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FORMULATION AND EVALUATION OF ATORVASTATIN CALCIUM LIQUISOLID TABLETS & COMPARING THE DISSOLUTION DATA WITH MARKETED TABLET

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ABSTRACT

Objective: The objective of the present investigation was to improve dissolution and bioavailability of practically insoluble lipid lowering drug Atorvastatin calcium using liquisolid technique. **Method**: Liquisolid compacts were prepared by using various carriers and a mathematical model for calculating the required quantities of powder and liquid ingredient to produce an acceptably flow and a compressible admixture. Micro crystalline cellulose, Lactose monohydrate, Hydroxy propyl methyl cellulose, Dicalcium phosphate , Silicon dioxide, Crosscarmellulose were employed as carrier, coating material and super disintegrant respectively. The prepared liquisolid compacts were evaluated for their micromeritic properties and drug-excipient interactions by FTIR. The liquisolid tablets were prepared and evaluated for their tableting properties. **Results:** The liquisolid systems showed acceptable micromeritic properties, the FTIR studies states that there is no chemical interaction between the drug and the excipients. The tableting properties of the liquisolid compacts were within the accepted limits. The release rate of Atorvastatin calcium was higher when compared to the marketed Atorvastatin calcium. **Conclusion**: In the present research work, the potential of liquisolid systems to enhance the dissolution properties of Atorvastatin calcium was investigated. In case of Atorvastatin calcium liquisolid tablets thereby revealing enhanced dissolution rate than marketed tablets. Thus the objective of incorporating Atorvastatin calcium into liquisolid system to achieve faster dissolution rates was met with success.

INTRODUCTION

The oral route of administration is preferred route for drug administration because of its high patient compliance and drug development, the problem associated with oral route was plasma drug concentration may not be reached. The solubility of drug is the major concern, it is the major factor to achieve desired concentration of drug in systemic circulation. Most of the hydrophobic drugs are slightly soluble drugs, for such drugs dissolution is the rate limiting step. The major Challenge for poorly soluble drugs is to enhance to dissolution rate, because the therapeutic dose of the drug substance depends upon bioavailability which in turn depends on the solubility and dissolution rate[1]. Various techniques have been employed in order to formulate drug delivery system which enhances the dissolution rate were lyophilization, microencapsulation, solid dispersion, inclusion, co precipitation, of drug solution or liquid drugs into soft or hard gelatin capsules. all the above techniques having high production cost and technology demanding[2]. By using the

liquisolid technology, a liquid may transfer into a free-flowing, readily compressible & apparently dry powder by simple physical blending with various excipients like carrier and coating material. Liquisolid technique is the most promising & new technique for improving dissolution among the various novel techniques. It promotes the dissolution rate of water insoluble drugs to a greater extent & also enhances the drug flow property[3]. In the liquisolid system drug is already exist in solution form in liquid vehicle and it is carried by the powder materials. Then the wetting properties increased due to increased surface area of drug available for dissolution[4]. Atorvastatin calcium is a synthetic lipid lowering drug. Now days it is being highly used for cardiovascular disease, hypercholesterolemia and many other diseases. Atorvastatin is an inhibitor of 3- hydroxy-3-methylglutaryl-coenzyme-A-(HMG-CoA) reductase. It is used to lower cholesterol and triglyceride levels in the blood. According to biopharmaceutical classification system (BCS), the Atorvastatin calcium having poor solubility and high permeability and the dissolution properties can be improved by application of liquisolid technique. In the present work, liquisolid tablets of Atorvastatin calcium were formulated with different carrier materials and evaluated for their Precompression and post compression parameters. Finally the i*n-vitro* dissolution rate compared with the marketed Atorvastatin calcium tablets.

MATERIALS:

Atorvastatin calcium Purchased from Yarrow Chem Products, Mumbai, Micro crystalline cellulose, Di calcium Phosphate, Lactose, HPMC and Crosscarmellulose sodium were obtained from S.D Fine Chem. Ltd, Mumbai and all the other chemicals were used as Analytical grade.

