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Formulation and evaluation of biocompounds of berberis asiatica compressed tablets in hyperlipidemia treatment

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ABSTRACT

The objective of the research is to design and evaluate the bio compounds of Berberis asiatica (BCBA) compressed tablets in the management of hyperlipidemia. BCBA of dose 500 mg was compressed into tablets by employing microcrystalline cellulose (MCC) and sodium starch glycolate (SSG) as super disintegrant and necessary excipients by employing direct compression method. The fourier transform infrared (FTIR) results depicts no incompatibility among the drug and excipients. The study results of pre-compression parameters has excellent flow qualities and compressibility.The post-compression parameters show that the results are within the specified standard deviations. SSG exhibit better disintegrating property than MCC. Better disintegration properties and in vitro drug release tests were exhibited by the optimized formulation F6.

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INTRODUCTION

A high amount of lipids in your blood, such as cholesterol and triglycerides, is referred to as hyperlipidemia. It is thought to be a Coronary heart disease (CHD) risk factor if the onset can happen at any age, with males experiencing it at >45 years of age and women experiencing it at >55 years of age [1]. Hyperlipidemia is a key source of increased atherogenic risk; both hereditary diseases and lifestyle (sedentary behavior and high-calorie, saturated-fat, and cholesterol-rich meals) contribute to dyslipidemias prevalent in advanced countries worldwide [2, 3].

There are four treatment lines available for hyperlipidemic patients including Statins, Bile acid sequestrants, Nicotinic acid and Fibric acid derivatives as explained, yet no treatment is effective enough to properly manage Hyperlipidemia due to the lack of compliance with patients and adherence to the therapy. Medical plants have played a significant part in ancient traditional medical systems.

Till now, plants remain one of the most affordable sources of medication for the vast majority of the population with secure and negligible side effects. The World Health Organization has endorsed the utilization of natural medications and traditional medicines for the benefit of the world's population owing to cost-effectiveness and fewer side effects.

Berberis asiatica is reported in having antihyperlipidemic activity at a dose of 500mg [4]. BCBA was formulated into tablet dosage form by direct compression method.

MATERIALS AND METHODS

Chemicals

The study made use of analytical grade chemicals (Sigma Aldrich, Hi-media, and Merck India Ltd).

Collection and Preparation of aqueous Extract of B. asiatica (BCBA)

The B. asiatica heartwood was obtained from the Sri Srinivasa ayurvedic pharmacy in Tirupati. The heartwood had been dried and roughly ground. At room temperature, 200 g of heartwood powder was macerated with 1L distilled water for 24 hours. The extract was concentrated, and the resulting semisolid mass of 20 g was housed in an airtight container devoid of excess heat, moisture, and air, and labelled BCBA.

UV spectral analysis of BCBA

The calibration curve is the primary basis for estimating rate of drug release in in vitro dissolution studies. To determine the maximum absorption wavelength of selected candidates, UV spectral analysis of BCBA was undertaken using a UV-Visible spectrophotometer between 200 and 400 nm.

Compatibility studies

Chemical compatibility between the BCBA and excipients was studied by FT-IR Spectroscopy. About 2% test sample was combined with potassium bromide (KBR) to obtain fine powder by grinding using small glass mortar and then crushed into KBR pellets by a hydraulic press at a pressure of 10000 psi and waited for 1 minute collecting the pellet. Each sample was screened for 32 single scans at the range of 400- 4000 cm-1.

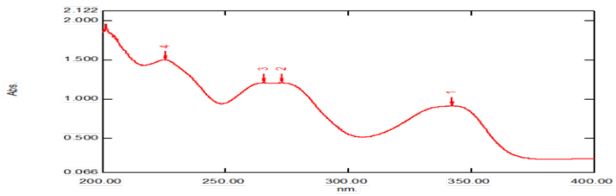

Figure 1: UV-Visible absorption spectra of BCBA

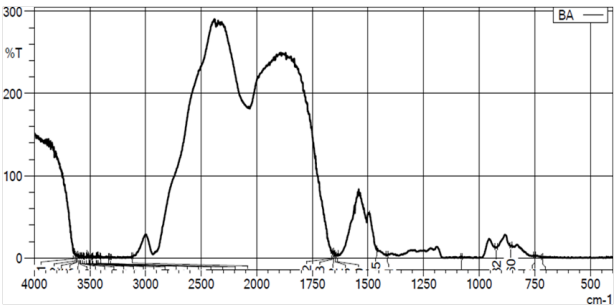

Figure 2: FTIR of BCBA

Preparation of BCBA compressed tablets

The BCBA tablets were manufactured adopting the direct compression approach. The calculated amount of drug & excipients was weighed individually, mix homogeneously and compressed [Table 1].

