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CUSTOMISED DRUG DELIVERY SYSTEM AN ADVANCED SYSTEM

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ABSTRACT

Customized dosage forms are emerging as a key component of precision medicine, enabling patient-specific therapies and improved clinical outcomes. Advances in technologies such as three-dimensional (3D) printing and artificial intelligence (AI) allow precise control over drug dose, formulation, and release profiles tailored to individual needs. Smart drug delivery systems further enhance therapeutic efficacy through controlled and stimuli-responsive release mechanisms. Integration with digital health platforms and telepharmacy supports real-time monitoring and dose adjustment, improving patient adherence. In addition, the development of novel biomaterials and automated manufacturing processes enhances scalability and production efficiency. Evolving regulatory frameworks and growing clinical research are expected to ensure safety, efficacy, and broader implementation of these systems. Overall, customized dosage forms hold significant potential to transform healthcare by advancing personalized treatment strategies and optimizing therapeutic outcomes.

KEYWORDS: Customized dosage forms, Technologies, Telepharmacy, Clinical research.

DEFINITION

Customized Drug Delivery Systems (CDDS) represent an advanced approach in modern pharmaceutics. They are also known as personalized or patient-specific drug delivery systems are designed to tailor drug therapy according to individual patient needs. These needs are based on genetic, physiological, and pathological conditions. The primary aim is to optimize therapeutic outcomes. At the same time, CDDS minimize adverse drug reactions. Traditional drug delivery systems follow a “one-size-fits-all” approach. However, this approach often fails due to inter-individual variabilities overcome this limitation by offering precise and controlled drug delivery. They ensure the right drug reaches the right site at the right time.[1]

Need for Customized Drug Delivery Systems (CDDS)

The development of Customized Drug Delivery Systems (CDDS) has become essential due to the growing recognition that conventional drug delivery approaches are inadequate for addressing patient-specific variability. The traditional “one-size-fits-all” model often results in suboptimal therapeutic outcomes, increased adverse effects, and poor patient compliance. One of the primary reasons for the need of CDDS is inter-individual variability. Patients differ significantly in terms of age, body weight, metabolic rate, organ function, and disease severity, which directly influence drug absorption, distribution, metabolism, and excretion. As a result, a fixed dose may be ineffective in some patients while toxic in others. The increasing prevalence of chronic and complex diseases, such as cancer, diabetes, cardiovascular disorders, and neurological conditions, further highlights the need for CDDS. These diseases often require long-term therapy with precise dosing and targeted delivery, which cannot be efficiently achieved using conventional systems. CDDS allow site-specific and controlled drug release, enhancing treatment effectiveness.

Importance of Customized Drug Delivery Systems (CDDS)

a) Enables personalized therapy by tailoring drug treatment according to individual patient characteristics such as age, genetics, and disease condition.[1]
b) Improves therapeutic efficacy by delivering the drug at the right dose, time, and target site.
c) Supports precision medicine through integration of pharmacogenomics and patient-specific data.
d) Enhances patient compliance by reducing dosing frequency and simplifying treatment regimens.[2]
e) Provides targeted drug delivery, ensuring higher drug concentration at the site of action.
f) Maintains controlled and sustained drug release, avoiding fluctuations in plasma drug levels.
g) Overcomes biopharmaceutical limitations such as poor solubility, low bioavailability, and instability of drugs.[3]

h) Plays a crucial role in management of chronic diseases like cancer, diabetes, and neurological disorders.
i) Integrates advanced technologies such as nanotechnology, 3D printing, and artificial intelligence (AI).
j) Reduces treatment failure rates and improves overall clinical outcomes.[4]

Personal Factors Affecting Customized Drug Delivery Systems (CDDS)

1. Age related factors

Significantly impacts physiological processes that influence drug delivery. Paediatric population[5]

- Immature liver enzyme systems
- Reduced renal clearance
- Higher membrane permeability
- Geriatric population:
- Decline in hepatic metabolism
- Reduced kidney function
- Increased drug sensitivity

2. Genetic Variability (Pharmacogenomics)

Genetic polymorphisms play a crucial role in drug response.

Variations in:

- CYP450 enzymes (CYP3A4, CYP2D6, CYP2C9)
- Drug transporters (P-glycoprotein)
- Drug receptors

3. Gender (Sex-Based Differences)

- Hormonal differences influence drug metabolism
- Variations in gastric motility and enzyme activity[6]

4. Disease State and Pathophysiology

- Disease conditions significantly alter drug delivery.
- Liver disease → impaired metabolism
- Renal disease → reduced drug excretion
- Cancer → enhanced permeability and retention (EPR effect)

- Inflammation → altered tissue environment

Impact: Drug accumulation or reduced efficacy.

