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A BRIEF REVIEW OF PUBLISHED RESEARCH WORKS ON NAGA BHASMA

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ABSTRACT :

Review of scholarly articles give a new interpretation of old material or combine new with old interpretations, trace the intellectual progression of the field, including major debates, depending on the situation, evaluate the sources and advise the reader on the most pertinent or relevant research and identify where gaps exist in how a problem has been researched to date. *Naga bhasma* is one of Ayurvedic preparation on which few researches has been conducted which covers large area of quality control and safety profile, however still much claim has been made against the therapeutic concerns of *Naga bhasma.* Therefore in present work an attempt has been made to make a brief review of published research works on *Naga bhasma.* Total twenty works has been reviewed. All work related to standardization, experimental study and review has been traced and the gist of these research works has been presented in this paper. These research work have built strong basis for quality control, quality assessment and safety data.

Key words: *Naga Bhasma*, review, published researches, standardization, safety.

INTRODUCTION: Conceptual study or literature review is most essential backbone of the any research work. Critical review of available information helps in understanding and framing an idea about the subject to be dealt. It deals with everything right from the past to the present, related to the subject and a clear picture of subject matter. Hence, for the complete knowledge of the subject, it is necessary to trace out its historical background, which gives a tangible firm in the development of stages from time to time. *Bhasma's* are one of the unique preparations therapeutically used in *Ayurveda* and have been used as effective drugs for centuries without any noticeable side effects. *Naga bhasma*is one such preparation which contains lead as a main ingredient.

Ayurvedic concepts as it is a vast system of knowledge, moreover it require much more skills to utilize modern parameters to study Ayurvedic principles. That is why, those research with are completed and published should be studied for updating Ayurvedic knowledge. Knowledge has little value when it is known to few persons but knowledge itself and its value too goes rapidly increasing when one starts spreading it. The similar thing is applicable regarding *Naga bhasma.* There are various research papers published which provides valuable information of safety profile, standardization and literary data on *Naga bhasma* but studying all these works is a

bit tedious task. Hence in present paper an attempt has been made to make a comprehensive review of available research works on *Naga bhasma*.

MATERIAL AND METHODS: Published articles on pharmaceutical, analytical, pharmacological, clinical studies and literary review are compiled in present paper. The gist of those papers have been described in brief with highlighting their precious findings which will help in knowing various research works on *Naga bhasma* from this single review.

OBSERVATION AND RESULTS: There are 20 research works found published on *Naga Bhasma* which occupied nearly every area of drug standardization and safety profile. These research works includes filed such as acute toxicity study, chronic toxicity study, pharmaceutical standardization, analytical standardization, characterization, anti-diabetic study, anti-hyperglycemic study, comparative study of *Bhasma* prepared from different methods, and histopathological studies and conceptual review. Detail of these research works has been presented in discussion which not only provides huge information but also saves the effort of studying many research works.

DISCUSSION:

Comparative study of some commercial samples of *Naga bhasma*:[1] In this work *Naga bhasma* manufactured by different Ayurvedic pharmacies, by following different methods was utilized. These products were not standardized either from chemical and structural point of view. Therefore, the comparative study of these samples using modern analytical techniques to understand their current status was conducted by Wadekar *et al*. This study elaborates standardization of *Naga bhasma* with chemical and structural point of view reported by using XRD, IR and UV spectroscopy and thermogravimetry. Commercial samples of *Naga bhasma* were collected from the following representative pharmacies,

Table 1: Different samples of *Naga bhasma* selected for analytical study of Wadekar *et. al*.

Sr.	Name of Pharmacy	Code Number
1	Koral Pharmacy (Nasik)	NAG.01
2	Baidyanath (Nagapur)	NAG.02
3	Hariparashuram (Pune)	NAG.03
4	Dootpapeshwar (Mumbai)	NAG.04
5	Krishna Gopal (Ajamer)	NAG.05

