Utilization and Investigation of Polymer in Drug Industry

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ABSTRACTS

This paper provides investigation about the links between Polymers and Drug, which can provide information for drug enforcement authorities. Oral route of drug administration is oldest and safest mode of drug administration which does not possess the sterility problem with minimal risk of damage at the site of administration. Close cooperation between laboratory and law enforcement personnel is essential to maximize the operational value of drug characterization studies. For stable & satisfactory extend release profile of drug from fabricated polymeric matrix preparation in the form of tablets were identified with different proportion. Chemical links between Drug (Trimetazidine.HCl) and Polymer (Metalose) were established, which was studied by FTIR, UV and with other technique. There were some comparative study between drug and polymer which, analytically determines the approach of stability. For stability measurement relative humidity was under taken; 30°C/65 % RH & 40°C/75 % RH for 30 days. Formulations of drug content, hardness, friability were measured. From drug formulation, measurement after 30 days (drug-polymer contact time), the drug content found to be ~95.92 which is nearly equivalent to original drug content. This experiment found that by using Metalose polymer causes no change in drug property and can satisfactorily use.

Key words*:* Trimetazidine HCL, Metalose, Spectroscopy, Extended release.

1. INTRODUCTION

Oral ingestion has long been the most convenient and commonly employed route of drug delivery due to its ease of administration, high patient compliance, least sterility constraints and flexibility in the design of the dosage form. Trimetazidine 1 (2, 3, 4-trimethoxybenzyl-piperazine hydrochloride) has been reported to exert anti-ischemic properties without affecting myocardial oxygen consumption and blood supply. In idiopathic dilated cardiomyopathy with heart failure, . Trimetazidine (TZ) increased cardiac function and had both cardiac and extra cardiac metabolic effects. It improves left ventricular function in diabetic patients with coronary heart disease. Recently, it has been shown to be effective in patients with heart failure of different etiologies [1]. Drug delivery is highly innovative in terms of materials to assist delivery, excipients, and technology which allow fast or slow release of drugs. Controlled release includes extended-release and pulsatile-release products. Pulsatile release involves the release of finite amounts (or pulses) of drug at distinct intervals that are programmed into the drug product [2]. Like Diclofenac matrix tablets formulated employing olibanum & its resin component provided slow and controlled release of diclofenac over more than 24 hr. Drug release from the matrix tablets was by Fickian diffusion and followed first order kinetics [3]. Metalose 90SH 1, 00,000 SR (Hypromellose) is high viscosity water soluble polymer (HPMC) used in hydrophilic matrices to control the release of active pharmaceutical ingredient [4].

2. EXPERIMENTAL PROCEDURE

The drug material Trimetazidine HCL (BP) taken which is collected from Sharon Bio-Medicine LTD and Metalose (I.P) collected from Arihant trading Co.Ltd. The materials are 99.99 % commercially purity. The raw materials of #10 mess size are mixed in a motar & pestle with presence of binder solution methanol. After confirmation of homogenization, the mixture is compressed by Compression Machine CIP Machineries Pvt. Ltd to form a pellet (Tablet). The prepared drug pellets having dimensions of 0.5 inch diameter & 2 mm thickness (as shown in figure-1). Total weight of the tablet was 180 mg, for preparing Standard Calibration of Trimetazidine HCL-100mg. Trimetazidine Hcl was taken in a 100-ml volumetric flask, Dissolve

dilute to volume with phoushphate buffer pH.6.8 from the stock solution 10 ml was further diluted to 100 ml with purified water. The Absorbance of above solution was measured at 269 nm by UV Spectrophotometer (Shimadzu Corporation). The formulation data for Trimetazidine HCL Matrix Tablets are given in [Table-1]. IR spectra of drug in KBr pellets at moderate scanning speed between 4000-400 cm^{-1} was carried out using FTIR *(*Thermo-Nicolet Nexus 870*).* Dissolution caliberated with UV scanning was done for 10 mcg/ml drug solution from 200-400 nm in phoushphate buffer 6.8 as a blank using double beams UV/VIS spectrophotometer. Selected formulations were subjected to stability studies as per I.C.H. Guidelines. The conditions used for stability studies are (i) 30°C/65 % RH analyzed till a period of 30 days and (ii) 40°C/75 % RH analyzed till a period of 30 days with the help of Dissolution Test Apparatus (Borosil, India).

