



Development and Assessment of Shilajit Sustained-Release Pellets as an Optimized Alternative to Traditional Dosage Forms

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Received: June 03, 2025

Published: June 16, 2025

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Abstract

Shilajit, a well-known Ayurvedic rasayana, has traditionally been consumed in various forms, including resin, and powder. This study explores the innovation behind Shilajit SR pellets, which were created to address common consumer concerns such as bitter taste, messy handling, and frequent dosing. These sustained-release pellets provide controlled absorption, improved handling, taste masking, and convenient once-a-day use. The SR pellets, developed by Umang Global Pvt Ltd, were evaluated against traditional Shilajit products for assay value, fulvic acid content, and dissolution profiles. Laboratory testing confirmed consistent active ingredient levels and extended-release performance, which promotes long-lasting energy, endurance, and wellness. Shilajit SR pellets provide a modern, user-friendly solution that bridges traditional Ayurveda and contemporary lifestyle needs by adapting to tablets, capsules, gummies, and drinks. This research article concludes that Shilajit sustained release (SR) pellets offer an advanced and user-friendly alternative, effectively integrating traditional supplements with modern drug delivery technologies. [1,2]

Keywords: Shilajit SR Pellets; Comparison Study; Release Profile; Shilajit Formulations; Improved Handling; Sustained Release Formulations

Abbreviation

SR: Sustained Release, UFBM- Umang Fluid Bed multiprocessor

Introduction

Shilajit is a dark brown to black, sticky, tar-like substance that naturally exudes from rocks in high mountain areas, particularly in the Himalayas, and has sparked interest for its potential health benefits. It is formed over hundreds of years through the slow breakdown of plants by microorganisms. This natural process primarily occurs in high-altitude regions (1,000-5,000 meters) throughout Asia, the Middle East, Africa, Europe, Australia, and Latin America [1-3].

Shilajit is known by a variety of names worldwide, including salajit, shilajatu, mummiyo, and mineral pitch. There are four different types of Shilajit: Tamra (copper), that is blue in color, Rajat (silver) which is white in color, Suvarna (gold) that is red in color and Lauha (iron) which is blackish brown in color. It has been used for thousands of years in traditional medicine, particularly in Ayurveda, where it is considered, a rejuvenating substance known as a "rasayana" [4-6].

The composition of this material is a complex mixture of minerals and organic matter. Its main constituents are minerals, proteins,

dibenzo- α -pyrones, and fulvic acids. The chemical composition of Shilajit varies depending on its geographical source, but it typically contains more than 80% humic substances and about 20% minerals such as calcium, potassium, and magnesium. It has been used to promote fertility, increase strength, increase energy, and improve general wellness [6,7].

Shilajit is available in various dosage forms in the commercial market, catering to both traditional and modern preferences. The most used form is the purified resin or raw form, which is a sticky, tar-like substance typically dissolved in warm water or milk before consumption. In addition, Shilajit is marketed in powdered form, often mixed with liquids or other herbal formulations, and in capsule or tablet form, which offer convenience and improved shelf life. Liquid extracts or tinctures are also available, offering a more rapid absorption, especially when taken sublingually [8,9].

Despite the widespread availability of Shilajit in traditional dosage forms such as resin, powder, tablets, capsules, and tinctures, these formats often suffer from issues like inconsistent dosing, unpleasant taste, variable bioavailability, and instability of bioactive compounds—particularly fulvic acid and dibenzo- α -pyrones. These limitations can hinder therapeutic effectiveness and consumer compliance [9-11].

In response to these challenges, the formulation of Shilajit SR pellet offers a promising alternative. The development of Shilajit SR Pellets presents a novel and effective approach to overcoming challenges associated with traditional dosage forms.

Shilajit SR pellets are small, free-flowing, spherical particulates manufactured by using a mixture composed of 75% Shilajit resins and 25% non-pareil seeds processed through a defined method. In this process, Shilajit is dissolved in water, while non-pareil seeds is incorporated into UFBM. The operation is carried out under controlled conditions, including a temperature and inlet temperature of 50-70°C, a blower speed of 1800-2100, and a pump setting ranging from 1.5 to 2. These multiparticulate systems offer a range of pharmaceutical advantages, including excellent flow properties, high surface area for active release control, and flexibility in de-

signing modified active delivery profiles. These SR Pellets can be integrated into capsules, gummies sachets or compressed into tablets, and are suitable for immediate or sustained release applications, with the added benefit of taste masking through functional coatings.