The XRD investigation of 5 samples mentioned in table 1, leads to general conclusions such as-(i) all the samples were predominantly crystalline in nature as indicated by the line structure of XRD patterns. (ii) All samples were complex mixtures of PbO,pb_3O_4 and other lead compounds; the sample NAG.05 being the most complex in nature (iii) from the composition observed through XRD, the first four samples seemed to be prepared using plant materials alone for *bhasmikarana* (i.e. they are *vanaspaty marit*). The fifth sample (NAG.05) seems tobe prepared by using arsenic sulfide for *bhasmikarana* as indicated by the presence of (AsO4)-3 in the sample (i.e. this is*manashila* As_2S_2*marit*). Infra red spectra data showed that samples of *Naga bhasma* contain hydroxyl group (OH) and

carbonate group $(CO_3)_2$ in all samples. The sample NAG.05 contain sulfate $(SO_4)_2$ and $(ASO_4)_3$ as the important constituents. Thus carbonate, lead sulfate andlead arsenate. Apart from these, presence of other minor constituents and trace constituents was also estimated. (Table 2)

Table 2: XRD Investigation of *Naga bhasma*

Sr.No.	Sample Code No.	Constituents Identified
1	NGA.01	PbO+Pb3O4+Pb (CO3)2(OH)2
2	NGA.02	PbO+ Pb3O4+ Pb (CO3)2(OH)2H2O+Pb10(CO3)6(OH)6O
3	NGA.03	PbO+ Pb (CO3)2(OH)2+ Pb10(CO3)6(OH)6O
4	NGA.04	PbO+ Pb (CO3)2(OH)2+ Pb10(CO3)6(OH)6O
5	NGA.05	[KNaPb8 AsO4)6]+[Pb4(SO4)(CO3)2(OH)2]+[NaPb4(AsO4)3] +[K2Pb(SO4)2]+[Pb2(SO4)O]

Lead and mercury each as prime matter in alchemy:[2] This study concluded that purification of ore of minium by fire gives lead. This study considered Lead became a drug of longevity. It was first consumed as such, later amalgamated with mercury. Later after discovery of ores of cinnabar. This could not stand heating and thus was powdered, lavigated filtered and taken orally. This study claims that first lead alone and then lead and mercury were the source of all metals.

A novel ayurvedic anti-diabetic medicine:[3] In conclusions the author of this work stated that Ayurveda has elaborately emphasized the *Rasayana* effect of *Naga Bhasma.* This clinical study of *Naga bhasma* showed no untoward effect in any of the patients during and after study, 90 % of the patients expressed sense of well-being and 70% of the patients showed improvement in the symptoms. 65% of the patients who were taking other hypoglycaemics along with *Sashtiputa Naga Bhasma* showed reduction in blood sugar level. 50 % patients, those on *Sashtiputa Naga Bhasma* alone alsoshowed reduction in blood sugar. About 25% of the patients who were taking both synthetic hypoglycaemics as well as *Sashtiputa Naga Bhasma*, had hypoglycaemia. No hypoglycaemic effects was observed in the patients who were treated with *Sashtiputa Naga Bhasma* alone. Thus this study concluded that *Sashtiputa Naga Bhasma* can be recommended as a medicine and also as an adjuvant along with synthetic medicines for the management of diabetes mellitus.

Physico- chemical characterization of lead based Indian traditional medicine-*Naga bhasma*:[4] In this study *Naga bhasma* of varying batches were procured from an Ayurvedic manufacturing company and labeled as XB1, XB2 and XB3 and subjected to various physicochemical parameters. This study reveals the presence of batch to batch variation in *Naga bhasma* samples prepared by the same manufacturer. This could be attributed to lack of gold standards for preparation of *bhasma*. The characterization of intermediates at every step of preparation and comparison with established benchmarks are required to address this issue. All samples analyzed were found to be crystalline with Pb_2O_3 and Pb_2O_4 phases. Also all samples were found to be containing co-ordination compounds.

Table 3: Elemental composition of different batches of *Naga bhasma*

Sample	Pb	Zn	Mn	Cu	As	Cd	Hg	Sn	Ag
XB1	59.05	-	-	0.09	4.47	-	-	-	-
XB2	59.40	-	-	0.01	4.47	-	-	8.31	-
XB3	53.00	0.15	0.01	0.54	6.29	-	0.06	2.70	-

Detection of Carbonaceous Material in *Naga Bhasma*:[5] In finding of this study, presence of carbonaceous material (hydrogenated amorphous carbon) has been identified in *Naga Bhasma*. This work also suggests the science and mechanism behind such complex preparations which could help in standardization of *Bhasma* medicines.

