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A REVIEW ON SUSTAINED RELEASE ANTIDIABETIC TABLET USING NATURAL POLYMERS: MECHANISM AND APPLICATIONS

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ABSTRACT

Diabetes mellitus is a long-term metabolic condition that requires constant treatment to keep normal blood glucose levels and avoid associated complications. Irregular blood drug levels, frequent dosing, and poor patient compliance can cause due to the traditional immediate release antidiabetic tablets that often release drug rapidly. To overcome these problems, sustained release oral dosage forms have been developed to deliver drug slowly for an extended duration, helping to maintain stable therapeutic levels and improve patient adherence. Lately, natural polymers have increased attention in the formulation of sustained release antidiabetic tablets because of their beneficial features safety, biocompatibility, low toxicity, affordability, and environmental friendliness. The role of natural polymers in developing sustained release antidiabetic tablets, focusing on their ability to control drug release through swelling, diffusion, and erosion mechanisms in this review discussed. Usually used natural polymers, including chitosan, xanthan gum, sodium alginate, gaur gum, and fenugreek mucilage are emphasized for their physicochemical characteristics and usefulness in matrix-based drug delivery approach. Various formulations methods, in-vitro evaluation tests, and drug release kinetic models used to study sustained release behavior are also outlines by this review. In addition, recent developments, regulatory aspects, and future research directions are briefly discussed. Overall, natural polymer-based sustained release antidiabetic tablets represent a reliable, efficient, and patient convenient strategy for long-term diabetes management.

Keywords: Antidiabetic drugs, Sustained release, Natural polymers, Oral dosage form, Matrix tablets

1. INTRODUCTION

Diabetes mellitus is a long-term metabolic condition marked by continuous elevated blood glucose concentrations caused by insufficient insulin production and decreased insulin activity, or both. The disease impacts carbohydrate, lipid and protein metabolism and leads to severe long-term complications if not adequately controlled. Diabetes mellitus is broadly categorized into type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM), gestational diabetes, and other distinct forms associated with genetic or secondary causes. A rapid increase in diabetes prevalence due to urbanization, dietary changes, and sedentary lifestyles are experiencing in developing countries, particularly India [1]. Diabetes is a lifetime disorder that requires continuous pharmacological interference to control blood sugar concentrations and escape neuropathy, nephropathy, cardiovascular diseases, retinopathy and stroke like complications [2]. In diabetes management conventional immediate release antidiabetic dosage forms are commonly used due to their simplicity and fast onset of action. However, these preparations often produce fast drug absorption, leading to variations in plasma drug concentrations [3]. Sustained release drug delivery approaches have been

developed to overcome these limitations and to provide regulated and sustained drug release for a sustained duration [4]. By escaping sharp fluctuations in drug concentration, sustained release preparations improve therapeutic efficacy and advance patient adherence [5]. Oral sustained release antidiabetic tablets help keep consistent glycemic control and decrease the frequency of dosing, thereby improving the quality of life of diabetic patients [6-10].

2. SUSTAINED THERAPEUTIC RELEASE SYSTEMS

2.1 Definition of Sustained Release

Sustained release dosage forms provide medication over a prolonged duration to sustain plasma levels above the lowest effective concentration. The primary goal involves extending drug action, mostly for agents with short half-lives, ensuring stable state conditions with reduced dosing intervals [11].

2.2 Benefits of Sustained Release Tablets Formulation

Multiple clinical benefits are provided by sustained release tablets, transforming patient management for chronic therapies.

- Reduced Dosing Frequency
- Improved Patient Compliance
- Better Glycemic Control

- Reduced side effects

2.3 Limitations of Sustained Release Systems

- Despite advantages, challenges persist in design and application.
- Dose dumping risks occur if formulation variable, leading to overdose [12].
- Not suitable for narrow therapeutic index drugs due to overdose potential
- Drug extraction by addicts poses abuse liability

3. ANTIDIABETIC DRUGS SUITABLE FOR SUSTAINED RELEASE

The challenges of frequent dosing in diabetes management are addressed by the sustained release preparations of antidiabetic drugs by providing prolonged therapeutic plasma levels. These systems are mainly valuable for oral hypoglycemics, enhancing glycemic control while minimizing fluctuations that lead to complications [13, 14].