METHODS:

Determination of λmax: An accurately weighed 10 mg of Atorvastatin calcium was transferred in a 100ml volumetric flask. To flask phosphate buffer was added in small proportion so as to dissolve Atorvastatin calcium. The volume was made up to 100 ml with phosphate buffer pH 6.8 to get a concentration of 100 µg/ml. 20 µg/ml solution of Atorvastatin calcium was prepared in dilution. The resulting solution was scanned in UV-Vis spectrophotometer from 400-200 nm to determine theλmax.

Calibration Curve: 100 mg of Atorvastatin calcium transferred into 100 ml volumetric flask and makeup the final volume with pH 6.8 phosphate buffer. From this stick solution different concentration 5 – 40 µg/ml was made up with pH 6.8 phosphate buffer. From each concentration sample was taken & the absorption was measured at 242 nm by using UV spectrophotometer by using pH 6.8 phosphate buffer as a blank. The graph was plotted by taking concentration on X-axis and absorption on Y-axis.

Drug Excipients Compatibility Studies: Compatibility study was performed by the KBr pellet method using the Fourier transform infraredspectrophotometer[5]. A baseline correction was made using dried potassium bromide, and then the spectra of Atorvastatin calcium, carrier and coating materials were obtained[6].

Solubility Analysis: Saturated solution were prepared by adding excess amount of Atorvastatin calcium to appropriate solvents like propylene glycol, Tween-80, Tween-40 and Span-80, then shaking on orbital shaker for 48hrs at 25 rpm under constant vibrations. The solution were filtered through 0.45micron filter, diluted suitably and analyzed by UV-visible spectrophotometer at 242 nm[7].

Determination of Flowable Liquid-Retention Potential (Ø-value): The admixture containing nonvolatile solvent and carrier or coating material were mixed using motor and pestle. In constant weight of nonvolatile solvent (Tween-40), increasing carrier or coating material (MCC, HPMC, DCP, Lactose and collodial silicon dioxide) was incorporated and on each addition, an angle of repose was determined. The flowable liquid retention potentional (Ø-value) of each liquid/powder admixture was calculated using the following equation[8].

Ø value = weight of liquid/weight of solid

Determination of Liquid Load Factors (LF) &Carrier and Coating ratio(R Value): The maximum amount of liquid load on carrier/coating material, termed "load factor" (LF). Appropriate amounts carrier and coating materials used to procedure an acceptable

flowing and compactable powder were calculated using following equation[9].

Lf = ØCA + ØCO (1/R) -----1

Where, **ØCA** and **ØCO** are flowable liquid retention potential value of carrier and coating material. Liquid load factor (Lf) is defined as ratio of the weight of liquid medication (W) over the weight of the carrier powder (Q) in liquisolid system, which should be possessed by an acceptably flowing and compressible system. **Lf = W/Q-------2**

R is calculated by using following equation

R = Q/q------3

R represents the ratio between the weights of carrier (Q) and coating material (q) present in the formulation. where, Q-Weight of carrier material, q-weight of coating material.

PREPARATION OF ATORVASTATIN CALCIUM LIQUISOLID COMPACT

Required quantity of Atorvastatin calcium was initially dispersed in nonvolatile solvent (Span-80) termed as liquid vehicle. Then a mixture of carrier and coating materials was added to the above liquid by continuous mixing for a period 10 to 20 minutes in motor[10]. The amount of carrier and coating materials are taken depends on above equations.

FORMULATION OF ATORVASTATIN CALCIUM LIQUISOLID TABLETS

Different formulation (F1-F8) of tablets were prepared by direct compression method[10]. To above binary mixture (liquisolid compact) disintegrant like Crosscarmellulose sodium and another remaining additive like magnesium stearte were mixed in mortar. The final mixture was directly compressed into tablets to achieve into tablet hardness or encapsulation. Tablet hardness was kept within range of 3-4kg/cm^2.

