REVIEW OF LITERATURE

**Gohel.M. C. et al** (2010). Presented the work of immediate release of paracetamol and tailored release of diclofenac sodium from bi-layer tablets. A $2^3$ full factorial design was adopted using the amount of polyethylene glycol, microcrystalline cellulose and crospovidone as independent variables for fabricating paracetamol tablets. Diclofenac sodium tablets were prepared using hydroxypropyl methylcellulose as a matrixing agent.

**Efentakis Met al** (2010). Studied the release performance of two model drugs, diclofenac sodium and furosemide, from two- and three-layer drug delivery systems using as carriers hydrophilic swellable polymers, namely, Metolose, Polyox, Xantham gum, and an erodible material Gantrez.

**NaeemMA et al** (2010). Microparticles were prepared by Coacervation via temperature change was the encapsulated method, with ethyl cellulose (EC) of medium viscosity as the polymer for extending drug release. The microparticles of the two drugs were prepared separately and then compressed into bilayer tablets.

**Yassin El-Said Hamza et al** (2009). double-layer tablets (DLTs) of lornoxicam, (a highly potent nonsteroidal anti-inflammatory drug with short half-life), were developed by direct compressed technique and characterized for initial burst drug release in the stomach and were complied with the release requirements of sustained-release products.

**Deelip Derle et al** (2009). Formulated and evaluated mucoadhesive bi-layer buccal tablets of propranolol hydrochloride tablets using the bioadhesive polymers such as sodium alginate and carbopol 971 P along with ethyl cellulose as an impermeable backing layer. The tablets were evaluated for weight variation, thickness, hardness, friability, surface pH, mucoadhesive strength, swelling index, and in-vitro drug release studies were performed.

**Bhavesh Shiyani et al** (2008). Had developed bi-layer tablet of Metoclopramid Hydrochloride (MTH) and Ibuprofen (IB) for the effective treatment of migraine. MTH and IB were formulated as immediate and sustained release layer respectively.
MTH was formulated as immediate release layer by using various disintegrants like Ac-Di-Sol, Polyplasdone XL, Explotab, Agar and Gellan Gum. Treated form of gellan gum and agar was prepared and compared for their disintegrant efficiency with other disintegrants.

Efentakis M. et al\textsuperscript{7} (2008). Developed and evaluated the different preparations of sustained delivery systems, using Carbopols as carriers, in the form of matrices and three-layer tablets with isosorbite mononitrate. Matrix tablets were prepared by direct compression whereas three-layer tablets were prepared by compressing polymer barrier layers on both sides of the core containing the drug. The findings of the study indicated that all systems demonstrated sustained release.

Chinam Niranjan Patra et al\textsuperscript{8} (2007). Bilayer tablets of propranolol hydrochloride were formulated using superdisintegrant like sodium starch glycolate for the fast release layer and water immiscible polymers such as ethylcellulose, Eudragit RLPO and Eudragit RSPO were used for the sustaining layer.

Mohammad Reza Siahi et al\textsuperscript{9} (2005). Designed an oral controlled delivery systems for the water-soluble drug, verapamil hydrochloride, using natural and semisynthetic polymers as carriers in the forms of 1- and 3-layer matrix tablets. Verapamil hydrochloride 1-layer matrix tablets containing hydroxypropylmethylcellulose, tragacanth, and acacia either alone or mixed were prepared by direct compression technique. 3-layer matrix tablets were prepared by compressing the polymers as release retardant layers on both sides of the core containing the drug.

Kale et al\textsuperscript{10} (2005). Matrix tablets of metformin HCl was evaluated for in-vitro drug release studies using USP-XXIII dissolution apparatus type I (basket) at rotation speed of 75 rpm. The dissolution medium consisted of 900 ml of distilled water at 37\textdegree +0.5\textdegree C.

Giacomo et al\textsuperscript{11} (2005). Developed a system that was able to sustain the release of high dose of metformin hydrochloride during the transit from stomach to jejunum.

Kesarwani et al\textsuperscript{12} (2005). An oral solid dosage form was formulated, that includes a combination of a biguanide as an extended release phase and a sulfonylurea as an immediate release coating form. A tablet was formulated which contains core material...
as metformin hydrochloride by using HPMC as a polymer; seal coating; then coating of glimepiride by using HPMC as a polymer; then film coating was done.

Chawla et al\textsuperscript{13} (2005). Developed the combination of the biguanide and a sulfonylurea. It provides the extended release of both the drugs i.e. Metformin and Glipizide.

Linhong et al\textsuperscript{14} (2005). Studied the metformin hydrochloride has synergistic effect with glimepiride; the medicinal compound has the advantage of reduced dose of each ingredient equivalent curative effect to single ingredient medicine and convenient administration.

Paradkar et al\textsuperscript{15} (2004). Sustained release matrices of metformin HCl were developed and in-vitro release was carried out in a USP 24 type II dissolution apparatus with a stirring rate of 100 rpm. Dissolution medium was 900 ml highly purified water maintained at 37 +0.5°C

Xiaochen et al\textsuperscript{16} (2004). Developed matrix tablets of acrivastine and pseudoephedrine and in-vitro drug release were carried out in distilled water using USP I apparatus at 50 rpm.

Tang et al\textsuperscript{17} (2004). A detailed explanation on metformin and glimepiride was emphasized that these drugs have tendency to decrease free fatty acid levels, body weight index, and blood glucose and insulin resistance. Free fatty level can reflect the index of insulin resistance to some degree.

Wagstaff et al\textsuperscript{18} (2004). Studies were conducted on release of metformin at a controlled rate from a central osmotic tablet core through a semi permeable coating. A decrease in fasting plasma insulin, a marker of insulin resistance was seen with metformin extended release but not with immediate release. It shows that the metformin extended release given in the single dose is equal to the metformin immediate release given in the divided dose.