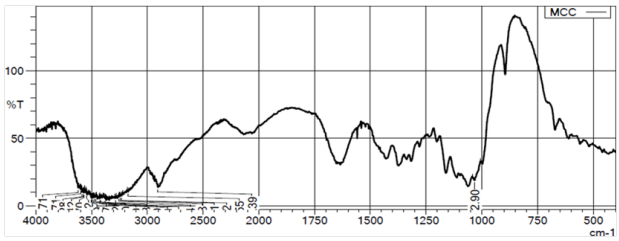

Figure 3: FTIR of MCC

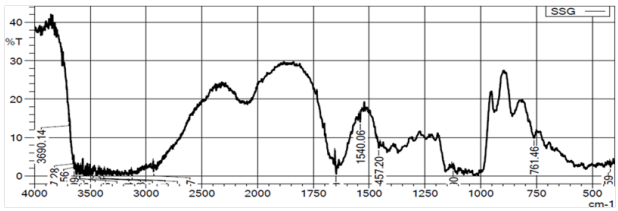

Figure 4: FT-IR of SSG

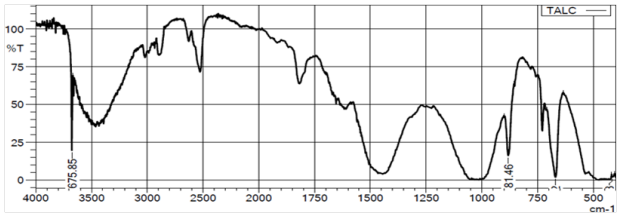

Figure 5: FT-IR of Talc

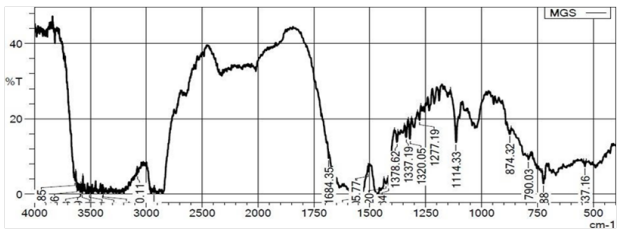

Figure 6: FT-IR of Magnesium stearate

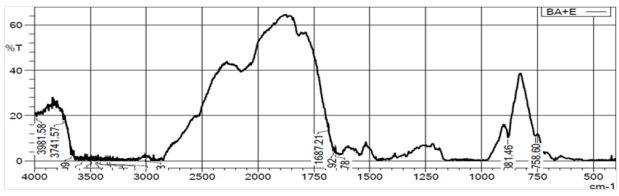

Figure 7: FT-IR of BCBA and excipients

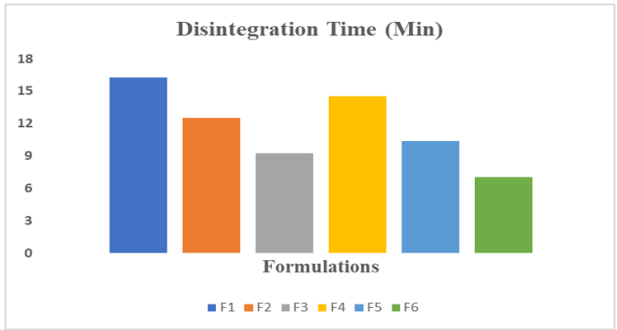

Figure 8: Disintegration time of Formulations F1-F6

Table 1: Formula for the Preparation of BCBA tablets

Ingredients	F1	F2	F3	F4	F5	F6
BCBA	500	500	500	500	500	500
MCC	12..5	25	37.5	-	-	-
SSG	-	-	-	10	20	40
Talc	37.5	37.5	37.5	37.5	37.5	37.5
Magnesium stearate	25	25	25	25	25	25

Table 2: Pre-compression parameters of formulation F1-F6

S.No	Formulation	Angle of repose	Bulk density	Tapped density	Carr's index	Hausner'sratio
1.	F1	21.38	0.86	0.87	1.14	1.01
2.	F2	23.49	0.89	0.91	2.19	1.02
3.	F3	24.07	0.86	0.89	3.37	1.03
4.	F4	22.09	0.87	0.88	1.13	1.01
5.	F5	23.02	0.88	0.90	2.22	1.02
6.	F6	21.63	0.87	0.92	5.43	1.05