Moreover, Sustained release (SR) Shilajit pellet formulations provide controlled release resulting in more consistent levels, reduced dosing frequency, and improved therapeutic outcomes. These SR pellets also offer a dose uniformity, flow properties, improved bioavailability and stability, addressing the key formulation challenges faced by conventional Shilajit formulations. By providing a more predictable and consumer-friendly delivery system, SR pellets present a modern solution aligned with current trends in evidence-based herbal medicine [12,13].

The excellent flow properties of Shilajit pellets facilitate high-speed capsule filling and tablet compression with minimal processing challenges. Furthermore, their spherical geometry and low surface area-to-volume ratio make them ideal for uniform and reproducible film coating. Compared to conventional tablets, pellet-based formulations help reduce the risk of dose dumping and lower the chances of adverse drug reactions due to their controlled release behavior [14,15].

These Sustained release pellets can be used in various oral dosage forms, enhancing delivery and consumer compliance. They can be used in capsules, tablets, gummies, chewing gum, sachets and beverages.

Shilajit SR pellets: An enhanced alternative to conventional shilajit formulations

Sustained release for enhanced efficacy

Shilajit SR pellets enable the gradual release of active compounds from Shilajit over an extended period. This sustained absorption maintains steady plasma concentrations, ensuring prolonged adaptogenic, antioxidant, and anti-fatigue effects. Unlike conventional forms that may result in peaks and troughs in bioavailability, SR pellets provide a consistent action, maximizing Shilajit's potential benefits throughout the day [15,16].

Reduced dosing frequency

Shilajit SR pellets minimize the need for frequent dosing. Most conventional Shilajit formulations require multiple daily intakes due to rapid metabolism or inconsistent absorption. With SR pellets, consumers benefit from once-day or twice-daily dosing, significantly improving compliance and convenience, especially for long-term users.

Improved handling and precision dosing

Traditional Shilajit, particularly in resin or tar-like form, is messy, sticky, and difficult to measure accurately. SR pellets overcome these challenges by offering a solid, spherical shaped and easily measurable format. This results in precise doses without the inconvenience of handling sticky substances, improving the user experience and enabling consistent use [17].

Versatile integration in dosage forms

SR pellets offer exceptional formulation flexibility. They can be seamlessly incorporated into a wide range of delivery formats, including tablets, capsules, gummies, Sachets, chewing gums, and functional beverages. This versatility supports broader market applications and meets diverse consumer preferences in both pharmaceutical and nutraceutical domains [18].

Enhanced odour and taste masking

Conventional Shilajit is often associated with a strong, bitter taste and pungent odour, which can negatively impact user experience and adherence. Shilajit pellets address this challenge through advanced coating and sustained release technology, which effectively masks unpleasant sensory characteristics. This results in a more neutral, palatable formulation, making it significantly more acceptable and user-friendly compared to traditional Shilajit dosage forms [19].

Improved tolerability and safety

Conventional Shilajit formulations, especially in high doses or when taken on an empty stomach, can sometimes cause gastrointestinal discomfort or irritation. SR pellets mitigate this issue

by releasing bioactive gradually, promoting better absorption and minimizing gastric side effects. This leads to improved long-term tolerability and patient safety, especially in chronic usage scenarios [20].

Broad consumer adaptability

SR pellets are well-suited for varied demographic groups, including elderly populations, athletes, corporate professionals, and wellness enthusiasts. Their ability to be incorporated into familiar formats (e.g., gummies, chewing gum, sachets and or drinks) also makes them appealing to consumers who are new to traditional medicine or reluctant to try raw Shilajit [21].

Objective

The primary objective of this study is to evaluate and compare the performance of Shilajit sustained release (SR) pellets developed by Umang Global Pvt Ltd with conventional Shilajit dosage forms commercially available in the market, such as resin and powder. The research aims to investigate the SR pellets' potential to overcome the limitations associated with traditional forms by examining key parameters such as assay value, content uniformity, stability of bioactive compounds, and in vitro dissolution profile—particularly focusing on fulvic acid, a key active constituent in Shilajit.

The study also seeks to assess the formulation advantages of SR pellets, including improved dose precision, taste and odor masking, ease of handling, and extended-release properties that may lead to reduced dosing frequency, better gastrointestinal tolerance, and enhanced patient adherence [22].