3.1 Suitable Antidiabetic Drugs

Due to their pharmacokinetic profiles several antidiabetic agents prove ideal for sustained release.

- **Glimepiride:** For 24-hour control without peak-related hypoglycemia, this long-acting sulfonylurea (5-9 hours half-life) adapts well to matrix tablets [15].

- **Sitagliptin:** A DPP-4 inhibitor with 12.4-hour half-life shows sustained preparations to keep postprandial glucose reduction and incretin effects [16].

3.2 Criteria for Drug Selection

Bioavailability and oral drug absorption are ensured by whole gastrointestinal absorption, preferably pH-dependent [17]. Polymer matrix entrapment for diffusion-controlled kinetics is facilitated by low aqueous solubility [18].

4. NATURAL POLYMERS IN SUSTAINED RELEASE TABLETS

In formulation of sustained release tablets naturally derived polymers have a crucial role, leveraging their inherent swelling and gelling properties to maintain drug liberation over sustained period. Hydrophilic matrices that hydrate upon gastrointestinal contact are formed by these biopolymers, generating diffusion barriers for zero order kinetics in antidiabetic treatments [19].

4.1 Advantages of Natural Polymers

1. Biocompatibility and Non-toxicity:

Good compatibility systems and minimal toxicity are usually exhibit by most plant derived ingredients contain mainly of polysaccharides containing sugar units.

2. **Local Availability:** Government creativities often inspire the cultivation and processing of plants used to get pharmaceutical excipients like gums and mucilage, enabling large-scale production.
3. **Better Patient Acceptance:** Patients and public generally well accepted natural materials. As they are less likely to produce adverse or side effects, which increases their suitability for pharmaceutical applications, when compared with synthetic substances [20].
4. **Eco-friendliness:** Synthetic processing emissions, aligning with sustainable development goals are minimize by bio-based origins. This aligns with ecofriendly processing techniques [21].

4.2 Classification of Natural Polymers

Categorization reflects molecular structure, dictating matrix performance in sustained release.

Polysaccharides: Cellulosic and non-cellulosic types swell to regulate diffusion. starch achieves pH-independent erosion [22].

Gums and Mucilage's: The gum possesses lot of hydrophilic functional groups that make them water soluble [23]. Seed or exudate hydrocolloids provide viscosity gradients.

5. COMMONLY USED NATURAL POLYMERS

1. Gaur gum

Guar gum, also known as Cyamopsis gum, Guaran, Cluster bean gum, and Guarem, is a naturally occurring polysaccharide derived from the endosperm of the seeds of *Cyamopsis tetragonoloba* Linn., a plant belonging to the Leguminosae family. Chemically, guar gum is classified as a galactomannan, made up of the monosaccharide's mannose and galactose. Its molecular structure it is made up of a linear chain of β -(1 $\rightarrow$ 4)-linked mannose residues, with α -(1 $\rightarrow$ 6)-linked galactose residues attached as side chains at regular intervals. Its biodegradable and bio adhesive properties make it particularly suitable for controlled and drug delivery systems targeting the colon. Additionally, gaur gum is utilized as disintegrants, binders and matrix-forming agents in tablets, where their high hydration and swelling capacity supports sustained drug release [20].



Fig. 1: Gaur Gum

2. Chitin and chitosan

Chitin and chitosan are two of most researched natural polymers, prized for their

cationic and multifunctional attributes in pharmaceutical formulations, particularly fast-dissolving tablets (FDTs) [18]. As super disintegrants, they enable sublingual disintegration in 10-30 seconds. Chitin (2-10%) swells and wicks saliva, while chitosan's repulsion mechanism protonation-induced charge buildup—accelerates breakdown, as patented in FDTs via direct compression [24]. Biodegradable by lysozymes, non-toxic, and hemostatic, they outperform synthetics in biocompatibility. Drawbacks like viscosity sensitivity are mitigated by derivatives.