PRECOMPRESSION PARAMETERS:

Before the compression the prepared blend was evaluated for the following parameters[11].

Bulk Density: Apparent bulk density was determined by pouring the 5 gm of powder into 100 ml measuring cylinder. The bulk volume (V) of the poured drug was determined and bulk density was calculated using the formula.

Db = M/Vb

Where; Db is bulk density, M is weight of powder and Vb is bulk volume of powder.

Tapped Density: Determined by 5 gm of powder placed in 100 ml measuring cylinder and tapped for 100 times. The minimum volume (Vt) occupied was measured. The tapped density was calculated using following formula.

Dt = M/Vt

Where; M is mass of powder and Vt is tapped volume of powder

Carr's Index: It indicates powder flow properties. It is expressed in percentage

I = Dt – Db/Dt *100

Where; Dt is tapped density and Db is bulk density of powder

Hausner's Ratio: Hausner's ratio is an indirect index of ease of powder flow. Hausner's ratio is the ratio of tapped density to bulk density. Lower the value of Hausner's ratio better is the flow property. Powder with Hausner's ratio less than 1.18, 1.19, 1.25, 1.3-1.5 and greater the 1.5 indicate excellent, good, possible and very poor, respectively. It was calculated by the following formula[12].

Hausner's ratio = Dt/Db

Where, Dt is tapped density and Db is bulk density

Angle of repose: The angle of repose was determined by using funnel method.

Θ = Tan-1(h/r)

Where, Θ = angle of repose, h = height of cone, r = radius of cone

POST FORMULATION STUDIES

Weight Variation: Twenty tablets were taken and then weight was determined individually and collectively on a digital weighing balance. The average weight of a tablet was determined from collective weight[13].

Thickness: Tablet thickness can be measured using a simple procedure 5 tablet was taken and their thickness was measured using Vernier callipers.

Hardness: It is force required breaking a tablet by compression in radial direction, it is an important parameter in formulation of ODTs because excessive crushing strength significantly reduces the disintegration time. In the present study crushing strength of tablet was measured using Pfizer hardness testers.

Disintegration time: One tablet in each 6 tubes of basket was placed and the apparatus subjected to run. The assembly should be raised and lowered between 50 cycles per minute. The time in second taken for complete

disintegration of tablet with no palpable mass remaining in the apparatus was measured and recorded[14].

Friability Test: Friability of tablets was determined using Roche friability.

$$\% \text{ Friability} = \frac{\text{initial weight} - \text{final weight}}{\text{Initial weight}} * 100$$

Drug Content Uniformity: The tablets were weighed and powdered. An amount of powder equivalent to 40 mg of Atorvastatin calcium was dissolved in 100 ml of phosphate buffer pH 6.8, filtered, diluted suitably and analysed for drug content at 242 nm using UV-Visible spectrophotometer. From absorbance value, amount of drug present in given tablet was calculated[15].

Wetting Time: Determined by placed five circular tissue papers in a Petri dish containing 10 cm diameter. Ten millimetres of water-containing Eosin, water-soluble dye, is added to Petri dish. A tablet was carefully placed on surface of tissue paper. The time required for water to reach upper surface of tablet was noted as a wetting time[16].

Dissolution Studies: *In vitro* drug release studies for liquisolid tablets of Atorvastatin calcium (which differ in carrier concentration & R-value) marketed tablets was studied using dissolution test apparatus (USP – II model) paddle type, for fabricated batches with rotation speed of 50 rpm using phosphate buffer pH6.8 as dissolution medium maintained at room temperature of 37±0.5°C. Samples were withdrawn at predetermined time interval and filtered through wattman filter paper, diluted suitably and analysed at 242 nm for cumulative drug release using double beam visible spectrophotometer. The dissolution experiments were conducted in triplicate[17].

RESULTS & DISCUSSION

Determination of λ_{max}: The 20 µg/ml Atorvastatin calcium solution was scanned in UV-Vis spectrophotometer from 400- 200 nm to determine the λmax. The λmax was found to be at 242 nm, so the calibration curve of Atorvastatin calcium was developed at this wavelength.