By integrating modern technology with a time-tested traditional ingredient, the objective is to verify whether the Shilajit SR pellet formulation provides a pharmaceutically and therapeutically superior alternative to conventional Shilajit formulations. Through this comparative analysis, the study evaluates whether Shilajit SR pellets represent a more effective, consumer-compliant, and pharmaceutically enhanced alternative to traditional Shilajit formulations [23].

Material and Methods

Chemical and apparatus required

All the chemicals and solvents, and elemental standards were purchased from Merck, India Distilled water, 0.1M Hydrochloric acid, Sodium Hydroxide. Glass funnel, 1000 ml Erlenmeyer flasks, measuring cylinders (100ml, 500ml), Graduated burette, Pipette.

Weighing Balance (Shimadzu ATX224), Lab Oven (Universal), Muffle Furnace (Universal), Sonicator (Life Care), pH Meter (DBK), Water Bath (Universal), Hot Plate (Universal).

Sample

The following Shilajit samples were produced from various commercial brands:

- Kapiva Origin Himalayan Shilajit (Kapiva)
- Dabur Himalayan Shilajit Resin (Dabur India Ltd.)
- Shilajit SR Pellets (Umang Global Pvt Ltd)

Procedure

Accurately weigh a representative sample and dissolve it completely in 100 mL of 0.1 N sodium hydroxide (NaOH) solution. Subject the solution to sonication for 6 minutes to ensure complete dissolution and uniformity. Centrifuge the solution to remove any undissolved particles. Carefully decant the supernatant into a clean container and acidify it by adding 20 mL of hydrochloric acid (HCl). Filter the resulting precipitate through a pre-dried and tared filter paper or a G4 crucible. Wash the precipitate with distilled water until the washings are free from chloride ions. Perform this washing step at least three times to ensure purity. Dry the washed precipitate at 120°C to a constant weight. Retain the filtration for the estimation of fulvic acid content. To the filtration, add NaOH to make it alkaline. Boil the solution for 5 minutes. Allow the solution to cool, then adjust its pH to acidic using 1 N HCl. Evaporate the acidified solution to a volume of 5–10 ml. Transfer the concentrated solution to a pre-weighed and pre-heated crucible. Evaporate and dry the contents at 105°C to a constant weight, denoted as W₁. Ignite the crucible containing the dried residue at 600°C to constant weight, denoted as W₂.

Calculation:

% Of fulvic acid= $\frac{W_1 - W_2}{W_1} \times 100$

Weight of Sample taken

Results and Discussion

Result

Assay

Product	Assay	
	Reading 1(%)	Reading 2(%)
Dabur Himalayan Shilajit Resin	66.20	66.25
Kapiva Origin Himalayan Shilajit	79.63	79.72
Shilajit SR Pellets Manufactured by Umang Global Pvt Ltd	65.55	65.57

Table 1

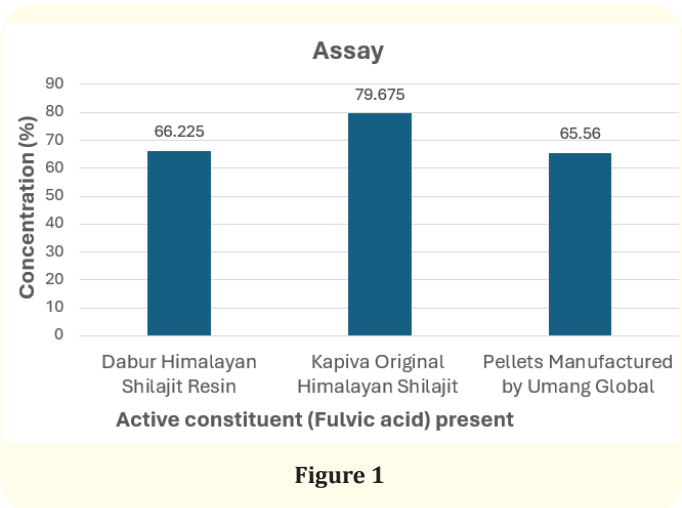


Figure 1

A repetitive assay analysis was conducted to evaluate the quantity of active constituents in various Shilajit formulations, including both conventional dosage forms and sustained-release pellets. The findings confirmed that all tested samples demonstrated a presence of Active constituents consistent with their respective label claims, indicating that the therapeutic integrity and potency of the products remains intact across different formats. Dabur Himalayan Shilajit Resin showed consistent assay readings of 66.20% and

66.25%, while Kapiva Origin Himalayan Shilajit recorded values of 79.63% and 79.72%. These results demonstrate that the formulations maintain their level of active ingredients as per label specification.

