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ADVANCES IN SUSTAINED RELEASE DRUG DELIVERY SYSTEMS FOR ANTI- HYPERTENSIVE THERAPY

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ABSTRACT

Hypertension is a major chronic cardiovascular disorder associated with significant morbidity and mortality worldwide, requiring long-term pharmacological management. Conventional antihypertensive therapy often demands frequent dosing, which may reduce patient compliance and lead to fluctuations in plasma drug concentration. Sustained release drug delivery systems (SRDDS) have emerged as an effective approach to overcome these limitations by providing controlled and prolonged drug release. These systems maintain therapeutic drug levels for extended periods, thereby improving treatment efficacy and minimizing dose-related adverse effects. The present review discusses the principles, advantages, and limitations of sustained release formulations in antihypertensive therapy. Various types of SRDDS, including matrix systems, reservoir systems, osmotic systems, and floating drug delivery systems, are comprehensively described. The review also highlights the importance of natural, synthetic, hydrophilic, and hydrophobic polymers used in sustained release formulations. In addition, evaluation parameters such as pre-compression studies, post-compression studies, dissolution testing, and drug release kinetic models are summarized. Recent advancements involving nanotechnology, smart polymers, and 3D printing have shown promising potential for the development of advanced sustained release systems with improved targeting and

therapeutic outcomes. Overall, sustained release drug delivery systems represent a significant advancement in antihypertensive therapy by enhancing patient compliance, reducing side effects, and improving long-term blood pressure management.

KEYWORDS: Antihypertensive Drugs, Controlled Drug Release, Hypertension, Matrix Tablets, Polymers, Sustained Release Drug Delivery System (SRDDS).

INTRODUCTION

Hypertension, commonly known as high blood pressure, is a chronic cardiovascular disorder characterized by persistent elevation of arterial blood pressure. According to current guidelines, hypertension is generally defined as systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥80 mmHg. It is considered one of the leading causes of cardiovascular morbidity and mortality worldwide. Persistent hypertension increases the workload on the heart and blood vessels, leading to structural and functional damage to various organs.[1]

Hypertension may be classified as primary (essential) hypertension or secondary hypertension. Primary hypertension accounts for the majority of cases and develops due to multiple factors such as genetic predisposition, high salt intake, obesity, stress, sedentary lifestyle, smoking, and alcohol consumption. Secondary hypertension results from identifiable causes including kidney diseases, endocrine disorders, diabetes, and certain medications.[2] Age, family history, and unhealthy dietary habits are also major contributors to the development of hypertension.

Uncontrolled hypertension can lead to severe complications affecting major organs of the body. Cardiovascular complications include myocardial infarction, heart failure, left ventricular hypertrophy, and coronary artery disease. Hypertension is also a major risk factor for stroke, renal failure, peripheral arterial disease, and hypertensive retinopathy. Long-term elevated blood pressure may damage blood vessels and impair organ function, significantly increasing morbidity and mortality.[3]

Antihypertensive drugs are medications used to lower blood pressure and reduce the risk of hypertension-related complications. The major classes of antihypertensive agents include diuretics, beta-blockers, calcium channel blockers, angiotensin-converting enzyme (ACE) inhibitors, and angiotensin II receptor blockers (ARBs).[4] These drugs act through different

mechanisms such as reducing cardiac output, decreasing vascular resistance, or inhibiting the renin–angiotensin–aldosterone system. Proper antihypertensive therapy helps in maintaining blood pressure within the normal range and prevents complications such as stroke, kidney failure, and heart disease.[5]

Sustained Release Drug Delivery System (SRDDS)

Sustained release drug delivery systems (SRDDS) are pharmaceutical formulations designed to release a drug at a predetermined rate in order to maintain a constant drug concentration in the systemic circulation for a prolonged period.[6] These systems reduce the frequency of drug administration and improve therapeutic efficacy by maintaining plasma drug levels within the therapeutic window for an extended duration. Sustained release formulations are commonly developed for drugs with short biological half-lives and frequent dosing requirements.[7]

The principle of sustained release systems is based on controlling the rate of drug release from the dosage form. Drug release is generally achieved through diffusion, dissolution, osmosis, erosion, or swelling mechanisms. In matrix systems, the drug is uniformly dispersed within a polymer matrix, and release occurs gradually through diffusion and polymer erosion. Reservoir systems use a coating membrane to regulate drug release. The primary objective is to maintain therapeutic drug concentration while minimizing fluctuations in plasma levels.[8-10]