Fig. 2: Chitosan

3. Fenugreek Seed Mucilage

Fenugreek mucilage emerges as a promising natural polymer with antidiabetic potential alongside pharmaceutical applications, as it is extracted from *Trigonella foenum-graecum* seeds. Fenugreek mucilage demonstrates its antidiabetic property like hypoglycemic effects by enhancing glucose transporter translocation, boosting hexokinase activity, and enzymes like α -amylase and glucose-6-phosphatase inhibiting, which collectively minor blood glucose levels. The mucilage shows superior swelling and disintegrant

characteristics as natural polymers when compared to synthetic alternatives like Crospovidone, enabling quicker tablet dissolution for better bioavailability. This mucilage formulations viable for antidiabetic drug delivery systems as shows dual role excipient and bioactive [25].



Fig 3: Fenugreek seed mucilage

4. Xanthan gum

Xanthan gum stands as one of the mostly used natural gums, well known for its exceptional gel forming ability, pseudo plastic rheology and biocompatibility in pharmaceutical and food applications. In matrix tablets, xanthan concentration inversely modulates hydrophilic drug diffusion, swelling via hydration while eroding slowly [26]. Additionally, XG is suitable carrier for drug delivery as it is nontoxic, biodegradable, and biocompatible [27]. Mucoadhesive properties drive buccal patches, in situ nasal gel, and nanoemulgels for carbamazepine. Hydrogels exhibit ionic strength-sensitive release (gentamicin burst then sustained). FDA approved (GRAS), its non-toxicity, biodegradability, and versatility cement

xanthan as a premier excipient for sustained oral, transdermal, and ocular delivery.

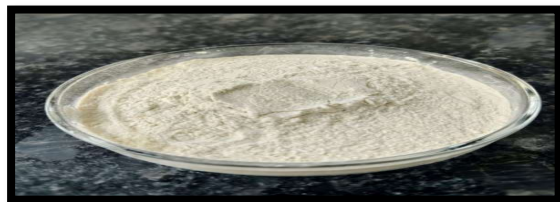


Fig. 4 Xanthan Gum

5. Tamarind Gum

Tamarind xyloglucan is a naturally derived polysaccharide derived from the endosperm of the tamarind seeds (*Tamarindus indica*), an evergreen plant species. The polysaccharide, commonly known as tamarind gum is isolated from the seed kernels through mechanical and aqueous processing. Due to these rheological properties, it is utilized stabilizing, gelling, and binding property in both food and pharmaceutical formulations. Recent studies have highlighted additional advantageous characteristics of tamarind seed polysaccharide, including non-carcinogenicity, biocompatibility, mucoadhesive nature, high drug-loading capacity, and excellent heat stability. These properties have promoted its use as a pharmaceutical excipient in hydrophilic and controlled drug transport systems, particularly for prolonged drug release applications [28, 29, 30].



Fig. 5: Tamarind Gum

6. Alginate

These polymers consisting of linear chains of (1→4)-linked β -D-mannuronic acid (M) and α -L-guluronic acid (G) residues, arranged into GG blocks, homopolymer MM, and heteropolymeric MG segments, inducing their functionality. Alginates are nontoxic, biodegradable, with properties like hydrophilic and biocompatible. They remain insoluble in ethanol (95%), chloroform and ether. In drug delivery via beads, nanoparticles, microparticles, and films for sustained release and cell encapsulation in tissue engineering, wound dressings leverage their moisture retention are biomedical uses applied. They soothe emulsions, create gels, and texture products are Industrial applications in Food. Current advances discover modified alginates for advanced hydrogels [31].



Fig. 6 Sodium Alginate

7. Plantago ovata seed mucilage

Psyllium, commonly called as ispaghula, is a commonly used word for numerous species belonging to the genus *Plantago*. *Plantago ovata* seed mucilage shows multifunctional pharmaceutical properties, including release retarding abilities, binding and disintegrating. This mucilage has been widely employed as a matrix forming material in regulated drug delivery, as an enteric coating agent due to their characteristics. The gelling and swelling nature of psyllium mucilage enables it to regulate drug release upon hydration by forming a viscous barrier upon hydration. Psyllium husk has been successfully combined with polymers such as hydroxypropyl methylcellulose to develop novel gastro retentive drug delivery systems in recent formulations. Psyllium based formulations capability in improving drug bioavailability and provide regulated delivery demonstrating, as such formulations have been investigated for drugs like ofloxacin [32, 33, 34, 35].