Calibration Curve of Atorvastatin calcium: The standard graph of Atorvastatin calcium in pH 6.8 PBS was constructed by making the concentration range 5 - 40 µg/ml solutions. The absorbance of solutions was examined under UV- spectrophotometer at an absorption maximum of 242 nm. The curve obeyed Beer-Lambert's law and the correlation coefficient value (R^2) of buffer was0.975

Solubility of Atorvastatin calcium: The solubility is an important aspect in liquisolid systems, as the higher solubility of the drug in the non-volatile solvent can lead to higher dissolution rates since the drug will be more molecularly dispersed and more surface of a drug will be exposed to the dissolution medium. Atorvastatin calcium appears to be more soluble in span-80 than other solvents propylene glycol, Tween-80 and Tween-40. So, Span-80 was the appropriate solvent in the preparation of Atorvastatin calcium liquisolid tablets.

Drug Excipients Compatibility Studies: The interaction studies were performed to find any kind of interaction between drug and excipients used in liquisolid tablets. FT-IR spectroscopy was used to determine the functional group present in the pure drug sample. The FTIR spectrum of pure Atorvastatin calcium was showed the characteristic peak at 1316.80 cm^{-1}(C-N – stretching), 1650.71 cm^{-1} (C=O – stretching am idic group), 3152.09 cm^{-1} (N-H - stretching), 1650.71 cm^{-1} (C=C - bending), 746.50 cm^{-1}, 691.35 cm^{-1} (C-F- stretching), 1159.08 cm^{-1} (O-H- bending).

Inference: The FTIR spectra of the Atorvastatin calcium and formulation excipients were shown in Figures. The spectra of drug and excipients employed were showed a broad peak at the same place of the peak observed at the spectrum of pure Atorvastatin calcium has been observed, which indicated that there was no chemical interaction with the formulation excipients.

Determination of Flowable Liquid-Retention Potential (Φ -value):

The liquisolid mixtures containing varying amount of carrier (MCC, HPMC, Lactose and DCP) were prepared according to method described previously. Thereafter, angle of repose of these liquisolid mixtures were determined. The liquid/solid mass ratio (m/m) of blends with angle of slide corresponding to ≤30 was taken as the -value for Φ calculation.

