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Preparation, Advantages and Pharmaceutical Application of Controlled Drug Delivery System: A Review

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ABSTRACT

With many highly advanced devices available on the market, controlled release medication delivery systems have drawn a lot of interest in the last 20 years. The current study was based on the preparation, advantages and pharmaceutical application of controlled drug delivery system. The majority of oral controlled release systems rely on dissolution, diffusion, or a combination of both mechanisms to generate slow release of drug to the gastrointestinal milieu. Sustained release oral products employing dissolution as the rate-limiting step are in principle the simplest to prepare. In swelling-controlled drug delivery systems, the drug is dispersed or dissolved in the hydrophilic polymer when in a glassy (hard and rigid) state. In an aqueous solution, water penetrates the matrix and the glass transition temperature of the polymer is lowered below ambient temperature. Osmotic pressure is the driving factor that produces continuous medication release in these kinds of drug delivery systems. A semi-permeable membrane is applied around an osmotically active drug core or an osmotically inert drug core combined with an osmotically active salt to create this system. Controlled drug delivery systems in the pharmaceutical industry refer to technologies that allow for precise control over the rate, time, and place of drug release within the body. In conclusion, the field of controlled-release technology is still being developed despite the numerous controlled-release appliances that have been studied and/or used recently. Significant improvements in medication research, together with improved and earlier preventive medicine diagnostics, have contributed to an increase in human life expectancy.

Keywords: Pharmaceutical application, controlled drug delivery system, merits, preparation techniques.

INTRODUCTION

Controlled Drug Delivery System

With many highly advanced devices available on the market, controlled release medication delivery systems have drawn a lot of interest in the last 20 years. The discovery of novel polymers, formulation optimization, improved comprehension of physiological and pathological constraints, the prohibitive cost of developing new drug entities, and the introduction of biotechnology and biopharmaceutics in drug product design are just a few of the numerous factors that have come together simultaneously to produce such advancements [1].

Many hydrophilic polymers have been studied recently and are now employed in the construction of intricate controlled release systems. In many situations, the formulator relies on the polymer's intrinsic rate-controlling mechanisms to distribute drugs at a steady pace. Attaining high gel-state viscosity and maintaining a constant gel layer in a monolithic sense for linear drug release over an extended period of time is difficult and

continues to be a challenge among the most commonly used polymers, such as the nonionic hydroxypropyl methyl cellulose (HPMC), hydroxypropyl cellulose (HPC), polyethylene oxide (PEO) types, cationic chitosan types, and anionic alginate types [2].

