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CHAPTER 2
LITERATURE REVIEW

➤ Brahmaiah Bonthagarala [12]

The present objective is to formulate and evaluate pulsatile drug of Atenolol by press coating with optimizing RRCT using varied proportions of HPMC K100 and ethyl cellulose 5Cps. Formulations are evaluated considering physical characteristics, disintegration time & drug release profile. Based on following evaluation parameters the optimized pulsatile release formulation (F3) has time of 2hrs followed by drug in-vitro release time as 8hrs and 97.8% released drug. Hence P3F3 formulation compliance in chrono therapeutic objective of hypertension.

➤ Akila RM [13]

The present objective is to develop the programmable releasing of pulsatile press coat tablets in levetiracetam for achieving a chrono therapy in nocturnal epilepsy. Core tablets of levetiracetam is prepared with Direct compression and press coat of HPMC K100M, MCC. The formulated tablets are considered for evaluation of in-vitro release to achieve required pulsatile release drug with a lag time 2.5 h. By using IR spectrophotometer compatability of Drug-excipient study showed that all excipients are compatible with drug. Stability study is carried to desired optimized formulation for 3 months showing insignificance in difference.

➤ Sagar J. Sonawane [14]

The coat layer of HPMC K100M and Ethyl cellulose used in different ratio. Resulting in in-vitro drug release of all formulations (F1 to F4) released slowly sustained of drug Losartan potassium for 12 hours. Hydrophilic polymers viz:- HPMC K100M of 60% and Ethyl cellulose of 10% was found to be optimum. HPMC K100M useful for formation of matrix & Ethyl cellulose used to swelling and rupturable action. DSC and IR studies conducted showing no interaction in drug, polymers and other excipients. The best fit model for optimizing batch is peppas with r value of 0.9938, n value 0.6998 and K value is 19.5516.
The core tablet is prepared using direct compression technique, press coating process used for coating outer layer of tablet. The immediate release core developed comprises salbutamol disintegrants croscarmellose sodium, crospovidone and SSG of different ratio along with drug. Outer coat was prepared by using hydrophilic HPMC along with hydrophobic EC polymer considering same viscosity. The polymers considered individually to determine affect on lag time later applied central composite design. All evaluations to post compression parameters and dissolution study performed by USP paddle method of 50 rpm 0.1 N HCl & phosphate buffer with pH 6.8. The formulation with 300 mg of EC N50 & 75-100 mg of HPMC E50 is minimum quantity for outer press coat for obtaining lag time of 6 h.

The present study is to formulate press coating tablet and investigate effect of polymer based lag time. Press coated tablet by direct compression process, contains rapid disintegrate core along with outer layer contains hydrophilic polymer viz: HPMC, HPC, Sodium carboxy methyl cellulose and hydrophobic polymer like EC. The study shows the concentration and viscosity grade of polymer of outer coat increase the lag time. The in vitro release of drug states that HPC and Sodium carboxy methyl cellulose cause lower effect in lag time and HPMC, Ethyl cellulose has 4-8 hrs lag time later fast release of the drug.

The present study is to formulate a pulsatile compression coat tablet. These was processed in two steps (i) core tablet prepared with Nifidipine; (ii) core tablet is coated of EC (water insoluble polymer) and Eudragit L 100 (Enteric polymer) as polymer mixture. coating level in 50% w/w to core and weight ratio between polymers ethyl cellulose & Eudragit L 100 (20%) shows lower release compared with other formulations i.e. 52.83% in 12hrs. By increasing weight proportion between polymers of EC to Eudragit L 100 causes better entrapped drug leads controlled releasing of drug.
Dharmeshkumar Patel [18]

The inner core of press coating tablet in lornoxicam is processed contains outer shell with varied weight proportions of hydrophobic polymer (EC) and hydrophilic polymers (sodium alginate). The release pattern in press coating exhibits lagged time later burst release, with outer shell ruptures as two halves. The lag time decreased with increasing amount of sodium alginate. The optimum formulation (F5) comprised 10: 90\%w/w ratio of sodium alginate: Ethocel with 10 cps in a 245 mg coating weight, has desired lag time 308 minutes, which states the fluctuation symptoms of rheumatoid arthritis, followed rapid releasing pattern of lornoxicam.

DR. S.S. Khadabadi [19]

The Ketoprofen inner core tablet is formulated in direct compression process with outer coating of HPMC K4Min varied proportions. The release process defines press coating tablet exhibits lag time depends on amounts of HPMC K4M by compression coated followed by burst release. Optimized formulation is achieved using 32factorial design by two independent factors at 3 levels. Data was statistically determined by Stat Ease Design 7.1.4 software. The optimized formulation F6 have lag time 6 hr with drug release 95.74% with 40% HPMC K4M, and 2% SSG. Chronodelivery Ketoprofen achieved by compression and press coating process.


The Cefpodoxime Proxetil is formulated by compression-coated tablets to gastroretentive drug delivery. Different polymer mixture is used to retain core tablet for 12hrs in stomach. The drug is dispensed into two halves as in core tablet and in coating. The outer coating layer is designed to releasedrug in 15minutes to acheive initialdose later core tablet drug release starts after 2 hrs and drug release therapeutic window takes for 12hrs and maintained from interval 4hrs to 12 hrs.

Ashwini Rajendra [21]

Diclofenac sodium tablets of fast disintegrated treated coating material okra mucilage, with HPMC K15M and determined for pre-post compression parameters.
These formulation has burst release after 6hrs in intestine and has great drug release made suitable for chronic colon drug delivery.

- **Bajpai [22]**

  Chrono therapy of losartan potassium is achieved by coating core tablet with polymers HPMC,HPC, SODIUM CARBOXY METHYL CELLULOSE for achieving burst release after pre-determined lag time of drug release. The sigmoidal pattern is seen by having effervescent agent in core tablet and coated with 200mg of cellulose gives lag time 4.5 hrs and drug release of 73% in 6 hrs.

- **Sumit Kumar [23]**

  Naproxen sodium of immediate release by direct compression are treated with coating of polysaccharides like xanthan gum and gaur gum, these prevent release of drug in upper parts of gastro intestinal tract and hence suitable for colon drug delivery.

- **Kapse Pankaj [24]**

  Low viscosity hydrophilic polymer of Hydroxy propyl methyl cellulose 3,5,6- cps powder with weight ratios 1:2.86:3:4:5 individually with core constant ratio for coating.

- **B.G. Prajapati [25]**

  Propranalol Hydrochloride of 40mg dose was developed with HPMC and EC for time controlled pulsatile release by retarding drug release in stomach and intestine for 1-2 hrs. To release mechanism optimized by order of kinetic release determination. Zero order model and Hixon Crowell, Korsmeyer–Peppas kinetic model explained kinetic release of optimized formula F3.

- **Janugade B. U. [26]**

  Montelukast sodium in inner core press coat tablets developed with outer layer of different proportions of hydrophobic polymer EC and Hydrophilic polymer of low-substituted HPC. The effect on formulation proportions on barrier layer based on hydrophilic & hydrophobic excipients on lag time drug release is determined. lag time is inversely proportional to low substituted HPC polymer as concentration increases lag time decreases. Wet granulation and dry mix methods are compared in developing press coated tablets and wet granulation shown less lag time compared to dry mix method.