Similarly, the sustained release Shilajit Pellets manufactured by Umang Global Pvt. Ltd. presented assay results of 65.55% and 65.57%, confirming that the active constituents’ content aligns with the product claims. The consistency in assay results observed across both conventional and pellet formulations underscores that the transition to a pellet form does not compromise the product’s therapeutic integrity.

Dissolution profile for Shilajit SR Pellets

Time	Limit	Release (%)
1 hr	NMT 15%	10.7
4 hr	NMT 55%	49.9
8 hr	NLT 80%	82.8

Table 2

Graphical representation of release profiles

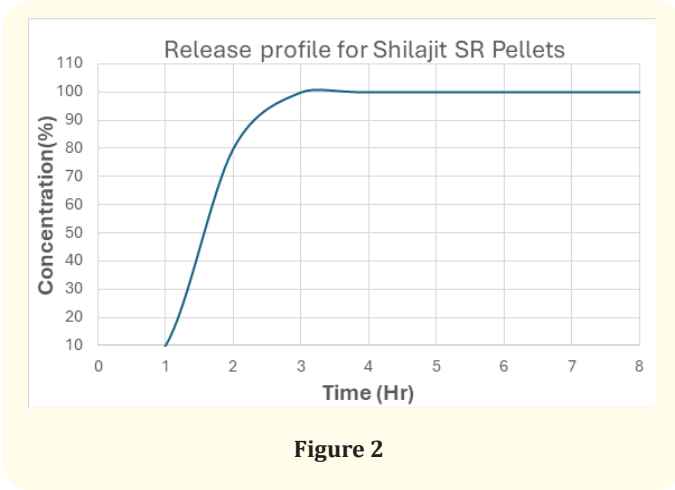


Figure 2

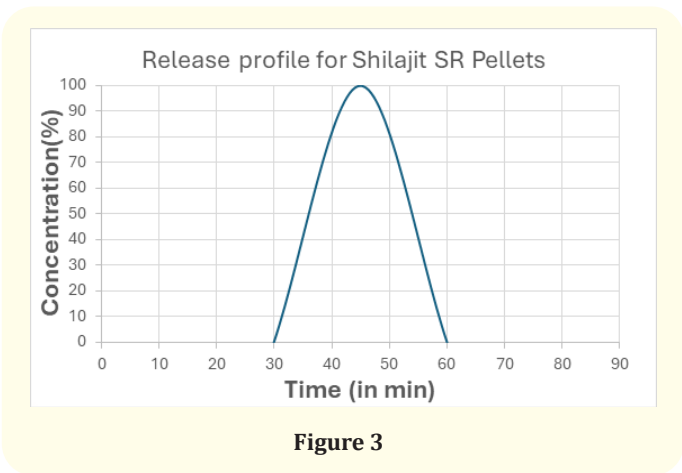


Figure 3

The dissolution study for conventional and sustained release (SR) Shilajit formulations highlights significant differences in how active constituents are released over time. As illustrated in the graphs, the conventional Shilajit formulations from Dabur and Kapiva exhibit a rapid release pattern, where 100% of the active ingredient is released within a minute. followed by a sharp and short-lived decline in concentration. This immediate-release behavior reflects the typical characteristics of conventional dosage forms, which are designed for quick absorption but have a limited duration of action. Such formulations may require multiple doses throughout the day to maintain their effectiveness, and the sharp rise and fall in concentration can lead to fluctuations in plasma drug levels.

In contrast, the sustained-release Shilajit pellets developed by Umang Global Pvt. Ltd. demonstrate a gradual and controlled release pattern. The assay results show that only 10.7% of the active ingredient is released at the first hour, increasing to 49.9% at four hours, and reaching 82.8% at eight hours. This extended-release profile supports a long-lasting therapeutic effect ensuring slower, more consistent delivery of the active constituents over an extended period, which can help maintain steady therapeutic levels and reduce the need for frequent dosing. This sustained release approach also reduces the likelihood of side effects associated with peak concentrations and provides better gastrointestinal tolerance by avoiding the sudden release of high doses in the digestive tract.

Unlike conventional dosage forms that offer immediate absorption, the SR Shilajit pellets provide a controlled and gradual release of active constituents over an extended period providing a long-lasting effect. This prolonged release mechanism enhances the overall duration of action, making the pellets especially advantageous for long-term use.