Table.1 Formulation of Trimetazidine HCL Matrix Tablets

Ingredients Ratio	F1	F2	F3	F4	F5	F6	F7	F8	F9
Trimetazidine Hcl	35	35	35	35	35	35	35	35	35
Metalose	40	52.5	70	45	60	65	15	25	35

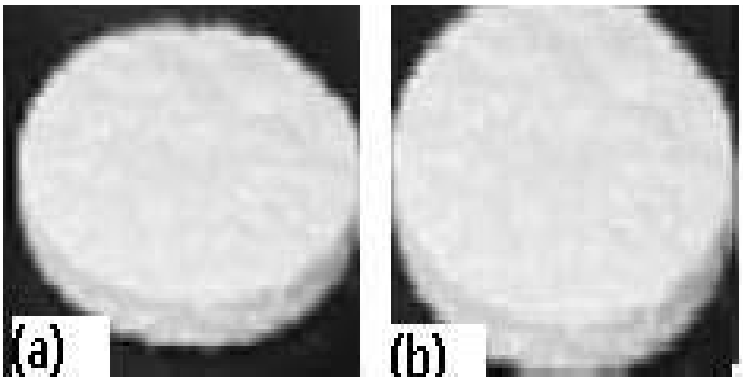

Fig 1. (a) Original drug pellet shapes (b) Drug pellet after 30.

3. RESULTS AND DISCUSSION

3.1 UV Analysis

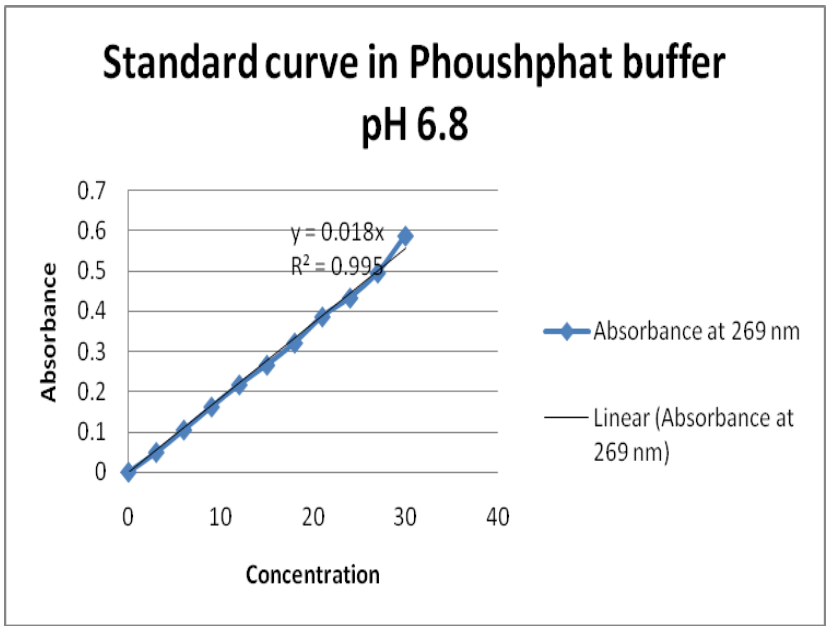

Fig 2. The wavelength maximum was found to be at 269 nm

3.2 FTIR Test:

The peak values of functional group shown in spectra which compare with standard value. The comparison of these results with Trimetazidine HCL chemical structure shows that the sample was pure Trimetazidine HCL [Figure 3]. The FTIR Spectrum of original Drug+Metalose (polymer) show that the prominent functional group peaks were remains unaffected [figure 4]. Comparing these two graphs it is found that, there is no change in chemical constituent for drug in contact with polymer in 30 days.