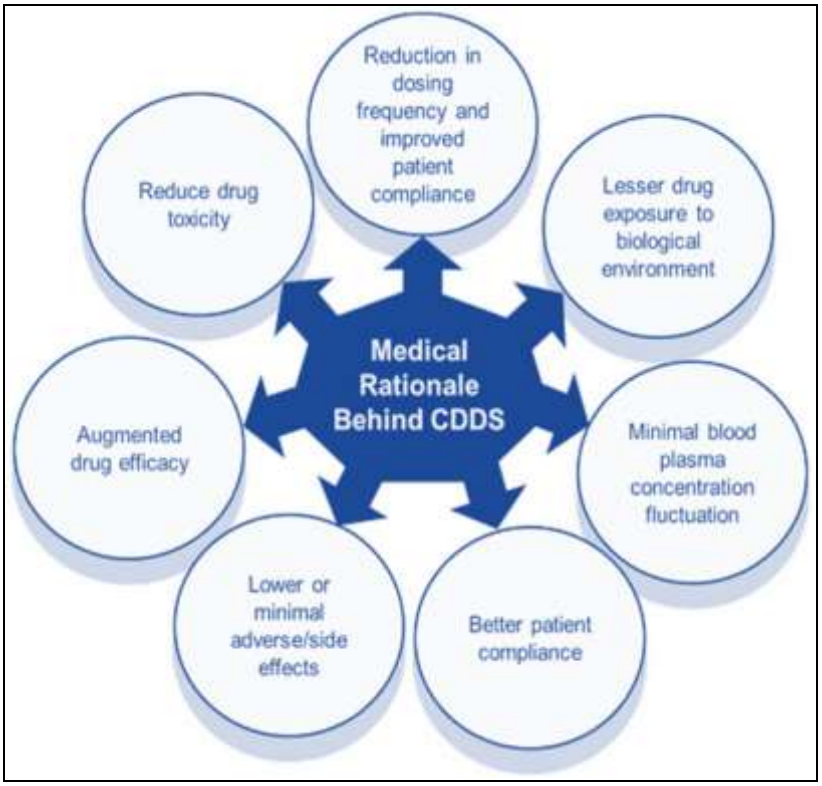

Fig 1. Benefits of CDDS

The optimal drug delivery system should possess qualities of inertness, biocompatibility, mechanical robustness, patient comfort, high drug loading capacity, prevention of unintended release, ease of administration and removal, and simplicity in fabrication and sterilization [3]. The primary objective of early controlled-release systems was to establish a drug delivery profile that would sustain elevated drug concentrations in the bloodstream across an extended duration. In conventional drug delivery approaches, blood drug levels exhibit a pattern characterized by post-administration escalation followed by a subsequent decline until the subsequent dose is administered. A fundamental principle of traditional drug administration is to maintain the blood concentration of the drug within a range bounded by an upper threshold, which could signify a toxic concentration, and a lower threshold below which the drug's efficacy diminishes [4].

Advantages and Disadvantages [5]

1. Decreased incidence and/or intensity of adverse effects and toxicity.
2. Better drug utilization.
3. Controlled rate and site of release.
4. More uniform blood concentrations.
5. Improved patient compliance.
6. Reduced dosing frequency.
7. More consistent and prolonged therapeutic effect.
8. A greater selectivity of pharmacological activity

Disadvantages

- Delayed initiation of drug effects
- Potential risk of dose release surge with inadequate formulation strategy

- Elevated susceptibility to first-pass metabolism
- Augmented reliance on gastrointestinal residence duration of dosage form
- Possible challenge in precise dose adaptation in certain scenarios
- Elevated cost per individual dose compared to conventional formulations
- Not all drugs are amenable to extended-release formulation

Methods of preparation [6]

Controlled drug delivery systems are broadly classified as follows:

Oral Controlled Release Drug Delivery Systems

The majority of oral controlled release systems rely on dissolution, diffusion, or a combination of both mechanisms to generate slow release of drug to the gastrointestinal milleu. Sustained release oral products employing dissolution as the rate-limiting step are in principle the simplest to prepare.

A. Dissolution Controlled Release

Sustained release oral products employing dissolution as the rate-limiting step are in principle the simplest to prepare.

1. Encapsulation dissolution control: These methods generally involve coating individual particles or granules of drug with a slowly dissolving material. The coated particles can be compressed directly into tablets as in Space tabs or placed in capsules as in the Spansule Products. Since the time required for dissolution of the coat is a function of its thickness and aqueous solubility, one can obtain repeat or sustained action by employing a narrow or a wide spectrum of coated particles of varying thickness respectively.

2. Matrix dissolution control: An alternative approach is to compress the drug with a slowly dissolving carrier of some sort into a tablet form. Here, the rate of drug availability is controlled by the rate of penetration of the dissolution fluid into the matrix. This, in turn, can be controlled by porosity of the tablet matrix, the presence of hydrophobic additives, and the wettability of the tablet and particles surface.

