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Research Article

DEVELOPMENT OF FILM COATED ORAL DOSAGE FORM OF ACAMPROSATE CALCIUM

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ABSTRACT

Objective: The present work is directed toward the development of film coated oral dosage form (tablet), which will extend the release of Acamprosate calcium.

Methods: Film-coating tablet containing Acamprosate calcium was prepared by the direct compression method.

Results: The hardness, drug content, disintegration, and dissolution profile of Acamprosate calcium batch F6 considered as optimized batch. This batch showed dissolution of the drug at 180 min about 94%. Drug content of optimized batch was 99.7%, Hardness and thickness of optimized batch (F6) were found to be 9.3–11.3N and 5.57–5.69 mm, respectively.

Conclusion: Prepared Film-coated tablets of Acamprosate calcium have extended release as expected.

Keywords: Acamprosate calcium, Film-coated tablets, Drug delivery system.

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INTRODUCTION

Recent global estimates of alcohol dependence vary, 12.5% of individuals (17.4% of men and 8% of women) in the United States will meet criteria for alcohol dependence in their lifetime. Not surprisingly, for the United States and most countries around the world, harmful alcohol use remains a significant cause of chronic disease and injury [1].

Alcoholism is a complex behavioral disorder characterized by excessive and compulsive drinking, chronic relapse, impaired control over intake, tolerance to the effects of alcohol, the presence of withdrawal symptoms, and impaired social and occupational functioning. As with most substance use disorders, the mainstay treatments for alcohol use disorders are self-help social support groups, 12-step programs, cognitive-behavioral therapies, or some combination of these [2]. Research shows that even with treatment, many individuals (estimates range from 20% to 80%) will eventually relapse, given the low success rate of even the best therapeutic interventions. Researchers and clinicians have long sought pharmacological adjuncts for the treatment of alcoholism [3,4].

Acamprosate calcium is used in the treatment of alcohol dependence. It is believed to act by blocking glutaminergic N-methyl-D-aspartate receptors and activation of gamma-aminobutyric acid type a receptor. It is an anti-dipsotropic agent that was approved by the USFDA in 2004 for use in alcoholic individuals to decrease alcohol hankering after alcohol detoxification. Acamprosate calcium has been commercially available since 1989 [5].

METHODS

Acamprosate calcium as an antialcoholic agent purchased from Sun Pharmaceutical Pvt. Ltd. Microcrystalline Cellulose (Avicel PH102) as a diluent, Sodium starch glycolate (ExplotabType A) as a super disintegrant, Polyvinyl Pyrrolidone (Plasdone 29/32) as a binder, Crospovidone (Kollidon CL) as a disintegrant, Purified Talc and Colloidal Anhydrous Silica as Glidant, Magnesium Stearate as a lubricant, and Hydroxypropyl methyl cellulose as a coating polymer, and other excipients were utilized from institute's lab.

To formulate the batch of acamprosate calcium film-coated tablet and evaluated the physical parameter by the changing the diluents to get desired release of the drug [6].

Formulation

Acamprosate calcium was mixed with microcrystalline cellulose, sodium starch glycolate, and magnesium silicate. This mixture was passed through a 40# mesh sieve. The sifted mixture was then added into the blender, and blending was continued for10 minutes**.** After that, colloidal silicon dioxide and talc were added, and blending was continued for an additional 3 min. For lubrication, magnesium stearate was passed through a 60# mesh and added into the blender. Blending was continued for 3–4 min. The final powder blend was ready for compression, which was carried out using a 16-station D-tooling Cadmach CD4 compression machine [7,8]. Unit composition is given in Table 1.

RESULTS AND DISCUSSION

Compatibility studies

These studies were done by mixing the drug with individual excipients as per the formulation ratio. Then these individual mixtures sifted through sieve no. #40, filled into the vials, sealed. The samples were kept at conditions of 40±2°C and 75±5% RH and were analyzed at intervals of 0, 30, 60, and 90 days for their physical changes and drug content as per ICH guidelines [9,18-20].