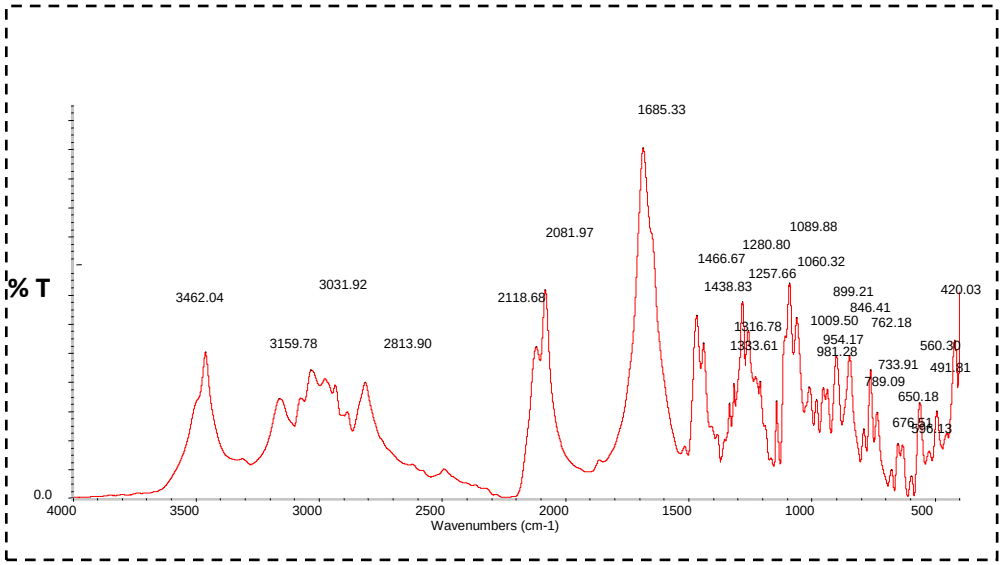

Fig 3. IR Spectrum of Pure Drug (Trimetazidine HCL)

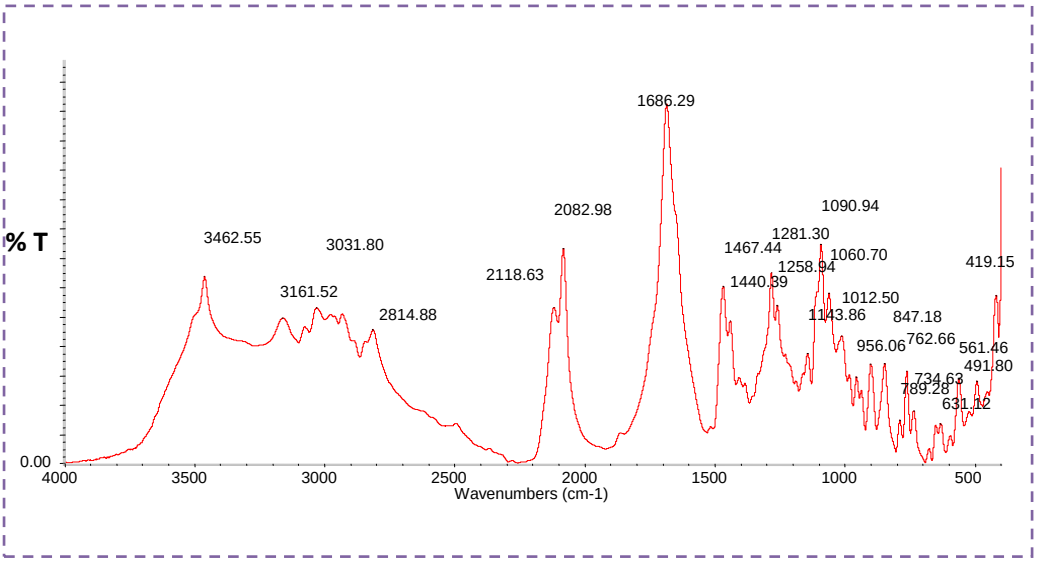

Fig 4. IR Spectrum of Drug + Metalose

3.3 Stability Study of Optimized Formulation

Table-2: Stability studies of formulation F-9 stored at 30°C/65 % RH & 40°C/75

Time (hr)	Cumulative % Drug Release		
	Initial	After 30 Days at 30°C/65 % RH	After 30 Days at 40°C/75% RH
0	0	0	0
1	34.61	34.01	33.53
2	50.36	50.98	50.12
4	68.95	67.33	66.65
6	72.98	71.61	72.53
8	80.77	80.11	79.78
Hardness	5.5	5.5	5.5
Friability	0.18	0.17	0.18
Drug content	96	95.92	94.99

4. CONCLUSIONS

The drug release from all matrix tablets showed a polymer concentration dependent. The drug release profile is satisfactory with the help of Metalose polymer. The compatibility of drug & polymer shows the stability & therapeutic effect in the formulation with satisfactory release of drug which was controlled by this suitable polymer with better sustained dissolution properties.

5. REFERENCES

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