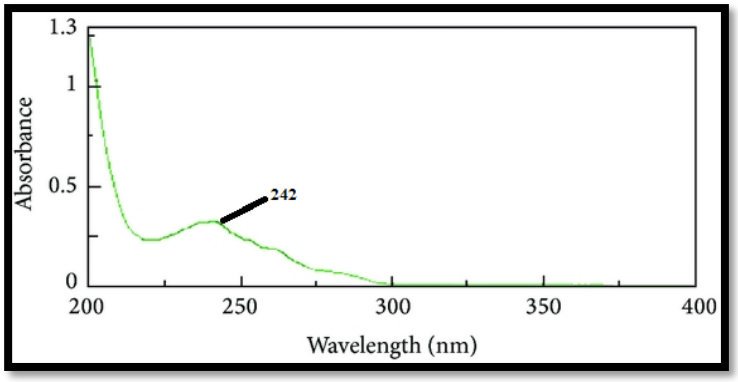

Fig-1:λmax of Atorvastatin calcium

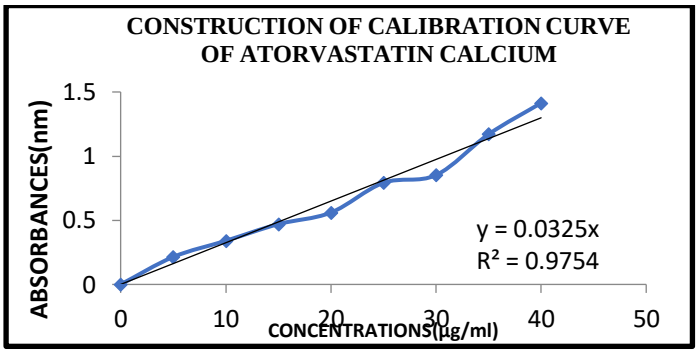

Fig-2: Calibration Curve of Atorvastatin calcium in pH6.8 PBS

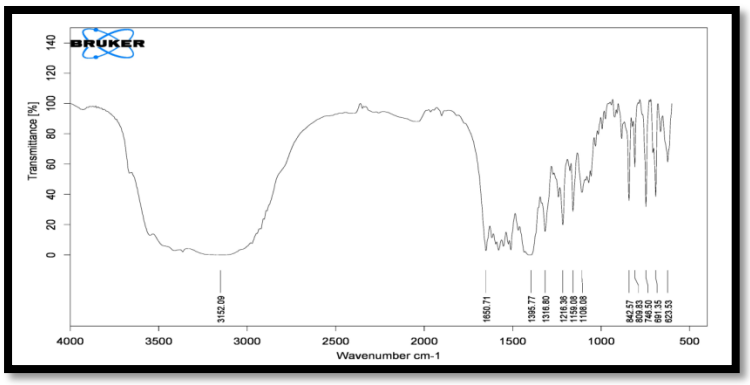

Fig -3: FT-IR Spectra for the Pure Atorvastatin calcium

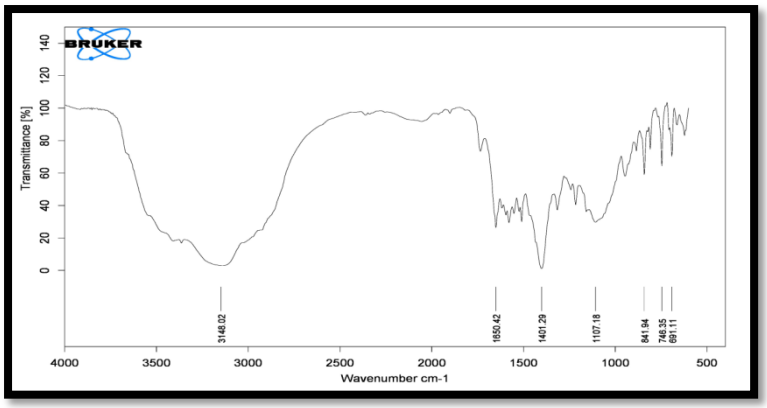

Fig - 4: FT- IR Spectra for Atorvastatin calcium + Formulation Excipients

Table – 1: Formulation of Atorvastatin calcium LST`s

S. No	Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
1	Atorvastatin calcium	40	40	40	40	40	40	40	40
2	Span -80	100	100	100	100	100	100	100	100
3	Microcrystalline cellulose	97.90	111.1	-	-	-	-	-	-
4	HPMC	-	-	112	126	-	-	-	-
5	DCP	-	-	-	-	125	140	-	-
6	Lactose	-	-	-	-	-	-	87.5	96.5
7	Silicon dioxide	19.19	18.7	18.9	19.1	18.9	18.9	19.8	18.6
8	Crosscarmellulose sodium	10	10	10	10	10	10	10	10
9	Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
10	Mg.sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
11	Total weight	270.09	282.8	284	298.2	297	311.9	260.3	268

Table–2: Precompression Parameters of all the Formulations F1 – F8

Formulation Code	Bulk Density ($Gm/Cm^{3)}$	Tapped Density ($Gm/Cm^{3)}$	Carr's Index	Hausner's Ratio	Angle Of Repose
F1	0.526±0.01	0.590±0.02	10.1±0.65	1.03±0.041	36.6±0.31
F2	0.456±0.02	0.483±0.49	6.26±0.50	1.40±0.54	42.2±0.41
F3	0.336±0.02	0.393±0.03	14.3±0.26	1.14±0.24	37.2±0.44
F4	0.420±0.11	0.460±0.05	17.9±0.20	1.27±0.19	32.5±0.55
F5	0.370±0.05	0.443±0.07	10.4±0.11	1.18±0.04	31.0±0.98
F6	0.480±0.04	0.520±0.09	11.03±0.62	1.11±0.06	33.9±0.51
F7	0.395±0.02	0.420±0.03	9.3±0.45	1.05±0.03	28.4±0.16
F8	0.550±0.03	0.620±0.04	14.5±0.3	1.28±0.27	28.1±0.80