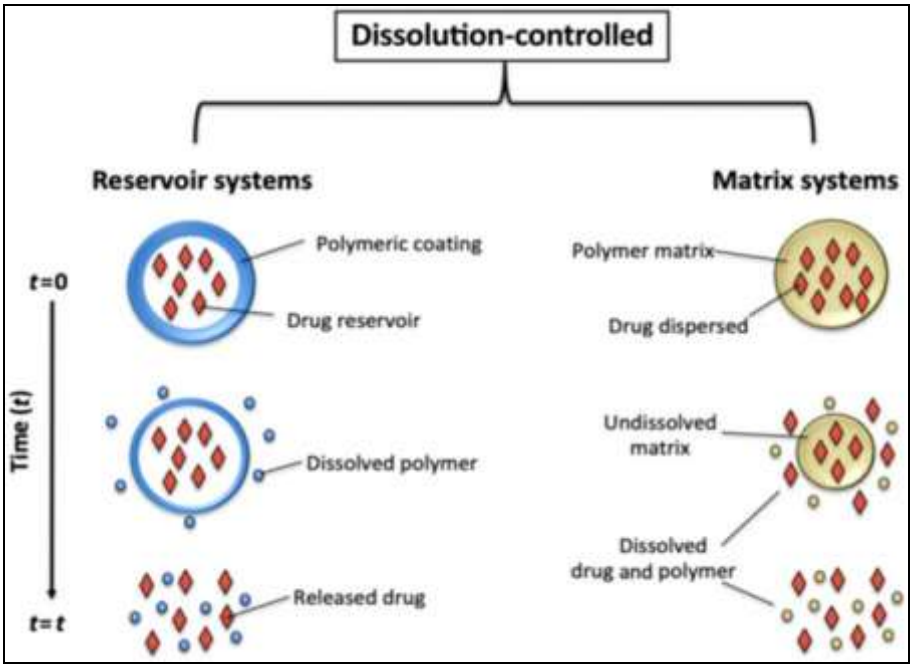

Fig 2. Dissolution Controlled Release

B. Diffusion Controlled Release

Diffusion systems are characterized by the release rate of a drug being dependent on its diffusion through an inert membrane barrier. Usually, this barrier is an insoluble polymer. There are basically two types of

diffusion-controlled systems which have boon developed over the past two decades, reservoir devices and matrix devices [7].

1. Reservoir devices: In this system, a water-insoluble polymeric material encases a core of drug. Drug will partition into the membrane and exchange with the fluid surrounding the particle or tablet. Additional drug will enter the membrane, diffuse to the periphery, and exchange with the surrounding media.

2. Matrix devices: In this system, a solid drug is dispersed in an insoluble matrix. The rate of drug release is dependent on the rate of drug diffusion but not on the rate of solid dissolution [8].

