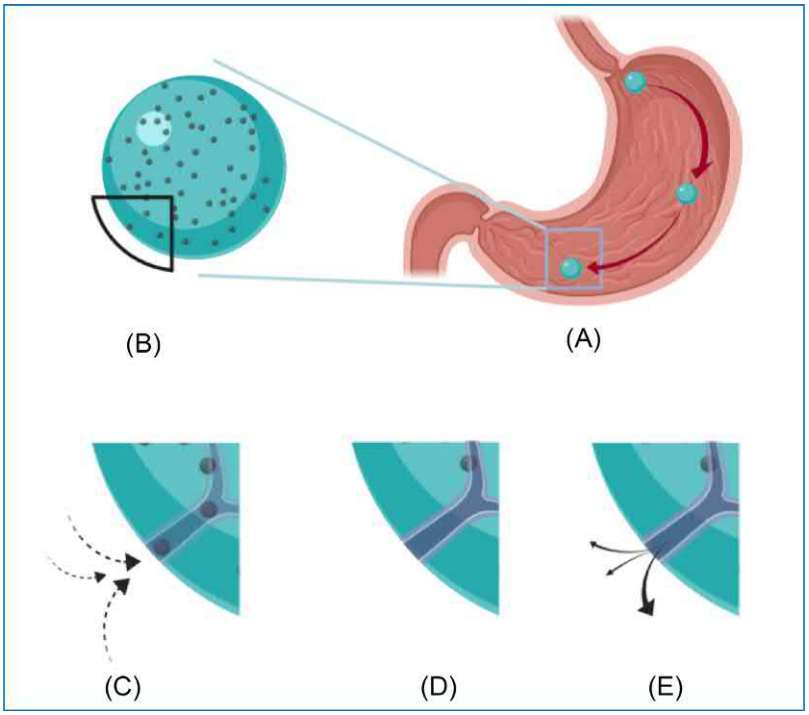

FIG. 3 Matrix (hydrophobic)-type diffusion-controlled system: (A) matrix tablet enters the GIT, (B) representative whole matrix system, (C) enlarged part of the matrix system, GI fluid enters the system through the channels, (D) drug solubilizes in the GI fluid, and (E) drug solution diffuses out of the system.

6. DRUG RELEASE CHARACTERIZATION FROM CONTROLLED-DRUG DELIVERY SYSTEMS

Release of drugs from controlled-release oral dosage forms is a prerequisite for its absorption and, hence, to its availability to the site of action [26]. These systems are designed to maintain a constant drug level in the blood for a predetermined time period. Therefore it is mandatory to know the true mass transfer mechanism involved in the release of the drug from the system, before materializing the dosage form. For this, the formulator should optimize the desired drug release from the delivery systems. The drug release from delivery systems with specific rate and kinetics need to be evaluated to establish optimum therapeutic efficacy. Furthermore, the in vitro drug release kinetic can be utilized to evaluate the stability of dosage form at various storage conditions and predict the in vivo performance [60–62].

6.1. Evaluation of Drug Release Characteristics From Delivery Systems

The following approaches can be utilized for the evaluation of drug-release characteristics from delivery systems:

1. Statistical methods.
2. Model-dependent methods:
   a. Zero-order kinetics.
   b. First-order kinetics.
   c. Higuchi's model.
   d. Korsmeyer-Peppas' model.
   e. Hixon-Crowell's model.
   f. Others (Baker and Lonsdale's model, Hopfenberg's model, Weibull's model, and Peppas-Sahlin's model, etc.).
3. Model-independent methods:
   a. Difference factor (f_1).
   b. Similarity factor (f_2).