Mean ± S.D. of three determinations

Table-3: Post compression Parameters of Atorvastatin calcium LST`s

Formulation Code	Hardness (Kg/Cm^2)	Friability (%)	Weight Variation (%)	Thickness (Mm)	Drug Content (%)
F1	4.8±0.23	0.238±0.019	3.4±0.48	8.2±0.007	97.90±0.09
F2	4.5±0.36	0.433±0.006	2.5±0.62	8.1±0.001	96,51±0.38
F3	4.9±0.27	0.210±0.003	2.7±0.11	8.2±0.003	96.81±0.14
F4	4.7±0.45	0.644±0.010	3.2±0.34	7.9±0.005	95.93±0.46
F5	4.8±0.51	0.817±0.004	1.6±0.26	8.1±0.002	97.45±0.26
F6	4.9±0.24	0.437±0.012	2.1±0.31	8.0±0.008	96.64±0.31
F7	4.2±0.28	0.377±0.008	2.8±0.13	8.1±0.002	98.51±0.18
F8	4.4±0.59	0.524±0.002	3.3±0.64	8.2±0.002	98.29±0.51

Mean ± S.D. of three determinations

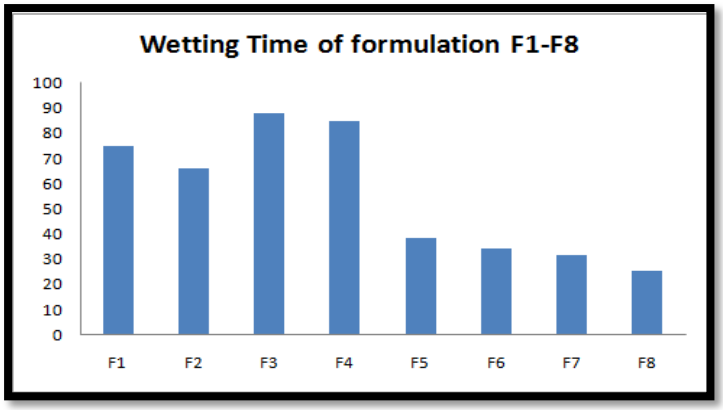

Figure-5: Comparison of Wetting Time of Formulations F1 – F8

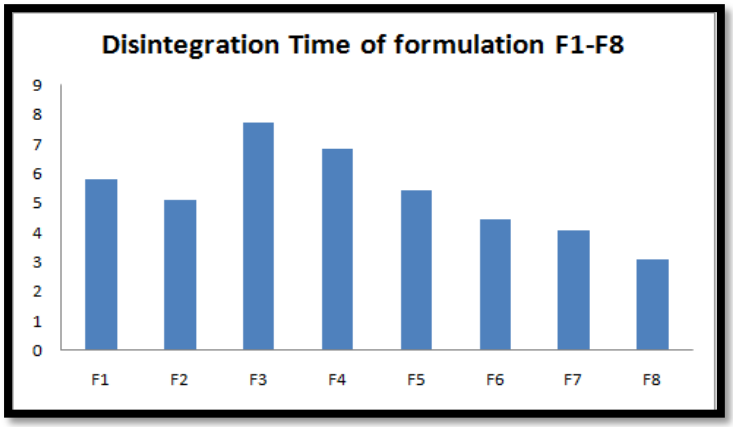

Figure 6: Comparison of Disintegration Time of Formulations F1 – F8

Table 4: Comparative Dissolution Profiles of the Formulations F1-F8

Time min	% Cumulative Drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	Marketed Tablet
10	29.6±0.9	20.2±1.2	23.3±4.1	24±2.7	26.1±3.5	28.5±1.1	42.1±5.0	45.6±5.0	41.1±4.2
15	43.6±3.5	40.4±1.13	31.8±3.2	44.31±1.7	37.6±2.8	42.2±3.8	53.4±3.9	51.9±2.04	55.6±3.6
20	51.2±1.9	53.3±0.67	43.47±3.8	55.1±3.8	57.8±1.3	54.3±2.04	63.7±4.0	66.8±3.61	63.9±7.21
30	62.8±3.1	65.5±3.3	51.1±1.7	63.6±3.0	66.2±3.17	63.6±3.17	74.5±4.6	78.4±4.6	70.4±1.26
45	70.6±3.1	72.1±2.02	67.3±2.8	73.1±3.04	75.5±2.25	78.1±0.7	82.4±2.5	86.7±1.9	82.6±2.9

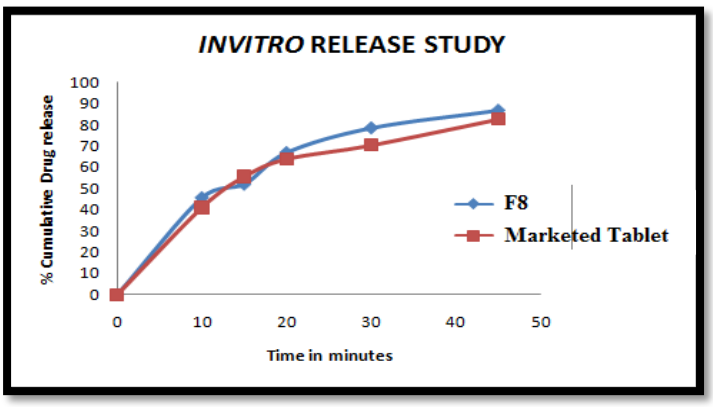