Study of standard operating procedure of *Naga bhasma* in relation to its physico-chemical properties:[6] This study showed presence of more agglomerates of particles in SEM of *Naga Bhasma* samples. The particle size varies from < 1µm to 20 µm. While in X-Ray Diffraction Study strongest peak identified in *bhasma* was Lead Germanium Oxide ($Pb_3Ge_2O_7$) & other phases were identified as Rubidium Thallium Lead Phosphate (RbTI Pb_8 $(PO_4)_6$) with some other compounds, peaks of which remain unidentified. On ICP-AES analysis it was observed that percentage of lead was decreased as the *Marana* process from 99.46 to 85% after first *Jarana*, after last *Jarana* it again decreased to 80% and at last it was 58.4%. While the percentages of the elements like Ca, Fe, Mg, K, Mn, Zn, etc. was increased with the progress of *Marana*. These additional elements may have their origin from the herbs and other additives used during the preparation. These additional elements seem to be quite useful for maintaining fluid balance and enzymatic processes in the body system. On XPS study, surface elemental composition of *Naga bhasma* shows comparatively more percentage of oxygen, carbon and sulphur than that of lead which indicate that these elements might be taking part in the reactions earlier than Lead when administered in the body. This study claimed that TGA has advantages over *Niruttha Pariksha* as it require less sample (up to few mg), specific controlled mode of heating can be maintained, automated mechanism increases perfection in results. TGA can be established as the quality control test of *bhasma* in relation to *Niruttha Pariksha*. In short, as per this research work, TGA can be used as an up gradation of *Niruttha Pariksha*.

Table 4: Elemental assay of *Jarit Naga* & *Naga Bhasma* using acid digestion and alkali fusion method, ICP-AES technique

Sr. No.	Element (unit)	Jarit Naag	Naag Bhasma
1	Lead (Pb) %	85.0	58.4
2	Calcium (Ca) %	0.38	5.10
3	Silica (Si) %	0.24	2.19
4	Iron (Fe) %	0.03	1.44
5	Aluminum (Al) %	0.03	0.60
6	Potassium (K) %	0.02	0.18
7	Arsenic (As) %	0.56	0.34

8	Magnesium (Mg) %	0.053	0.96
9	Nickel (Ni) mg/g	< 10	79.9
10	Magnese (Mn) mg/g	29.9	13.1
11	Cadmium (Cd) mg/g	< 10	65.9
12	Zinc (Zn) mg/g	78.0	77.1

Pharmaceutical and Identification Study of *Naga Bhasma*:[7] In this study A.F.I (Ayurvedic formulatory of India) procedure was selected for the preparation of *Naga bhasma*. The lead content at the end of 50 and 60 *puta* have shown decrease in lead. The trace elements remain within the *bhasma* in the form of various oxides of calcium, tin, potassium, arsenic etc. The percentage of lead in the *Naga bhasma* samples of 50 *puti* and 60 *puti* were 14.118% and 13.872% respectively.

Table 5: Elemental Composition of *Naga bhasma*

Sample name	% of Lead	% of Fe
Naga bhasma (50 puta)	14.118	1.391
Naga bhasma (60 puta)	13.872	1.618

Pharmaceutical Standardization of *Naga Bhasma*:[8] In this study, an attempt was made to introduce SOPs for *Naga Bhasma*. *Naga Bhasma* was prepared three times by adopting two different methods. In the first method *Parada* and *Gandhaka* were taken as media, while the second method consists of *Ashwattha* (*Ficus religiosa*) and *Manahshila* (Realgar) used as media. The percentage increase in the *Naga Bhasma* prepared by first method was 5.03%, while in case of *Naga Bhasma* prepared by second method was 6.09%. The average percentage purity of *Naga* decreased from 97.38% to 81.44% after *Shodhana*. The percentage of (Pb) lead in *Naga Bhasma* was 28.29% and 30.80% in first and second methods respectively. Both *Bhasmas* were in PbS form chemically with other elements in traces. This study concluded that for preparation of good quality *Naga Bhasma* processes like *Shodhana, Jarana, Bhavana* and *Putapaka* are very important. *Laghuputa* of 50 *Upalas* (5 kg) for 1 kg *Naga* is found sufficient in initial stages of the *Marana* process. *Naga Bhasma* is found as lead sulphide (PbS), both the prescribed methods and having particle size between 57.4-120 m.