Sustained release drug delivery systems offer several therapeutic and clinical advantages. They reduce dosing frequency, thereby improving patient compliance and convenience. SRDDS maintain relatively constant plasma drug concentrations, reducing peaks and troughs associated with conventional dosage forms.[11,12] These systems minimize side effects caused by sudden high drug concentrations and improve therapeutic efficacy. Sustained release formulations can also reduce total dose requirements and improve bioavailability of certain drugs. Additionally, they are particularly beneficial in chronic diseases such as hypertension, diabetes, and cardiovascular disorders where long-term therapy is required.[13]

Despite their advantages, sustained release systems have certain limitations. Dose dumping may occur if the formulation fails, leading to rapid release of the drug and possible toxicity.[14] SRDDS are not suitable for drugs with very short half-lives, narrow therapeutic indices, or poor absorption characteristics. The manufacturing process is often more complex and expensive compared to conventional dosage forms.[15] Variability in gastrointestinal transit

time and physiological conditions may also affect drug release profiles. Furthermore, sustained release formulations are difficult to formulate for drugs requiring high doses.[16]

Conventional vs Sustained Release Plasma Concentration Profile

Conventional dosage forms produce rapid drug release, resulting in sharp peaks and troughs in plasma drug concentration after administration.[17] In contrast, sustained release formulations release the drug gradually over an extended period, maintaining relatively constant plasma levels within the therapeutic window.[18] This controlled release minimizes fluctuations in drug concentration and reduces the frequency of dosing. Sustained release systems improve therapeutic efficacy and patient compliance while decreasing the risk of dose-related side effects. Therefore, SR formulations are widely preferred for chronic diseases such as hypertension requiring long-term therapy.[19,20]

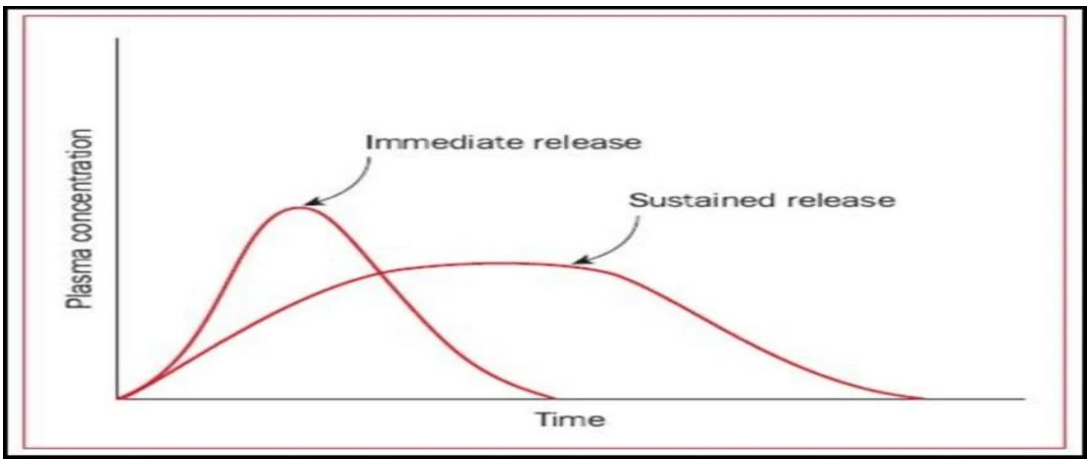

Fig 1: Concentration vs time profile of extended / sustained release oral dosage form compared to an immediate-release dosage form.[21]

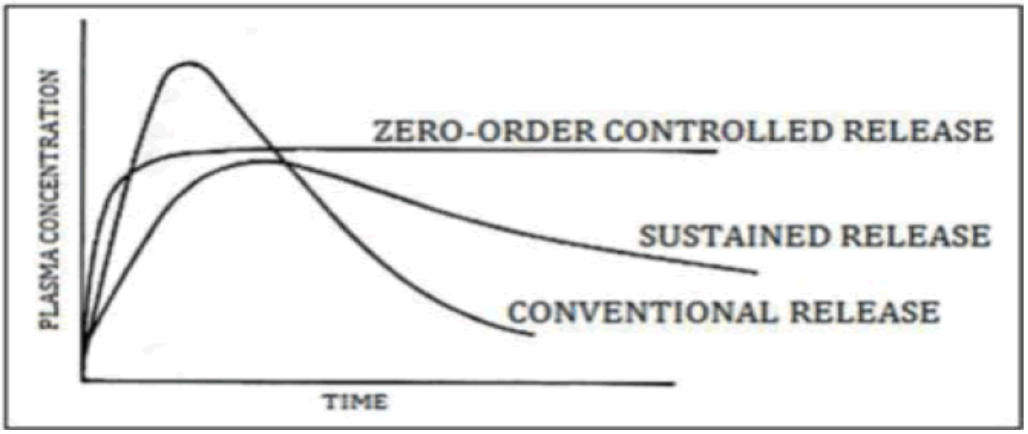

Fig 2: Plasma drug concentration vs. Time profile for oral conventional dosing and single oral dose of sustained and controlled release formulation.[22]