Figure-7: Comparative Dissolution Profiles of F8 & Marketed Tablets

Determination of Liquid Load Factors (Lf) & Carrier and Coating Ratio (R): Mathematical model equation for carrier and coating material in Span-80 can be given according to values of (ΦCA) and (ΦCO) as given as follow:

$$Lf = \Phi CA + \Phi CO\ (1 / R) \ldots (1)$$

Based on this equation, Lf is calculated by using different R values and based on value of W (liquid medication), amount of carrier can be calculated according to equation (2), and then amount of coating can be calculated by applying equation (3) depending on R value. The liquisolid tablets were formulated.

PREPARATION OF ATORVASTATIN CALCIUM LIQUISOLID COMPACT

Liquisolid compacts were prepared by using eight different carriers to coating ratio i.e. F1 (MCC: silicon dioxide–97.90/19.19), F2 (MCC: silicon dioxide – 111.1/18.7), F3 (HPMC: silicon dioxide – 112/18.9), F4 (HPMC: silicon dioxide – 126/19.1), F5 (DCP: silicon dioxide – 125/18.9), F6 (DCP: silicon dioxide – 140/18.9). F7 (Lactose: silicon dioxide – 87.5/19.8), F8 (Lactose: silicon dioxide – 96.5/18.6), Liquisolid blend was formulated as represented in Table 1.

FORMULATION OF ATORVASTATIN CALCIUM LIQUISOLID TABLETS

Eight tablet formulations (F1 – F8) were prepared by direct compression method. To the liquisolid compacts crosscarmellulose sodium, magnesium stearte and talc were added and compressed into tablets. Atorvastatin calcium liquisolid tablets were formulated as represented following table 1.