Fig.7: Plantago ovata seed mucilage

8. Pectin

Pectin is a straight chain, non-starch polysaccharide naturally present in plant cell

walls, particularly in tissues associated with actively proliferating cells. It is broadly distributed in plant materials and, in conjunction with cellulose, acts as an intercellular structural component. Pectin is readily dissolved in water but not in 95% ethanol and common organic solvents. Furthermore, pectin exhibits significant possibility as a hydrophilic polymeric material for the development of controlled-release matrix-based drug delivery systems. However, its high solubility in aqueous environments may result in premature and rapid medication release from the matrix formulation. In tablet formulations, pectin derived hydrogels are frequently utilized as binding agents in pharmaceutical application [32, 36, 37].

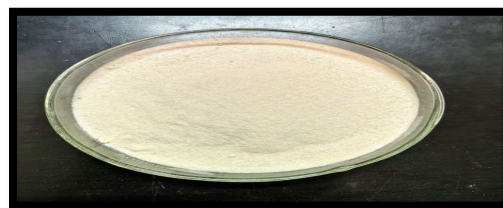


Fig. 8: Pectin

9. Hibiscus Mucilage

Mucilage may serve as isolated from the fresh *Hibiscus rosa-sinensis* leaves, a plant commonly referred to as a China rose and belonging to the *Malvaceae* family. The mucilage isolated from the dried *Hibiscus rosa-sinensis* leaves has been explored as a matrix generating polymer for the formulation

of controlled release tablets. Plant mucilage is widely applied in pharmaceutical formulations as thickening agents, suspending agents, water retaining materials, and disintegrate, demonstrating their versatility as natural excipient [34, 38, 39].



Fig. 9: Hibiscus Mucilage

10. Starch

Starch is predominantly found in seeds as well as underground plant structures and it represents the primary storage form of carbohydrate in green plants. It occurs as microscopic granules, usually referred to as starch grains, whose size and morphology vary dependent on the plant species. Major components like amylose and amylopectin its relative proportion also differs among species. Different types of starch including those obtained from maize, wheat, potato, rice are widely used in pharmaceutical applications. In the oral administration to improve stability during gastrointestinal transit of protein or peptide drugs, microcapsule system including the therapeutic protein beside with a proteinase inhibitor have been developed. Starch is commonly employed as a binding

agent, compression aid, and granulating agent, in medicinal formulations, among other functional roles [33, 35, 40].



Fig No. 10 Starch

6. MECHANISM OF DRUG RELEASE

Natural polymer matrix tablets employ biocompatible materials such as xanthan gum, chitosan, alginate, and guar gum to achieve controlled drug release, offering advantages in sustainability and reduced toxicity over synthetic alternatives [41]. These systems release drugs via swelling, diffusion, erosion, or hybrid processes upon gastrointestinal fluid contact, tailoring profiles to drug solubility and transit time [42].

6.1 Swelling-Controlled Release

Swelling-controlled release predominates in hydrophilic natural polymers that rapidly hydrate to form a viscous gel layer, restricting drug diffusion. Higher polymer concentrations yield thicker gels, as seen in karaya gum tablets where swelling index rose from 120% to 250% with 30-50% gum loading, curbing initial burst from 50% to 15% in 1 hour [41].

6.2 Diffusion-Controlled Release

Diffusion-controlled release involves drug partitioning through matrix pores without substantial polymer degradation, leveraging semi-permeable barriers in polymers like chitosan or modified starch. Release obeys Higuchi's square-root-time law, driven by concentration gradients across the hydrated zone, ideal for low-solubility drugs [43].

6.3 Erosion-Controlled Release

Erosion-controlled release entails matrix degradation via surface dissolution prominent in pH-responsive polymers like alginate that gel in acidic gastric fluid but erode in alkaline intestines. Surface erosion progressively exposes drug layers for zero-order kinetics, while bulk types involve internal chain scission followed by disintegration [44]. Karaya gum eroded at 2-5% per hour in pH 6.8, correlating to linear release; starch matrices underwent amylase-mediated bulk erosion for colon targeting, with lag phases until enzyme activation [45].