Need of SRDDS in Antihypertensive Therapy

- **Patient Compliance**[23]

Hypertension is a chronic disorder that requires long-term medication therapy. Frequent administration of conventional antihypertensive drugs often leads to poor patient adherence and missed doses. Sustained release drug delivery systems improve patient compliance by simplifying the dosing regimen and reducing the number of daily doses. Improved adherence helps maintain effective blood pressure control and reduces the risk of cardiovascular complications.

- **Reduced Dosing Frequency**[24]

Many antihypertensive drugs possess short biological half-lives and therefore require multiple daily administrations to maintain therapeutic plasma concentrations. SRDDS are designed to release the drug slowly over an extended period, allowing once-daily or twice-daily dosing. Reduced dosing frequency enhances convenience for patients and improves treatment continuity, especially in elderly patients and those receiving multiple medications.

- **Controlled Drug Release**[25]

Sustained release systems provide controlled and predictable drug release over a prolonged duration. This helps maintain relatively constant plasma drug concentrations within the therapeutic range while minimizing fluctuations associated with conventional dosage forms. Controlled drug release improves therapeutic efficacy and provides better management of blood pressure throughout the day and night. It also reduces the chances of sudden hypertensive episodes caused by variations in plasma drug levels.

- **Reduced Side Effects**[26]

Conventional immediate-release antihypertensive formulations may produce high peak plasma concentrations, leading to adverse effects such as hypotension, dizziness, headache, and fatigue. SRDDS minimize these peak-trough fluctuations by releasing the drug gradually. Maintenance of stable plasma drug levels reduces dose-dependent side effects and improves the safety profile of antihypertensive therapy. This contributes to better patient tolerance and long-term treatment success.

Types of Sustained Release Drug Delivery Systems (SRDDS)

- **Matrix Systems**[27]

Matrix systems are one of the most commonly used sustained release drug delivery systems. In this system, the drug is uniformly dispersed within a polymer matrix composed of hydrophilic or hydrophobic materials. Drug release occurs gradually through diffusion, dissolution, or erosion of the matrix. Hydrophilic polymers such as hydroxypropyl methylcellulose (HPMC) are widely used because they form a gel layer upon contact with gastrointestinal fluids, controlling drug release over an extended period. Matrix tablets are simple to manufacture, cost-effective, and widely used in antihypertensive therapy.

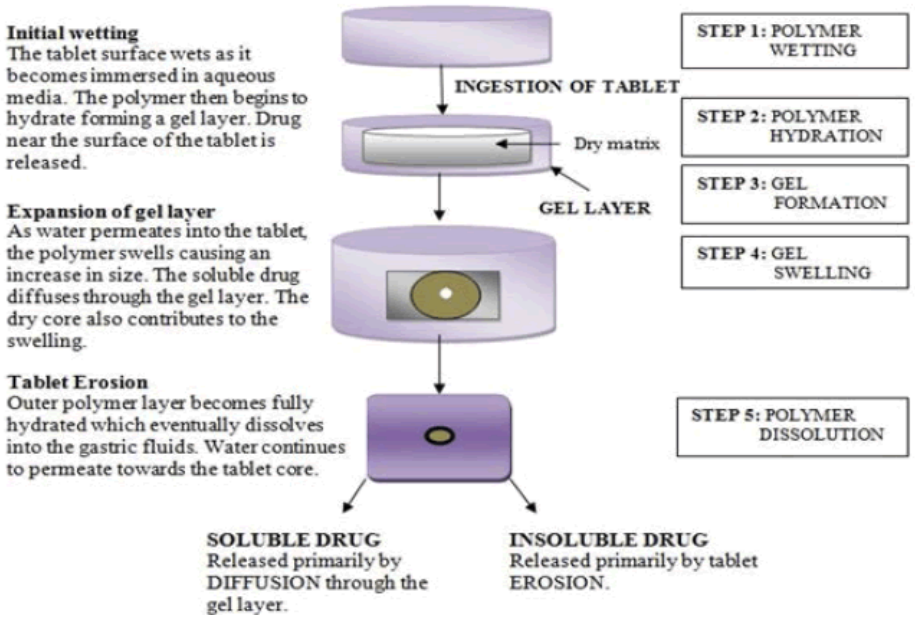

Figure 3- Mechanism of drug release from hydrophillic matrix tablet.[28]

- **Reservoir Systems**[29]

Reservoir systems consist of a drug-containing core surrounded by a polymeric membrane or coating that controls the release of the drug. The release rate depends on the permeability and thickness of the coating membrane. Drug molecules diffuse slowly through the membrane into the surrounding environment, resulting in sustained drug release. Reservoir systems provide more precise control over drug release compared to matrix systems; however, damage to the coating may lead to dose dumping and toxicity.