CDDS Strategy: Targeted drug delivery systems. Stimuli-responsive systems (pH, enzymes)

5. Lifestyle and Environmental Factors

- Diet affects drug absorption
- Smoking induces metabolic enzymes
- Alcohol alters liver metabolism[7]

6. Patient Compliance and Behavioural Factors

- Non-adherence leads to therapeutic failure
- Complex dosing reduces compliance
- Impact: Poor treatment outcomes.
- Circadian Rhythm (Chronobiology)
- Biological rhythms influence drug metabolism and disease progression.[8]

Drug selection according to disease

Drug selection according to disease is an essential step in modern pharmaceutics, particularly in the context of Customized Drug Delivery Systems (CDDS). Traditional drug delivery approaches often fail to address variability in disease conditions and patient response. CDDS overcome these limitations by selecting drugs based on disease-specific requirements and individual patient characteristics, ensuring improved therapeutic efficacy and safety.

Principles of Drug Selection According to Disease

Drug selection is guided by several important factors, including disease pathophysiology, site of action, and disease severity. Understanding the molecular and cellular mechanisms of diseases helps in identifying appropriate drug targets. The site of action determines the route of administration and type of delivery system required. Additionally, acute diseases require rapid drug action, whereas chronic diseases benefit from sustained-release formulations.

Drug Selection Based on Disease Categories

1. Cancer

Cancer treatment requires the selection of cytotoxic drugs, targeted therapies, and immunotherapeutic agents. Drugs such as doxorubicin and paclitaxel are widely used, while targeted therapies improve specificity. Nanocarrier-based systems enhance tumor targeting through the enhanced permeability and retention (EPR) effect.

2. Cardiovascular Diseases

In cardiovascular disorders, drugs such as antihypertensives, statins, and anticoagulants are selected. Controlled-release formulations help maintain consistent plasma drug levels, improving therapeutic outcomes.

3. Diabetes Mellitus

Drug selection in diabetes includes insulin and oral hypoglycemic agents such as metformin. Advanced CDDS include glucose-responsive delivery systems and insulin pumps for personalized therapy.

4. Neurological Disorders

Neurological diseases require drugs capable of crossing the blood-brain barrier. Examples include antiepileptics and dopaminergic agents. Nanoparticle-based and intranasal delivery systems enhance brain targeting.

5. Infectious Diseases

Drug selection depends on the type of pathogen involved. Antibiotics, antivirals, and antifungals are commonly used. Targeted delivery systems help overcome antimicrobial resistance and improve efficacy.

6. Respiratory Diseases

Respiratory conditions such as asthma are treated using bronchodilators and corticosteroids. Inhalation drug delivery systems provide rapid and localized drug action.

7. Gastrointestinal Diseases

Drugs such as proton pump inhibitors and anti-inflammatory agents are used. Enteric-coated and colon-targeted drug delivery systems enhance therapeutic effectiveness.

8. Autoimmune and Dermatological Diseases

Immunosuppressants and biologics are used for autoimmune diseases, while topical formulations are preferred for dermatological conditions. Nanocarriers improve drug penetration and targeting.

Challenges in Drug Selection

Despite advancements, challenges such as drug resistance, toxicity, variability in disease progression, and regulatory issues remain. Addressing these challenges is essential for effective implementation of CDDS.

❖ Bioelectronic medicines

Bioelectronic medicines are devices that use electrical signals to modulate physiological functions for therapeutic purposes. These systems interact directly with the nervous system to control organ function. They provide an alternative to conventional pharmacological treatments. Bioelectronic medicines enable precise and targeted therapy. The therapy is delivered through electrical stimulation rather than chemical agents.[8]

- **Role in Customized Dosage Forms**

Bioelectronic systems allow patient-specific customization of treatment. Dosage can be adjusted by modifying electrical stimulation parameters. These systems enable real-time control over therapeutic delivery. Integration with sensors allows feedback-based drug delivery. This approach supports personalized medicine and precision therapy.[9]

- **Advantages & Applications**

1. Bioelectronic medicines reduce systemic side effects compared to drugs.
2. They provide high specificity in targeting diseased tissues.
3. These systems are used in neurological, cardiovascular, and inflammatory diseases.
4. They enable continuous monitoring and adaptive therapy.
5. Overall, bioelectronic medicines offer a promising approach for customized and efficient treatment.[10]