6.4 Combined Release Mechanisms

Combined mechanisms integrate swelling-diffusion-erosion for versatile profiles, reflecting real GI dynamics in natural polymer blends. Initial swelling erects a diffusion barrier, transitioning to erosion as the gel front advances, yielding anomalous transport [46]. Karaya-locust bean (1:1) optimized via

response surface methodology balanced hydration (locust bean) and dissolution (karaya), achieving 85% diltiazem release in 12 hours with flat profiles [41]. Guar-chitin hybrids modulated pulsatile patterns, mitigating monodimensional limits [43].

7. FORMULATION APPROACHES FOR SUSTAINED RELEASE TABLETS

Sustained release tablets are developed through various techniques to embed drugs. These methods balance manufacturability, drug stability, and release kinetics, with selection depending on API properties and scale-up needs [47].

7.1 Direct Compression: Direct compression blends drug, retardant polymers like HPMC or xanthan gum, diluents such as lactose, and lubricants into tablets without granulation. This rapid, cost-effective method preserves polymer hydration properties, ideal for moisture-sensitive drugs, yielding uniform matrices with friability under 1% and sustained diffusion over 12 hours [48].

7.2 Wet Granulation: Wet granulation involves kneading powders with binder solutions, drying, and sizing to form granules before compression, improving content uniformity in viscous polymer blends [47].

7.3 Dry Granulation: Dry granulation compacts blends into slugs or ribbons, then mills to granules, suiting heat/moisture-labile

drugs and natural polymers like guar gum [49].

7.4 Matrix Tablet Formulation Using Natural Polymers:

Natural polymer matrices employ xanthan, karaya, or chitosan via direct/wet granulation, leveraging biocompatibility for swelling-diffusion control. Karaya-locust bean (1:1) blends optimized by response surface methodology

yielded 85% release in 12 hours, pH-responsive for colon targeting [50, 51].

8. EVALUATION OF SUSTAINED RELEASE ANTIDIABETIC TABLETS

Sustained release antidiabetic tablets undergo rigorous pre- and post-compression evaluations to ensure uniformity, mechanical strength, and controlled release profiles for optimal glycemic control [52].

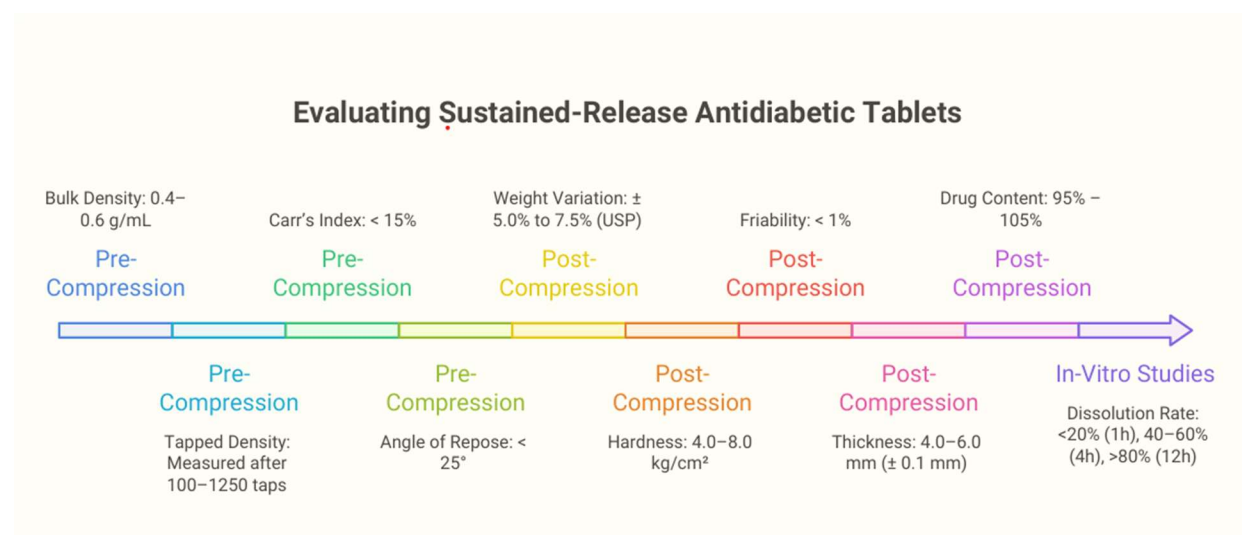


Fig 11: Systematic Evaluation of Sustained-Release Antidiabetic Tablets [53, 54]

9. MODELS OF DRUG RELEASE KINETICS

Models of Drug release kinetic mathematically describe sustained release profiles from polymer matrices, aiding formulation optimization and IVIVC predictions. These models distinguish Fiskian diffusion, erosion, or relaxation mechanisms [55].