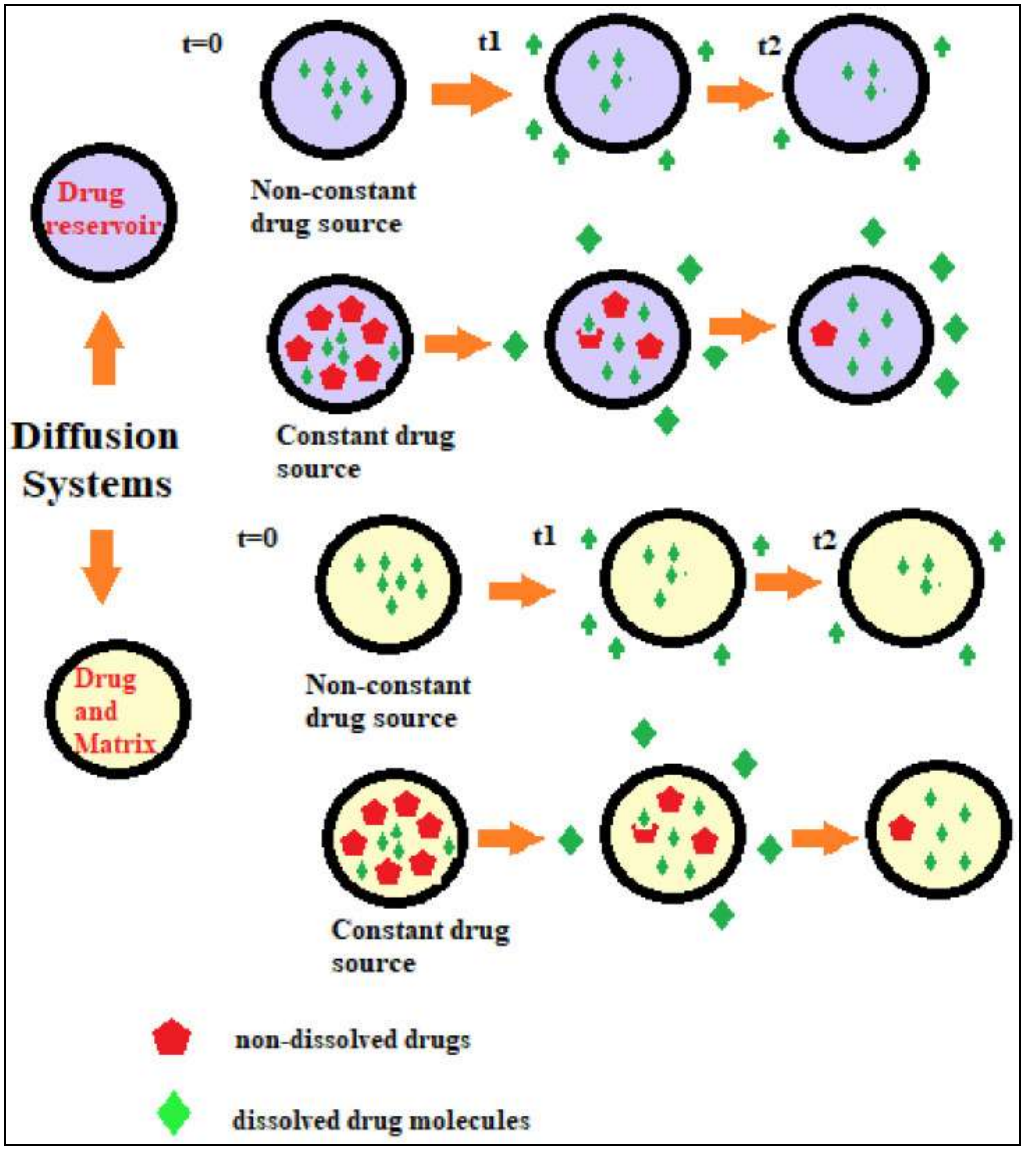

Fig 3. Diffusion Controlled Release

C. Diffusion and Dissolution Controlled Systems

The main feature of this system is that the drug core is enclosed with a partially soluble membrane. Dissolution of part of the membrane allows for diffusion of the contained drug through pores in the polymer coat [9].

D. Ion-Exchange Resins

Resins are water-insoluble materials containing anionic or cationic groups in repeating positions on the resin chain. The drug-charged resin is prepared by mixing the resin with drug solution either by repeated exposure of the resin to the drug in a chromatographic column or by keeping the resin in contact with the drug solution for extended periods of time. The drug-resin is then washed to remove contaminant ions and dried to form

particles or beads. When a high concentration of an appropriately charged ion is in contact with the ion-exchange group, the drug molecules is exchanged and diffuses out of the resin to the bulk solution.

E. Ph - Independent Formulations

The granules are designed for the oral controlled release of basic or acidic drugs at a rate that is independent of the pH in the GI tract. (Pederson, A.M, German patent). They are prepared by mixing a basic or acidic drug with one or more buffering agents, granulating with appropriate pharmaceutical excipients, and finally, coating with a gastrointestinal fluid permeable film-forming polymer. When the GI fluid permeates through the membrane, the buffering agents adjust the fluid inside to a suitable constant pH, thereby rendering a constant rate of drug release.

F. Osmotically Controlled Release

Osmotic pressure is the driving factor that produces continuous medication release in these kinds of drug delivery systems. A semi-permeable membrane is applied around an osmotically active drug core or an osmotically inert drug core combined with an osmotically active salt to create this system. Each method uses either a high-speed mechanical drill or a laser to drill a delivery orifice [10]. Osmotic medication delivery employs osmogens and osmotic pressure to deliver pharmaceuticals under regulated conditions. The process of solvent moving over a semipermeable membrane from a lower concentration of solute to a greater concentration of solute is known as osmosis. The pressure created when water passes across a semipermeable membrane dividing two solutions with varying solute concentrations is known as osmotic pressure. Both oral and injectable modes of administration are compatible with these systems [11].