- **Osmotic Systems**[30]

Osmotic drug delivery systems utilize osmotic pressure as the driving force for controlled drug release. These systems generally consist of a core containing drug and osmotic agents

enclosed within a semipermeable membrane with a small delivery orifice. Gastrointestinal fluids enter through the membrane, generating osmotic pressure that pushes the drug solution out through the orifice at a controlled rate. Osmotic systems provide predictable and reproducible drug release independent of gastrointestinal pH and motility.

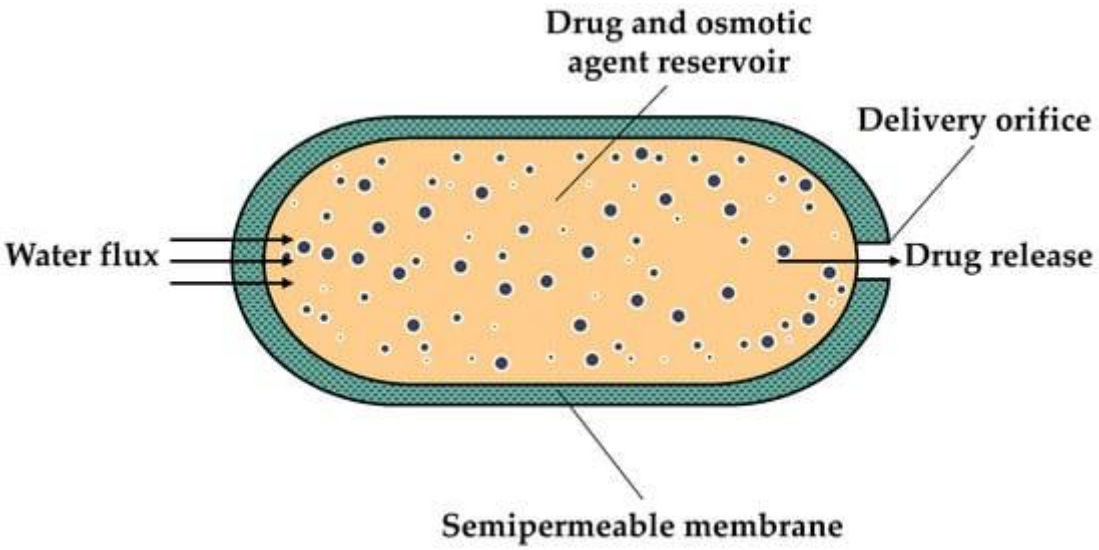

Figure 4- Schematic diagram of an elementary osmotic pump (EOP)[31]

- **Floating Systems[32]**

Floating drug delivery systems are designed to remain buoyant in the stomach for a prolonged period without affecting gastric emptying. These systems have a lower density than gastric fluids, allowing them to float on the stomach contents. Floating systems prolong gastric residence time and enhance drug absorption, particularly for drugs absorbed mainly in the upper gastrointestinal tract. They are useful for improving bioavailability and sustaining drug release in antihypertensive therapy. Floating systems may be effervescent or non-effervescent depending on their mechanism of buoyancy.

Polymers Used in Sustained Release Formulations

- **Hydrophilic Polymers[33]**

Hydrophilic polymers are widely used in sustained release formulations because of their ability to swell in the presence of water and form a gel barrier around the dosage form. This gel layer controls the penetration of dissolution fluid and regulates drug diffusion from the matrix system. Common hydrophilic polymers include hydroxypropyl methylcellulose (HPMC), hydroxypropyl cellulose (HPC), sodium carboxymethyl cellulose, and polyethylene

oxide. These polymers are preferred due to their biocompatibility, safety, and ease of formulation.

- **Hydrophobic Polymers**[34-36]

Hydrophobic polymers are water-insoluble materials used to retard drug release by forming an inert matrix structure. Drug release from hydrophobic matrices mainly occurs through diffusion via pores and channels formed within the polymer network. Ethyl cellulose, Eudragit RS/RL, and waxes are commonly used hydrophobic polymers in sustained release formulations. These polymers provide prolonged drug release and are particularly useful for drugs requiring extended therapeutic action.