Pre compression Parameters: The powdered blends of all the formulations were evaluated for bulk density and tapped density by using bulk density apparatus and the results were shown in Table. The bulk density was found in the range of 0.336±0.02 - 0.550±0.03 gm/cm^3. The tapped density ranged between 0.393±0.03 - 0.620±0.04 gm/cm^3. Which indicate that powder is loosely packed. These values were further used for calculating Carr's index and Hausner's ratio to check its flow ability of powder. The Compressibility index and Hausner's ratio values of all the formulations indicate that the prepared blends possessed minimum interparticlulate interactions and good flow property which is preliminary requirement for formulating the tablets. The prepared powder blends of all the formulations were evaluated for the flow properties. The angle of repose of all the formulations was within the range of 28^0 - 42^0. These values indicate that the powder blend F7 & F8 had excellent flow properties; F4, F5 & F6 had good flow properties, and F1, F2 & F3 had exhibited poor flow properties.

Post-compression Parameters: All the formulations were prepared under similar conditions and the tablets exhibited white colour, convex in shape with smooth surface. The characteristics of prepared LST`s of Atorvastatin calcium are discussed below. The hardness for the tablets of all formulations was adjusted to 3–5 Kg/cm^2 so that the effect of carrier on the dissolution rate could be evaluated accurately. The friability of all the formulated tablets was within 1%, which is an indication of good mechanical resistance of the tablet. The drug content varied between 95.93±0.46 to 98.51±0.18 for all the formulations. The thickness was measured for the tablets of all formulations and was found to be within the acceptable range. The variation in weight was within the range of ± 5% complying with pharmacopoeial specification.

Wetting Time: For all the formulations, with increase in the carrier concentration, the wetting time was decreased accordingly. It is clear from the results that the formulation containing MCC & HPMC had shown more wetting time than lactose and DCP. This may be due to the fact that MCC & HPMC is disintegrated by swelling mechanism leading to longer wetting time and lesser water absorption ratio. The formulations that contain lactose have the shortest wetting time, which may be attributed to the strong wicking action of this carrier. The wetting time was in the range of 25 seconds to 88 seconds and the formulation F8 showed minimum wetting time of 25.3 seconds.

Disintegration time: The *invitro* disintegration time of prepared tablets (F1 – F8) was present between 3.1 to 7.7 minutes. Out of eight formulations, the tablets prepared using 96.5 mg of lactose showed rapid disintegration in 3.1 min. It was clear that the disintegration time of lactose containing tablets were comparatively lower than tablets containing

MCC, HPMC and DCP. This may be due to its rapid capillary activity and hydration when comes in contact with buffer and water.

EVALUATION OF *INVITRO* RELEASE STUDIES:

The cumulative percentage release in pH 6.8 PBS for all the formulations was recorded and the formulation F2, F4, F6 and F8 showed higher drug release than compared to F1, F3, F5 and F7. It was found that there is a relationship between the carrier to coating material ratio (R value) and the *in vitro* release of Atorvastatin calcium from liquisolid tablets. An increased increase R value associated with enhanced wicking, disintegration and thus, enhanced drug release. The tablets formulated with lactose showed greater rate of dissolution when compared to the tablets formulated with MCC, HPMC and DCP. In formulation F8 containing 96.5 mg of lactose along with 10 mg of Crosscarmellulose sodium showed better dissolution rate than those of all other formulations. This might be because of its high disintegrating nature. The dissolution study of an optimized formulation (F-8) compared with marketed tablets (Lipvas – 40 mg) and it was found that F-8 showed significant higher drug release rate than marketed tablet.

CONCLUSION:

In the present research work, the potential of liquisolid systems to enhance the dissolution properties of Atorvastatin calcium was investigated. It was found that there is a relationship between the carrier to coating material ratio (R value) and the *in vitro* release of Atorvastatin calcium from liquisolid tablets. An increased R value associated with enhanced wicking, disintegration and thus, enhanced drug release. The optimized formulation F-8 revealed a percentage cumulative drug release (CDR) of 86.7% at the end of 45 min, while marketed tablets (Lipvas) revealed a % CDR value of 82.6%. In case of Atorvastatin calcium direct compressible tablets thereby revealing enhanced dissolution rate. Thus the objective of incorporating Atorvastatin calcium into liquisolid system to achieve faster dissolution rates was met with success.

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