for the bioavailability of a drug substance.
- It is useful to determine the form of drug and processing of its dosage form.
- The most frequent causes of low oral bioavailability are attributed to poor solubility and low permeability^[9].

KMNC is soluble in major solvents (H_2SO_4 , HCl) and sparingly soluble in water proves that its efficiency of solubility in the stomach indirectly, increasing the bio availability.

Specific gravity

The trial drug "*Kaalamega Narayana Chendhooram*" shows (0.956) low specific gravity compared to water. Thus it flows in water and indicates lightness of the medicine. This lightness of the medicine indicates its nature of absorption.

pH value

- *Kaalamega Narayana Chendhooram* shows acidic pH.
- The p^H level plays a role in enzyme activity by maintaining the internal environment, thus it exhibits an important role in regulating homeostasis.
- It is also an important factor for drug absorption^[10]. Because of the acidic nature, the drug is more readily absorbed in an acidic medium like stomach which enhances the bioavailability of the drug.

Loss on drying

- Loss on drying (LOD) of *KMNC* gives the total amount of volatile content and moisture (water) present in the drug.
- The stability of a drug and its shelf-life are depends on moisture content. Moisture increase can adversely affect the active ingredient.
- Low moisture content- drug could get maximum stability and better shelf life. The low moisture content of *KMNC* indicates that it has long shelf life. Since the drug has low loss on drying (0.61%), the moisture content is less which is suitable for medicine.

Ash values

Total Ash value

High level of total Ash value of the trial drug *KMNC* contains (97.78%) indicates the richness of organic substances. These organic compounds are responsible for mineral supplements and therapeutic effect of *KMNC* and also it indicates it was under the process of incinerations.

Acid insoluble ash

Lower acid insoluble ash value (0.23%) better will be the drug quality^[11]. The drug ensures a low value of acid insoluble ash indicating that the preparation did not contain any sand, dust and stones.

Water soluble ash

Water soluble ash value (4.76%) indicates the easy facilitation of diffusion and the osmosis mechanisms.

Conclusion

The major bottle neck for the wider acceptance of Siddha medicine is due to the lack of standardization of Siddha formulations. The pharmacology of siddha system of medicine was vast and complex due to their preparations. The preparations are tedious in process. The purification process takes many steps to attain non-toxic form. In this study the higher order siddha formulation KMNC was undergoes for purification process to attain the GMP. The purified form of KMNC showed the various results in the preliminary physico-chemical screening will give stepping stone for clinical trail.

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