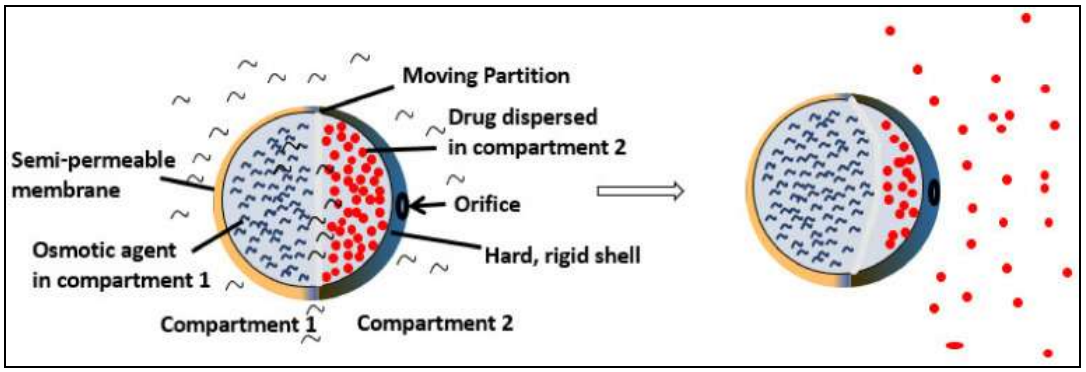

Fig 4. Osmotically Controlled Release

G. Swelling-Controlled Drug Delivery Systems

In swelling-controlled drug delivery systems, the drug is dispersed or dissolved in the hydrophilic polymer when in a glassy (hard and rigid) state. In an aqueous solution, water penetrates the matrix and the glass transition temperature of the polymer is lowered below ambient temperature. This makes the matrix swollen and rubbery, which results in slow drug diffusion out of the swollen rubbery polymer matrix [12].

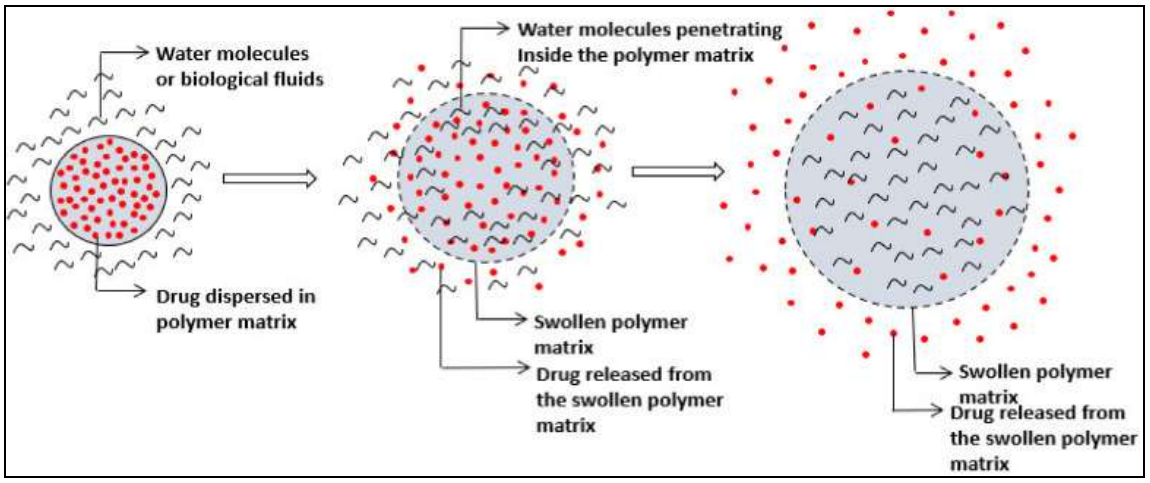

Fig 5. Swelling-Controlled Drug Delivery Systems

H. Altered Density Formulations

It is reasonable to expect that, unless a delivery system remains in the vicinity of the absorption site until most, if not all of its drug contents is released, it would have limited utility. To this end, several approaches have been developed to prolong the residence time of drug delivery systems in the GI tract. One such approach is the bioadhesion approach, which is based on the adherence of bioadhesive polymers to the mucin on epithelial surface of the GI tract. The other approach is to alter the formulation's density by using either high- or low-density pellets [13].

1. High - density approach

In this approach, the density of the pellets must exceed that of normal stomach content and should therefore be at least 1.4. In preparing such formulations, drug can be coated on a heavy core or mixed with heavy inert materials such as barium sulfate, titanium dioxide, iron powder, and zinc oxide. The weighed pellet can then be covered with a diffusion-controlled membrane.

2. Low-density approach

Globular shells which have an apparent density lower than that of gastric fluid can be used as carrier of drug for sustained release purposes. Polystyrol, poprice, and even popcorn are all candidates as carriers. The surface of these empty shells is undercoated with sugar or with a polymeric material such as methacrylic polymer and cellulose acetate phthalate. The undercoated shell is then coated by a mixture of drug with polymers such as ethyl cellulose and hydroxyl propylcellulose. The final product floats on the gastric fluid for a prolonged period, while slowly releasing drug [9].