Studies on testicular regenerative potential of *Naga bhasma*:[9]Sing Maksoodan *et al*. studied testicular regenerative potential of *Naga bhasma* and concluded that *Naga bhasma* has noticeable regenerative potential on partially degenerated testes as it showed specific regenerative effect on germinal epithelium of testes. At higher doses *Naga bhasma* was found very effective, thus these findings are well collaborated with the *Ayurvedic* concept of *Vrishya* property of *Naga bhasma*. *Naga bhasma* is recommended in *Prameha* group of diseases and as *Deepana, Pachana, Vrishya* and *Balya*. The *Vrishya* property of the drug indicates its beneficial effects on testes. However, such property of *Naga bhasma* has not previously been worked out experimentally in animals. Considering this facts author conducted this study. As observed by other workers, out experimental study also revealed toxic effects of Cd Cl_2 on testes in the form of

fatty vacuolization and necrosis of germinal epithelium of seminiferous tubules. It was observed that higher the dose of administered *Naga bhasma*; lesser the (from 3 mg to 12 mg) toxic effects of Cd Cl_2 and the best result was noted at 12 mg dose where minimal degenerative changes were noted in one out of four animals. *Naga bhasma* when administered on partially damaged testes (by Cd Cl_2) the drug showed its regenerative potential. The drug showed best regenerative capability at 12 mg dose. Only one animal out of 4 revealed minimal degenerative change. At 6 mg dose level though all the four animals showed degenerative changes these were of very mild nature. The present study reveals that Cd Cl_2 is toxic to testicular germinal epithelium and its effects can be minimize by *Naga bhasma*. *Naga bhasma* also has testicular regenerative potential. In higher doses the drug is very effective. Thus these findings are well corroborated with the Aurvedic concept of *Vrishya* property of *Naga bhasma*. At the end author suggested that, to arrive at the valid conclusion further studies on larger groups of animals at different dose and duration are needed.

Some observations on the metal-based preparations in the Indian Systems of Medicine:[10]As per this study red lead, Pb3O4 is a compound oxide (2PbO.PbO2); it is not for internal use; it is harmful if inhaled or swallowed; it may cause harm to the unborn child or impair fertility. The *Naga bhasma* has several variants: black, white, yellow, redand green, made using different methods; these may differ from each other in composition. Plumbous oxide(PbO) is yellow, lead sulfide (PbS) is black, plumbic oxideis purple brown; no other simple inorganic compound of lead is green except pyromorphite (lead chlorophosphate:$Pb_5(PO_4)_3Cl$), a mineral green, yellow and brown in colour. Litharge - PbO is not for internal use; it may cause reproductive disorders; PbO is harmful by inhalation, ingestion and through skin contact. PbO_2 is a strong oxidizer giving off oxygen and PbO; may be fatal if swallowed or inhaled; a neurotoxin). PbO is dimorphous, in yellow and red form.

Synthesis, Characterization and Histopathological Study of a Lead-Based Indian Traditional Drug: *Naga Bhasma*:[11]According to this work, grinding and heating of the material several times in presence of some herbal juices leads to the generation of specific compound form of the elemental lead of highly crystalline nature. Submicron size particle of the sample may be attributed to the grinding of raw materials for a long duration (similar to the Top-Down approach of the formation of nanostructure materials in modern nanotechnology) as well as the heat treatment which causes the change in the chemical nature of the raw materials. This study hypothesized that the *Naga bhasma* acts as the carrier of the medicinal property of *Nirgundi*, turmeric, *Vasa* and *Neem*. Presence of carbon and oxygen on the surface of the drug by XPS analysis also supports the idea of the association (coating) of organic molecules on the surface of the metallic compounds. These macro molecules associated with the *bhasma* certainly play an important role in increasing the efficacy and efficiency and in making these drugs biologically assimilable. The study suggested that, effort in the detection and role of these organic molecules is highly needed. Elemental analysis shows the presence of different nutrient elements in considerable trace amount. The specific role of these

elements in the *bhasma* is not yet very clear. Histopathological study in the article is preliminary and shows the non-toxic nature of the drug at low dosages. An extensive study is needed for the complete pharmacokinetic study on the animal system.