Table 3: Post compression parameters of formulation F1-F6

S.No	Formulation	Thickness& Diameter (Limit:<5%)	Hardness(Limit 5 Kg/cm^2)	Friability (Limit:<1%)	% Weight variation
1.	F1	Within limits	4.5	0.68	Pass
2.	F2	Within limits	3	0.79	Pass
3.	F3	Within limits	4	0.67	Pass
4.	F4	Within limits	4	0.93	Pass
5.	F5	Within limits	3	0.46	Pass
6.	F6	Within limits	3.5	0.54	Pass

Table 4: Release kinetics of formulations F1-F6

Formulati	Zero Order (r)	First Order (r)	Higuchi(r)	HixsonCrowell (r)	Korsmeyer Peppas	
					(r)	(n)
F1	0.9465	0.9913	0.9723	0.9154	0.8785	0.31
F2	0.9531	0.9937	0.9134	0.9274	0.8683	0.29
F3	0.9559	0.9957	0.9265	0.9156	0.8753	0.36
F4	0.9642	0.9991	0.8923	0.9356	0.8469	0.35
F5	0.9102	0.9902	0.9014	0.9216	0.8961	0.28
F6	0.9546	0.9992	0.9112	0.9057	0.8521	0.27

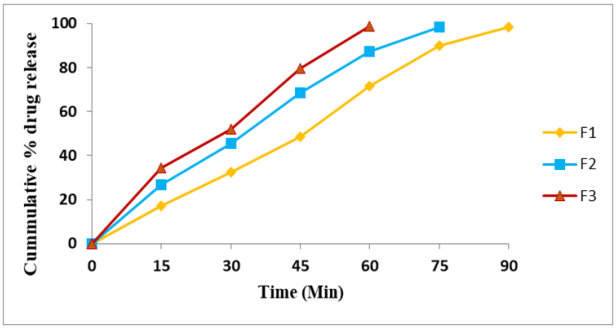

Figure 9: Dissolution studies of formulations F1-F3

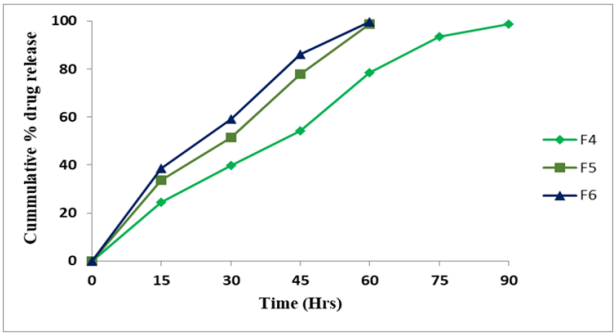

Figure 10: Dissolution studies of formulations F4-F6

Pre compression parameters

Bulk density (Db)

A bulk density apparatus was used to determine the bulk density of the powder mixture. It is the ratio of total powder mass to total powder volume. It was calculated by pouring the weighted powder into a measuring cylinder and recording the volume. It is presented in g/ml and is represented as

D_b= M/V_b

Tapped density (D_t)

It is the ratio of total powder mass to tapped powder volume. Tapping the powder to constant volume yielded the tapped volume. It is measured in g/ml and is provided by [5].

D_t = M/V_t

Compressibility index (I) and Hausner's ratio

Carr's index and Hausner's ratio measure the compressibility and the flow nature of powder mixture. It was calculated employing following formula [6].

I= D_t - D_b/D_t x 100

Hauseners ratio = Dt / Db

Angle of repose

The angle of repose is frequently used to determine the frictional forces in a loose powder. This is the maximum angle that formed between the surface of powder pile and the plane. A weighed powder were delivered via a funnel from a specific height (2 cm) onto a level surface, forming a heap. The heap's height and radius were recorded. The formula used to determine the angle of repose [7].

Angle of repose ø = tan-1(h/r)

Post compression parameters Dimensions

The tablets thickness and diameter evaluated using digital vernier callipers or screw guaze. The permitted difference is ±5% [8]

The percent difference in thickness and diameter can be calculated by using the formula:

Percent difference = Average – Individual reading /AverageX100

Hardness

It was performed with a hardness tester and stated in kg/cm^2.

Friability (F)

Friability was determined using the Roche friabilator and represented as a percentage. Randomly collect 20 tablets and weighed collectively and record as W1 and placed in the friability chamber, which was rotated at 25 rpm for 4 minutes. Then collect the tablets and weigh record as W2. The % friability computed using the formula below [9].