Moreover, sustained-release pellet formulation demonstrated multiple advantages, including improved handling characteristics, effective taste and odor masking, controlled active release kinetics, enhanced gastrointestinal tolerance, and increased user convenience attributed to reduced dosing frequency. These advantages make them a suitable choice for consumers seeking reliable, long-lasting supplementation without sacrificing efficacy.

Discussion

This study was conducted to compare the performance of conventional Shilajit dosage forms, such as resin and powder, with the newly developed Shilajit sustained release pellets by Umang Global Pvt. Ltd. The comparison was based on key parameters including assay value, uniformity, and dissolution release profile of fulvic acid, one of Shilajit's main active components.

Assay testing of all evaluated samples, including Dabur Himalayan Shilajit Resin and Kapiva Origin Himalayan Shilajit, confirmed compliance with their respective label claims, demonstrating consistent levels of active constituents and thus confirming their retained therapeutic potency. Furthermore, the sustained-release (SR) Shilajit pellets exhibited stable and uniform assay values across multiple batches, suggesting that the novel formulation successfully preserves the integrity and concentration of the active compounds. This stability is critical for ensuring predictable pharmacological effects and emphasizes the SR pellets' potential as a viable alternative to conventional formulations, especially in applications that require prolonged effectiveness and improved compliance. However, while the conventional forms are effective, they typically release their contents rapidly, leading to quick absorption but also shorter duration of action and the need for repeated dosing throughout the day.

The dissolution study for the conventional forms shows an immediate and complete release of active constituents within the first hour; their effects are short-lived, leading to rapid depletion and potential fluctuations in therapeutic efficacy. This release pattern may necessitate multiple daily doses, affecting consumer compliance and increasing the risk of side effects associated with peak plasma concentrations. Whereas the dissolution profile for Shilajit SR Pellets formulated by Umang Global shows a gradual active release over an extended period. This sustained release helps maintain more consistent levels of fulvic acid in the body, providing longer-lasting effects and stable plasma concentration. These SR pellets ensure consistent dosing, improved handling, masked taste, enhanced bioavailability and potentially improving overall therapeutic outcomes. This sustained or controlled release can be especially beneficial in reducing the frequency of dosing, improving user convenience, and minimizing fluctuations in active ingredient levels, which can sometimes lead to reduced effectiveness or side effects.

Moreover, the Shilajit SR pellets offer several additional advantages, including improved stability of bioactive compounds, enhanced dose accuracy, extended shelf life, and increased consumer compliance. Traditional resin and powder forms often present challenges such as unpleasant taste, inconsistent dosing, and faster degradation, all of which can negatively affect both user experience and therapeutic efficacy. The pellet formulation effectively addresses these issues by providing enhanced palatability, consistent dosing, greater stability, and ease of administration, ultimately leading to a more user-friendly and adaptable consumer experience.

Furthermore, the versatility of SR pellets allows them to be incorporated into a wide range of consumer-friendly formats such as capsules, sachets, gummies, and functional beverages, offering broader market adaptability and appeal across different age groups and lifestyles.

In summary, while traditional Shilajit products remain effective, the SR pellet formulation presents a modern and improved alternative. It combines the natural benefits of Shilajit with enhanced

pharmaceutical properties, making it more suitable for long-term and consistent use. This approach aligns with the growing demand for more reliable and user-friendly herbal supplements, suggest-

ing that Shilajit SR pellets have the potential to become a preferred dosage form for delivering the health benefits.

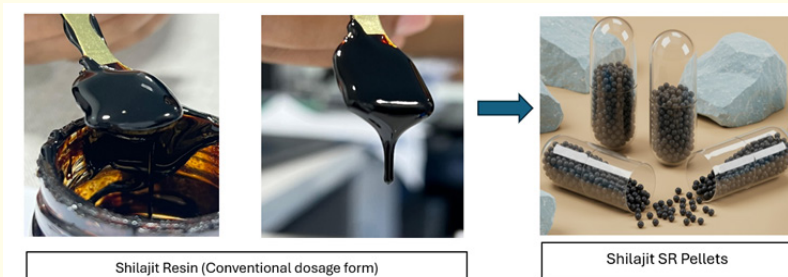


Figure 4

Conclusion

Shilajit SR pellets are a modern and effective alternative to traditional Shilajit formulations, offering sustained release, improved bioavailability, and increased patient compliance. The formulation addresses important limitations such as unpleasant taste, inconsistency in dosing, and short duration of action. These findings show that Shilajit SR pellets as a pharmaceutically superior and user-friendly delivery system that combines traditional benefits with modern therapeutic requirements.

Conflict of Interest

None.

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