Effect of dose on lead retention and distribution in suckling and adult female mice:[12] In this study, single doses of lead (trace to 445 mg/kg) were administered *per os* to suckling and adult mice. Both groups exhibited dose-independent lead retention when doses of 4 to 445 mg/kg were administered. However, developmental differences in the fraction of initial dose (FID) retained were evident for all doses administered. A much larger FID was retained in both age groups following administration of carrier-free ^{203}Pb. Developmental differences were also observed in organ lead concentration relative to whole body concentration for kidneys, skull, and brain 6 days following lead administration. Lead retentions (relative to whole body retention) in brain and in bone were linearly related to dose of lead administered in both suckling and adult age groups. Though uptake of lead into brain and into femur was observed to be directly related to dose over a wide range, relative blood lead concentrations were not linearly correlated with dose administered. The relationships between lead concentrations of blood and organ(s) were also shown to be nonlinear relative to dose.

The effect of dose on the disposition of lead in rats after intravenous and oral administration:[13] In this study single doses of lead acetate were administered to 250- to 350-g rats by both intra-venus (0.5–15 mg Pb/kg) and oral (1–100 mg Pb/kg) routes, and blood lead concentrations were measured up to 25 days following dosing. The area under the blood lead concentration vs time curve (AUC) after IV dosing increased in proportion to increases in the dose. It was observed that total blood lead clearance and renal lead clearance were not related to the magnitude of the injected dose. After oral dosing, blood lead concentrations (and AUC) did not increase proportionately with dose. After a 1 mg/kg lead dose, the extent of absorption was estimated at 42%; this decreased to 2% when the dose was increased to 100 mg/kg. Lead concentrations in the blood, kidneys, liver, and brain of both adult and suckling rats recovered 24 hr after various single oral doses also indicated that the extent of lead absorption decreased substantially with increasing dose. The results suggested that the mechanism for gastrointestinal absorption of lead is largely capacity-limited in adolescent and adult rats.

Kinetics of lead retention and distribution in suckling and adult rats:[14]The kinetics of lead distribution was studied in suckling and adult rats 8 days after a single intraperitoneal injection of ^{203}Pb. Marked differences were observed in the kinetics of lead retention and distribution in suckling as compared to adult rats. The rate of ^{203}Pb disappearance was lower in the whole body, blood and kidneys, but higher in the liver, while the deposition processes predominated in the brain, femur and teeth of suckling as compared to adult animals.

A Preparative and analytical study of Ayurvedic *Bhasmas* with regards to *Naga Bhasma*:[15] This analytical study of *Naga Bhasmas* was taken up to study the pharmaceutical standardization of *Naga Bhasma* and to evaluation of physico-

chemical nature of final products. For pharmaceutical standardization, traditional *puta* as well as electrically heated muffle furnace were used. For the analysis of *basmas* conventional qualitative and quantitative chemical analytical methods were applied and found that *bhasma* of *Naga* contain 55 %, 56 % or 69 %, 70 % Pb. The findings of Infrared spectroscopy metallography and X-ray diffraction techniques suggest polymeric phases in *bhasmas*.

Anti-diabetic formulations of *Nāga bhasma* (lead calx)[16]: In this study author reviewed 44 formulations of *Nāga bhasma* mainly indicated for *Prameha* (diabetes). This work found that, according to the properties of *Nāga bhasma,* it is mainly useful in *Vātaja-Kaphaja Prameha* and should be used cautiously in *Pittaja* type of *Prameha. Haridrā, Āmalakī, Guḍūci* and *Madhu* enhance the antidiabetic action of *Nāga bhasma* and also are helpful in preventing diabetic complications. Most of the formulations of *Nāga bhasma* are not available in the market and no research work has been performed on the safety of these formulations. Thus, there is an urgent need to conduct research on safety and efficacy of antidiabetic formulations of *Nāga bhasma.*