%F = W1-W2/W1 X 100

Weight variation test

Collect randomly 20 tablets, weighed individually. Determine the average weight for 20 tablets. Calculate the % weight variation for 20 tablets individually. Not more than two individual weights of tablets should fall out of the limits i.e.,±5%.

% Weight variation = Average weight – Individual tablet weight / Average weight x 100

Disintegration test

Disintegration test can be done by using tablet disintegration tester which contains 6 glass tubes with mesh of size 10 at bottom of each glass tube. Tablets are placed in glass tubes and dip in a one litre beaker of water maintained at body temperature. The basket operated at a speed of 28 to 32 cycles per minute by employing a motor. The time required to tablet to completely disintegrate into pieces is noted which gives disintegration time [10].

Dissolution studies

Rotating paddle apparatus (USP type II) employed. Tablet was placed in 900 ml of Phosphate Buffer Saline 7.4 dissolution medium. The dissolution medium was stirred at a rate of 50 rpm and maintained at a temperature equivalent to that of body

temperature. The sample of 1 ml pipette out, diluted to 10 ml at every 15 min interval upto 90 min. The amount of drug release at every interval was calculated by using UV-spectrophotometer Wavelength: 340 nm.

Release kinetics

Data obtained from the in vitro release studies were fitted to various kinetic equations such as zero order, first order, Higuchi model and Korsmeyer-Peppas model [11].

RESULTS AND DISCUSSION

UV Spectral Analysis of BCBA

The BCBA solution was examined between 200 and 400 nm showed in the Figure 1. The absorption maximum was found to be 340 nm used for further studies showed in Figure 1.

FTIR study

The FTIR studies reported compatibility of BCBA with excipients and no significant interactions were observed [Figures 2, 3, 4, 5, 6 and 7].

Precompression parameters

Pursuant to the study results of pre compression parameters include angle of repose, cars index, and hausners ratio, the powder mixture of all formulations (F1-F6) has excellent flow qualities and compressibility [Table 2].

Postcompression parameters

The observation of results of post-compression parameters depicts that thickness and diameter of the compressed tablets are within the limits (i.e<5%) states that no variation in the tablet weight. Hardness and friability reveals the tablets of all formulations (F1-F6) are having sufficient strength and surface strength. The results of percentage weight variation of formulations F1-F6 reveals variation of tablet weight are within the prescribed limits [Table 3].

Disintegration time

The disintegration time of formulations F1-F6 was in the range of 16 min 25 sec to 7 min 2 sec which falls within in the prescribed limits. Disintegration time of the tablets was highly influenced by the super-disintegrating agents and its concentration. The increased concentration of microcrystalline cellulose in formulations F1-F3 the disintegration time decreased from 16 min 25 seconds to 9 min 27 sec. The increased concentration of sodium starch glycolate in formulations F4-F6 the disintegration time decreased from 14 min 55 sec to 7 min 2 sec. In comparison to microcrystalline cellulose sodium starch glycolate exhibits better disintegrating property. The results show that the disintegration time of the tablets lowers as the concentration of super disintegrating agent increases. The F6 formulation with sodium starch glycolate was optimized which disintegrates in less time than the formulations with microcrystalline cellulose as a super disintegrant [Figure 8].

Dissolution studies

The rate of drug release is high in formulations contain SSG as super disintegrant in comparison to formulations prepared with MCC. The F6 formulation prepared with 8 % SSG releases the complete drug at the end of 60 min in comparison with the formulations prepared with 4% and 6% SSG. The rate of drug release is high in F6 formulation, hence it was optimized [Figures 9 and 10].

Mathematical Model Fitting of Obtained Drug Release Data

The obtained drug release profiles data from all 6 runs of BCBA compressed tablets at different time intervals was fitted to various drug release kinetic models. As mentioned in the table the correlation coefficient value (r) was found to be maximum for first order model. The maximum r value for first order model confirmed that the diffusion of drug into dissolution medium is dose-dependent [Table 4].

CONCLUSION

Bioactive compounds of Berberis asiatica compressed tablets were successfully processed by direct compression method. The FTIR studies reported compatibility of BCBA with excipients. Pre-compression parameters depicts the powder mixture of all formulations (F1-F6) has excellent flow qualities and compressibility. The post-compression parameters depicts that the tablets are having sufficient hardness, surface strength, thickness and diameter are within the limits, passes the percentage weight variation test. Sodium starch glycolate exhibit better disintegrating property than microcrystalline cellulose. The optimized formulation F6 showed better disintegrating property and In vitro drug release studies.

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Conflict

Nil.

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