❖ 3D printing

3D printing is an additive manufacturing technique used to fabricate dosage forms layer by layer. It enables precise control over the shape, size, and structure of pharmaceutical products. This technology allows fabrication of complex and personalized drug delivery systems. Different 3D printing methods include fused deposition modeling, inkjet printing, and stereolithography. It provides flexibility in designing customized dosage forms for individual patients.[11]

- **Role**

3D printing enables patient-specific dosing by adjusting drug quantity and geometry. It allows fabrication of polypills containing multiple drugs in a single dosage form. Drug release profiles can be tailored by modifying internal structure. It supports on-demand manufacturing of medicines in clinical settings. This approach enhances precision medicine and individualized therapy.[12]

- **Advantages & Applications**

1. 3D printing improves patient compliance through personalized dosage forms.
2. It enables production of complex drug delivery systems not possible by conventional methods.
3. The technology allows controlled and sustained drug release.
4. It is widely applied in paediatrics, geriatrics, and chronic disease management.
5. Overall, 3D printing offers a promising platform for customized and efficient drug delivery.[13]

❖ **Tele pharmacy**

Tele pharmacy is the provision of pharmaceutical care through telecommunication and digital technologies. It enables pharmacists to deliver services remotely without physical presence. Tele pharmacy includes medication review, counselling, and monitoring. It improves access to pharmaceutical care in rural and underserved areas. This approach supports safe and effective medication management.[14]

- **Role**

Telepharmacy facilitates personalized medication management based on patient data. Pharmacists can adjust dosage regimens remotely according to patient response. It enables continuous monitoring and follow-up of patients. Integration with digital health tools supports individualized therapy. It enhances patient adherence to customized dosage regimens.[15]

- **Advantages and Applications**

1. Tele pharmacy reduces the need for hospital visits and improves convenience.
2. It ensures timely access to medications and pharmaceutical care.
3. The system supports chronic disease management and long-term therapies.
4. It improves patient outcomes through better monitoring and communication.
5. Overall, tele pharmacy is an effective tool for delivering customized and patient-centred care.[16]

❖ Formulation design

Formulation design involves the systematic development of dosage forms to achieve desired therapeutic outcomes. It includes selection of appropriate drug, excipients, and delivery system. The design process considers physicochemical properties of the drug. It aims to ensure stability, efficacy, and safety of the dosage form. Patient-specific factors are increasingly considered in modern formulation design.[17] Formulation design is the process of developing dosage forms to achieve optimal therapeutic effect. It involves selection of active pharmaceutical ingredient and suitable excipients. The physicochemical properties of the drug are carefully evaluated during design. Stability, solubility, and compatibility are key considerations. The aim is to ensure safety, efficacy, and quality of the final product. Modern formulation design focuses on patient-centric approaches. It supports development of personalized and targeted drug delivery systems.[18]

- **Factors in Customized Formulation:**

1. Drug solubility and permeability influence formulation strategy.
2. Selection of polymers and excipients determines drug release profile.
3. Dosage form design can be modified based on patient age and condition.
4. Route of administration plays a key role in formulation development.
5. Manufacturing techniques such as 3D printing support personalized formulations.[19]

❖ Current Challenges

Customized dosage forms face several technical challenges, including difficulty in achieving precise dose accuracy and uniform drug distribution. Limited availability of suitable pharmaceutical-grade materials also restricts development. Controlling drug release profiles and ensuring long-term stability of formulations remain complex issues.[20] In addition, regulatory challenges exist due to lack of clear guidelines for personalized medicines. Scaling up production and maintaining quality control are also difficult compared to conventional dosage forms. High manufacturing costs further limit widespread adoption.[14] From a clinical perspective, limited long-term safety and efficacy data are available. Patient-specific variability makes dose optimization challenging. Overall, these technical, regulatory, and clinical barriers hinder the large-scale implementation of customized dosage forms.[21]

❖ Future perspective

Customized dosage forms are expected to play a transformative role in future healthcare by enabling highly personalized and patient-centric therapies. Advances in technologies such as 3D printing and artificial intelligence will allow precise control over drug dose and release profile. Smart drug delivery systems will further enable controlled and responsive drug release.[22] Integration with digital health platforms and tele pharmacy will support real-time monitoring and dose adjustment. These systems will improve patient adherence and therapeutic outcomes. Development of novel biomaterials and automated manufacturing will enhance efficiency and scalability.[23] Additionally, regulatory frameworks are expected to evolve to support personalized medicine. Increased clinical research will provide better safety and efficacy data. Overall, customized dosage forms will significantly improve precision medicine and healthcare delivery.[24]

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