Turner et al\textsuperscript{19} (2004). Emphasized a detailed description on monolithic matrices because of simplicity in processing technology required, reproducibility and stability of the materials and dosage forms as well as ease of scale-up operation. The main
potential disadvantage of the matrix system is the lack of zero-order release kinetics due to time dependent changes in drug depleted matrix surface area and that seek to manipulate tablet structure or geometry have been developed.

**Hosseinali et al** (2003). Sustained release matrix tablets of aspirin were designed and evaluated for in-vitro drug release using USP type II dissolution apparatus at 30 rpm. Dissolution medium was 1000 ml distilled water maintained at 37 ±0.5°C.

**Haider et al** (2002). Fatty based matrix tablets of metoclopramide Hcl were developed and the in vitro release was studied using USP dissolution apparatus type 1 at 50 rpm. The dissolution media employed were 900 ml of 0.1 N HCl (pH 1.2) for the first hour, followed by medium of pH 4.5 for the next hour followed by medium of pH 7.5 for the remaining period of the experiment.

**Shanghvi et al** (2002). A sustain drug delivery system of two or more antidiabetic agents was developed and drug release kinetics at different times was studied after oral administration, for the treatment of diabetic mellitus. The delayed release metformin hydrochloride core granules were prepared and mixed with the immediate release glipizide granules and encapsulated in hard gelatin capsules.

**Jain NK et al** (2002). A detailed study was conducted on granulation techniques for oral sustained release products, were their performance have gained importance in zero order release rate of the therapeutic substances. In contract it is not possible to get an ideal sustained effect where the drug is given orally because the rate processes are influenced grossly by a number of factors.

**Vyas SP et al** (2002). Emphasized a detailed study on sustained release systems which have been widely used in oral medication, the earliest examples are enteric-coated orally ingested tablets, encapsulated pellets of beads, sparingly soluble salts, complex systems, drug embedded in matrix, ion exchange resins, and swelling hydrogels. Most of the early products can be classified under sustained delivery systems, which means the release of active agent is slower than any conventional formulation, but is significantly affected by an external environment. In contrast, controlled release systems provide a release profile independent of external environment and predominantly controlled by the design of the system.
**Gul MK et al**\(^{25}\) (2001). Reviewed and enlisted that various authors were proposed different types of drug release mechanism from matrices. It has been proposed that drug release from matrices usually implies water penetration in the matrix, hydration, swelling, diffusion of the dissolved drug (polymer hydro fusion), and/or the erosion of the gelatinous layer. Several kinetics models relating to the drug release from matrices were described.

**Manuel Efentakis et al**\(^{26}\) (2000). Complied the release behavior of single-unit (tablets, capsules) and multiple units (minitablets in capsules) of controlled-release systems of furosemide. The swelling and erosion behaviors of these systems containing the swellable hydrophilic polymers sodium alginate (high viscosity) and Carbopol974P were compared. Swelling and erosion experiments showed a high degree of swelling and limited erosion for the Carbopol preparations, whereas less swelling but greater erosion was observed for the sodium alginate preparations.

**Darshan et al**\(^{27}\) (2000). Designed and evaluated matrix tablets of Prochlorperazine maleate and in-vitro studies were done using a USP XXIII dissolution apparatus type II at 100 rpm in simulated gastrointestinal fluid (first 2 hours in 0.1 N HCL and phosphate buffer pH 6.8 subsequently).

**Guruvinder et al**\(^{28}\) (1999). Oral extended release solid dosage forms of metoprolol tartrate were developed by using hydrophilic polymer system preferably HPMC (methocel K100 LV) and studies on the critical formulation and process variables on scale up was conducted.

**Yang et al**\(^{29}\) (1997). Controlled release three layer oral matrix tablets formulation containing 150 mg diclofenac sodium were formulated and evaluated for zero order release kinetics or optionally deliver a portion of the dose instantaneously followed by linear zero order release. Both biphasic release and zero order release kinetics for up to 24 hours were achievable in dissolution studies. The mechanism of drug release was based on both dissolution and swelling/erosion for the linear portion of the release profile and disintegration/dissolution when the burst effect option was considered.
Levy et al\textsuperscript{30} (1997). Studied the effect of additives on drug release kinetics from biodegradable matrices. Double-layered poly-DL-lactic acid-co-glycolic acid (poly(lactic-co-glycolic acid)) matrices containing U-86983 alone and with varying concentrations of L-tartaric acid dimethyl ester, poloxamer 407 (Pluronic F-127), 2-hydroxypropyl-beta-cyclodextrin, methyl beta-cyclodextrin, or yellow wax (beeswax). U-86983 showed typical biphasic release kinetics that included slow diffusion at first followed by a fast erosion-mediated release. The water-soluble additives changed the biphasic release pattern to a near monophasic profile by increasing the release rate in the first phase. Increasing the ratio of additives caused a significant increase in drug release rates.

Huey LJ et al\textsuperscript{31} (1997). Compared therapeutic performances of two medicinal products containing the same active substance is a critical means of assessing the possibility of alternative using between the innovator and any essentially similar medicinal product. The dissolution profile comparison may be carried out using model independent or model dependent method. A simple model independent approach was used calculation of difference factor ($f_1$) and a similarity factor ($f_2$) to compare dissolution profiles.

Robinson JR et al\textsuperscript{32} (1987). Explained about newer drug delivery systems are being investigated so as to alter the bio distribution of drug(s) with a view to reduce the toxicity of drug and/or deliver them more efficiently to their site of action. In generalized way, the sustained release or controlled release systems are intended to exercise control on drug release in the body, whether this be of a temporal or spatial nature or both: In other words, the system attempts to regulate drug concentrations within the tissue or cells.