Comparative pharmaceutical standardization of *Naga Bhasma* (Incinerated Lead) prepared by two different methods[17]: Aim of This study was to establish comparative pharmaceutical standardization of *Naga Bhasma* prepared by two different methods. *Samanya shodhana* of *Naga* was done by three times quenching in *Tila taila*, *Takra*, *Gomutra*, *Kanji* and *Kulattha kwatha*. *Vishesha shodhana* was done by seven times quenching of melted *Naga* in *Churnodaka*. *Naga Bhasma* was prepared in six batches, three batches with *Vasa* (*Adhatoda vasaica* Niss.) as herbal media and three batches with *Parada* as media. This work concluded that gravimetrically double quantity of liquid media than weight of *Naga* is more suitable for *shodhana* process. *Jarana* and *Pishti* preparation makes further incineration procedure easier in the method which utilizes herbal and *Parada* media respectively. Average 69.4 % and 30.11 % *Naga Bhasma* can be prepared in seven incineration cyclesin EMF at maximum temperature 6500C by *Vasa* and *Parada* media respectively. Preparative procedure of *Naga Bhasma* with *Vasa* media is easier *Naga Bhasma* prepared form *Parada* media.

Standard operating procedure of *Naga Shodhana* and study of chemical changes in the media and *Shodhita Naga*[18]: In this work, *Naga Samanya* and *Vishesha shodhana* was done according to the reference of *Sharangadhara samhita* and *Rasatarangini* respectively. Physico-chemical analysis of *shodhana* media was done before quenching and after quenching of melted *Naga*. Analysis of *Ashuddha Naga* (raw lead) and *Vishesh shodhit Naga* was done by purity testing, FTIR (Fourier Transform Infrared Spectrometry) and TGA (Thermogravimetric Analysis). According to this study, increase in SG and total solid content of *shodhana* media indicate dissolution of some particles of *Naga* or some impurities. The report of TGA showed the presence of non-volatile organic compounds in *shodhita Naga*. FTIR analysis of *ashuddha Naga* was evident of inorganic molecules while in *shodhita Naga* various organic functional groups like CH and C-N were found.

Analytical finding of *shodhita Naga* were suggestive of organo-metallic complex formation.

Pharmaceutical standardization of *Naga bhasma* (Incinerated lead) prepared by using herbal media[19]: Pharmaceutical standardization in preparation of medicines is an essential requirement for good manufacturing practices as well as to insure the quality and quantity of final product. The preparative technology of *Naga bhasma* is complex, laborious and time consuming procedure. *Shodhana* process helps in increasing brittleness of metal. *Jarana* procedure plays vital role in exposing maximum surface are of *Naga* for *bhavana* and incineration cycles. For preparation of *Naga bhasma* gradual increasing followed by alternate increasing and decreasing pattern of temperature is necessary. *Naga bhasma* can be prepared in 28 days with 96.24% yield.

Experimental study on anti-hyperglycemic effect of *Naga Bhasma* (incinerated lead)[20]: This experimental study shows that *Naga bhasma* prepared from *Parada* media and herbal media have no hypoglycemic action but possess moderate anti-hyperglycemic effect after one hour and significant anti-hyperglycemic effect compared to initial BSL. But this difference is statically non-significant when compare in between both the groups. More numbers of are required to induce better significant antihyperglycemic property in *Naga Bhasma.*

Literary study on Ayurvedic view on heavy metal poisoning with special reference to *Naga bhasma* (Incinerated Lead)[21]**:** Present work centered on the fact of heavy metal poisoning and Ayurvedic point of view towards the use of such metals with special reference to current research on toxicity of *Naga bhasma*. This study clearly shows that *t*he herbo-metallic preparations of ayurveda including *Naga bhasma* are safe and devoid of any major untoward effects, when manufactured and administered by following specified classical guidelines. The direction given by *Acharya Charaka* support this theory that is even fatal poison when used with skill and knowledge proves to be a good medicine, and a medicine used ignorantly acts as a poison. For the better safety of ayurvedic herbo-metallic medicines, it is high time that instead of blindly following the text and prescribing the medicine, one should test it thoroughly for its side effects, dose, duration and toxicity in the target organ of the body. These tests will allow us to form some guidelines regarding contra-indications of our drug, and also unravel the myths and ambiguities about *Rasaushadhis*.

CONCLUSIONS:*Naga bhasma* is one of valuable medicament discovered by seers of Ayurveda but it is also a drug which is facing great concern of heavy metal poisoning. Therefore Ayurveda researchers have conducted significant work on nearly every major aspect of related with this drug which includes conceptual review, toxicity studies, standardization, characterization, anti-diabetic study, anti-hyperglycemic study, comparative evaluation and histopathological studies. All these research works have built guideline for quality standards and safety profile of *Naga bhasma*.

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