Pharmaceutical applications

Controlled drug delivery systems in the pharmaceutical industry refer to technologies that allow for precise control over the rate, time, and place of drug release within the body. These systems have various applications, offering benefits such as improved efficacy, reduced side effects, and increased patient compliance. Here are some pharmaceutical applications along with examples [14][15][16]:

Oral Drug Delivery

1. Extended-Release Tablets release the drug over an extended period, maintaining therapeutic levels and reducing dosing frequency.
2. Gastric Retentive Systems ensure prolonged drug presence in the stomach, which can enhance absorption or provide a local effect. Example i.e., dexlansoprazole.
3. Colon-Specific Delivery utilized for drugs that need to reach the colon for local or systemic effects i.e., mesalamine in ulcerative colitis.

Transdermal Drug Delivery

1. Patches deliver drugs through the skin at a controlled rate, offering prolonged systemic effects.
2. Topical Gels/Creams control the release of drugs for localized effects on the skin or underlying tissues.

Intravenous Drug Delivery

1. Infusion Pumps deliver a constant and controlled infusion of drugs directly into the bloodstream.
2. Liposomes and Nanoparticles can encapsulate drugs, allowing for targeted delivery and controlled release. i.e., liposomal doxorubicin.

Intramuscular and Subcutaneous Injections

1. Depot Injections release the drug slowly from an injected depot, providing sustained effects.

Ocular Drug Delivery

1. Sustained-Release Implants slowly release drugs into the eye for conditions like macular degeneration.
2. Ophthalmic Inserts deliver drugs to the eye over an extended period.

Pulmonary Drug Delivery

1. Dry Powder Inhalers (DPIs) deliver drugs to the lungs in a fine powder form for localized or systemic effects.
2. Nebulizers convert liquid medication into a mist that can be inhaled for respiratory conditions i.e., Budesonide in asthma.

Nasal Drug Delivery

1. Nasal Sprays can provide controlled delivery of drugs for local or systemic effects.

Intrauterine Devices (IUDs)

1. Hormonal IUDs release hormones for contraception over an extended period.

Intraperitoneal Drug Delivery

1. Intraperitoneal delivery can provide controlled release of chemotherapy drugs directly into the abdominal cavity for treating ovarian cancer.

Implantable Devices

1. Drug-Eluting Stents are used to prevent restenosis (re-narrowing) of arteries after angioplasty.

These examples demonstrate the diverse range of controlled drug delivery systems and their applications in the pharmaceutical industry, allowing for more precise and effective treatment options for various medical conditions [17][18].

The several kinds of controlled drug delivery systems include diffusion, water penetration, dissolution, and chemically controlled drug delivery systems. Delivery methods that respond to stimuli can be used to target and regulate the release of substances in a variety of illness situations, including cancer and infections. To further accomplish controlled targeted delivery, nanocarriers with intelligent biomaterials and additive manufacturing processes can be developed. Patient-specific therapy using microfluidic-based, 3D-printed devices, and CRISPR cas9-based delivery systems linked with quantum sensing are the main goals of drug delivery in the future [19].

CONCLUSION

In conclusion, the field of controlled-release technology is still being developed despite the numerous controlled-release appliances that have been studied and/or used recently. Significant improvements in medication research, together with improved and earlier preventive medicine diagnostics, have contributed to an increase in human life expectancy. As a result, more medications are needed to treat a variety of illnesses, including coronary artery disease, diabetes mellitus, chronic pain, chronic lower respiratory disease, Alzheimer's disease, and Parkinson's disease. The first and most crucial step is to find medications for these illnesses. Drug candidates with poor water solubility can be transformed into therapeutically useful drug formulations, while those with short half-lives can be transformed into formulations for sustained release. The advancement of novel medications will greatly benefit from the drug delivery technology.

To deliver medications with various distinct qualities, a variety of drug delivery methods must be devised. The evolution of medication delivery systems has resulted from many iterations and failures, or trials and errors. It is necessary to test a wide range of medication delivery methods and to iterate on the most promising ones.

CONFLICT OF INTEREST

Authors declare for none conflict of interest.

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