9.1 Zero-Order Kinetics:

Zero-order kinetics occurs in reactions where the drug release rate stays constant over time, independent of the concentration of the drug or reactant in the system.

9.2 First-Order Kinetics:

A first-order reaction is characterized by a rate that is directly related to the amount of drug remaining in the dosage form. As the drug

content diminishes over time, the release rate also decreases proportionally, resulting in a concentration-dependent release pattern.

9.3 Higuchi Model:

The Higuchi model is commonly implemented in matrix-based modified release formulations. In such systems, the drug diffuses from the matrix into the surrounding medium.

9.4 Korsmeyer–Peppas Model:

The Korsmeyer–Peppas equation is used to analyze drug release from polymeric matrices, notably when the release pathway is complex or involves multiple release modes [56].

10. RECENT ADVANCES

Recent advances in natural polymer-based sustained release (SR) antidiabetic tablets focus on enhancing glycemic control through innovative polymer engineering for metformin, glimepiride, and insulin analogs.

10.1 Polymer Modification

Modified xanthan gum matrices sustained metformin release over 16 hours in pH 1.2–6.8, with swelling indices rising 180% due to enhanced hydrophilicity, reducing burst effect by 40% [57]. Thiolation of guar gum enabled mucoadhesion, prolonging gastric retention 3-fold in diabetic models [58].

11. REGULATORY AND QUALITY ASPECTS

Plant derived polymers such as xanthan gum, guar gum, chitosan, and alginates are widely accepted in pharmaceutical sustained release formulations due to GRAS status by FDA, listed under 21 CFR for direct food/drug contact as safe, biocompatible excipients [59].

11.1 Safety and Toxicity Considerations

These polymers exhibit low acute oral toxicity with no genotoxicity or carcinogenicity per ICH M7. Microbial limits ($<10^3$ CFU/g aerobic, $<10^2$ CFU/g pathogens) mandate gamma irradiation or lyophilization to prevent endotoxin contamination in hydrophilic gums [56]. Hypersensitivity rare; heavy metal specs enforced via ICP-MS [58].

11.2 Stability Studies

ICH Q1A(R2) requires 6-month accelerated and 12-month long-term testing showing metformin SR matrices retain $>95\%$ assay, $f_2 > 50$ dissolution similarity. Photostability minimal; karaya gum hydrates 15% less post-6 months but kinetics unchanged [60].

11.3 Regulatory Guidelines

FDA Inactive Ingredient Database lists approved level; USP-NF monographs specify viscosity/swelling indices. EMA permits novel excipients via certificate post-toxicology. cGMP (21 CFR 211) mandates batch CoA with residual solvent and particle size distribution controls.

12. FUTURE PERSPECTIVES

Standardization of natural polymers remains critical for pharmaceutical adoption, requiring pharmacopeial monographs with defined viscosity, purity (>98%), and molecular weight specifications to eliminate batch variability [59].

12.1 Advanced Polymer Combinations

Interpenetrating polymer networks (IPNs) combining pH-responsive alginate-chitosan with swellable HPMC-PEO will enable colon-specific antidiabetic delivery, synchronizing release to circadian glucose fluctuations via 4D printing technologies [56]. Thiolated guar gum-mucin hybrids promise 5-fold mucoadhesion enhancement [58].

12.2 Personalized Diabetes Therapy

3D-printed mucoadhesive patches with patient-specific polymer ratios (xanthan: karaya 2:1 to 4:1) and API loading, guided by pharmacogenomic CYP2D6 polymorphisms, target individualized glycemic control [60]. Wearable biosensors will trigger magnetic nanoparticle-embedded matrices for pulsatile insulin release [59].

12.3 Research Opportunities

AI-driven QBD optimization of Hibiscus mucilage composites, CRISPR-engineered microbial polysaccharides with designer release profiles, and exosome-mimicking nanogels for oral insulin represent high-

impact areas [61]. Blockchain-tracked botanical supply chains ensure GMP compliance [62].

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