- **Natural Polymers**[37-40]

Natural polymers are obtained from plant, animal, or microbial sources and are increasingly used in pharmaceutical sustained release systems because of their biodegradability, biocompatibility, low toxicity, and environmental safety. Common natural polymers include alginate, chitosan, guar gum, xanthan gum, and gelatin. These polymers can control drug release by swelling, gel formation, or matrix erosion mechanisms. Natural polymers are widely investigated for oral controlled drug delivery applications.

- **Synthetic Polymers**[41]

Synthetic polymers are chemically manufactured polymers designed to provide controlled and reproducible drug release characteristics. They offer advantages such as better stability, mechanical strength, and controlled physicochemical properties compared to natural polymers. Examples include polymethacrylates (Eudragits), polyvinylpyrrolidone (PVP), polyethylene glycol (PEG), and poly(lactic-co-glycolic acid) (PLGA). Synthetic polymers are extensively used in sustained release dosage forms because of their versatility and predictable performance.

Evaluation and Drug Release Kinetics

- **Pre-compression Studies**[42-45]

Pre-compression studies are performed to evaluate the flow and compression characteristics of powder blends before tablet formulation. These parameters help ensure uniform die filling and proper tablet formation during compression. Common pre-compression parameters include angle of repose, bulk density, tapped density, Carr's index, and Hausner's ratio. Good

flow properties and compressibility are essential for producing tablets with uniform weight and drug content.

- **Post-compression Studies**[46]

Post-compression studies are conducted to evaluate the quality and performance of prepared tablets. Important parameters include tablet thickness, hardness, friability, weight variation, drug content uniformity, and disintegration time. Hardness and friability determine the mechanical strength of tablets, while weight variation and drug content ensure dose uniformity. These tests are essential for maintaining the quality, stability, and effectiveness of sustained release formulations.

- **Dissolution Studies**[47-50]

Dissolution studies are carried out to determine the rate and extent of drug release from sustained release formulations under specified conditions. These studies are generally performed using USP dissolution apparatus in suitable dissolution media at controlled temperature and agitation speed. Dissolution testing helps evaluate the release profile of the drug and ensures that the formulation provides prolonged therapeutic action. It is also useful for comparing different formulations and predicting in vivo drug performance.

- **Release Kinetic Models**[51]

Drug release kinetic models are used to analyze and describe the mechanism of drug release from sustained release formulations. Zero-order kinetics indicates a constant drug release rate independent of concentration, while first-order kinetics depends on the concentration of the remaining drug. The Higuchi model explains drug release through diffusion mechanisms, and the Korsmeyer–Peppas model is used to determine whether release follows diffusion, erosion, or anomalous transport mechanisms. These models help optimize formulation design and predict drug release behaviour.

Recent Advances and Future Perspectives in Sustained Release Drug Delivery Systems-

Nanotechnology has emerged as an advanced approach in sustained release drug delivery systems due to its ability to improve drug solubility, stability, targeting efficiency, and bioavailability. Nanoparticles, liposomes, nano-emulsions, dendrimers, and polymeric nanocarriers are widely investigated for controlled drug delivery applications. These systems can provide site-specific drug delivery and prolonged therapeutic action while reducing

systemic side effects. Nanotechnology-based sustained release formulations are particularly useful for chronic diseases such as hypertension and cardiovascular disorders.

Smart polymers, also known as stimuli-responsive polymers, are materials that respond to environmental changes such as pH, temperature, light, or ionic strength. These polymers can alter their physical or chemical properties in response to specific physiological conditions, thereby controlling drug release in a predictable manner. Smart polymer-based drug delivery systems enhance therapeutic efficacy and reduce adverse effects by releasing drugs at the desired site and time. Their application in sustained release formulations is gaining significant attention in modern pharmaceutical research.

Three-dimensional (3D) printing technology is an innovative advancement in pharmaceutical drug delivery systems. It enables the fabrication of personalized dosage forms with precise drug release characteristics, complex geometries, and controlled drug distribution. 3D printing techniques such as fused deposition modelling and inkjet printing are being explored for the development of sustained release tablets with customized release profiles. This technology offers flexibility in dose adjustment and has significant potential in personalized medicine.

The future of sustained release drug delivery systems is focused on the development of safer, more effective, and patient-specific therapies. Advances in nanotechnology, biomaterials, artificial intelligence, and personalized medicine are expected to improve the design of sustained release formulations. Future research aims to develop intelligent drug delivery systems capable of site-specific targeting and controlled release according to patient needs. Integration of biodegradable polymers, advanced manufacturing technologies, and smart delivery systems may significantly enhance therapeutic outcomes and patient compliance in chronic disease management.

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