Fourier transform infrared (FTIR) spectroscopy

Infrared spectroscopy (Shimadzu) is used to predict possible drug-excipients interaction study. It was observed that IR spectra of physical mixture exhibit similar frequency of wavelength as that of the drug (Fig. 1). This indicated that there was no physical change in the

Table 1: Unit composition for film coated tablet

Ingredient	F1 Qty/Tab (mg)	F2	F3	F4	F5	F6	F7	F8
Acamprosate calcium	333.00	333.00	333.00	333.00	333.00	333.00	333.00	333.00
Microcrystalline cellulose (Avicel pH 101)	-	115.00	66.00	72.00	70.00	68.00	68.00	68.00
Microcrystalline cellulose (Avicel pH 102)	117.00	-	-	-	-	-	-	-
Sodium starch glycolate (Explotab type A)	3.00	3.00	3.00	3.00	3.00	3.00	3.00	3.00
Polyvinyl pyrrolidone (Plasdone 29/32)	-	-	45.00	45.00	45.00	45.00	45.00	45.00
Magnesium silicate	30.00	30.00	30.00	30.00	30.00	30.00	30.00	30.00
Crospovidone (Kollidon CL)	2.00	4.00	8.00	2.00	4.00	8.00	8.00	8.00
Blending								
Colloidal silicon dioxide (Aerosil 200)	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Talc	5.00	5.00	5.00	5.00	5.00	5.00	5.00	5.00
Lubrication								
Magnesium stearate	9.50	9.50	9.50	9.50	9.50	9.50	9.50	9.50
Total weight of core tablet (mg)	500.00	500.00	500.00	500.00	500.00	500.00	500.00	500.00
Enteric coating								
Hydroxypropyl methylcellulose	25.00	25.00	25.00	25.00	25.00	25.00	18.75	31.25
Propylene glycol	3.75	3.75	3.75	3.75	3.75	3.75	2.78	4.63
Talc	11.25	11.25	11.25	11.25	11.25	11.25	8.44	14.00
Purified water	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.	Q. S.
Total weight of coated tablet (mg)	540.00	540.00	540.00	540.00	540.00	540.00	530.00	550.00

Table 2: Results of pre-compression parameters of all the batches

S. No.	Average weight (mg)	Thickness (mm)	Hardness (n)	Friability at 100 revolutions	Disintegration time (min)
F1	498±2.45	5.66±0.26	4±0.25	0.27±0.02	6 min 25 s–6 min 55 s
F2	500±3.15	5.68±0.20	5±0.3	0.27±0.03	9 min 25 s–9 min 45 s
F 3	501±0.40	5.65±0.20	7±0.45	0.30±0.02	9 min 30 s–10 min 10 s
F4	503±0.15	5.65±0.21	7±0.40	0.14±0.03	9 min 35 s–10 min 20 s
F5	498±2.15	5.59±0.09	7±0.25	0.39±0.02	8 min 55 s–9 min 25 s
F6	500±2.30	5.58±0.04	7±0.5	0.29±0.02	9 min 45 s–10 min 15 s
F7	496±3.40	5.57±0.11	7±0.35	0.10±0.02	10 min 25 s–11 min 00 s
F8	501±2.45	5.69±0.04	9.3±0.40	0.29±0.03	10 min 35 s–11 in 55 s

Values are expressed as mean±standard deviation, n=3

Table 3: Evaluation of assay and content uniformity

Batch code	%Assay	Content uniformity
F3	95.5	100.02
F4	98.3	99.89
F5	96.1	99.84
F6	97.6	99.74
F7	99.4	99.94
F8	94.9	99.91

Table 4: Unit composition optimized batch for film-coated tablets

Ingredient	Quantity
Acamprosate calcium	333.00
Microcrystalline cellulose (Avicel pH 101)	68.00
Sodium starch glycolate (Explotab Type A)	3.00
Polyvinyl pyrrolidone (Plasdone 29/32)	45
Magnesium silicate	30
Crospovidone (Kollidon CL)	8
Blending	
Colloidal silicon dioxide (Aerosil 200)	0.5
Talc	5
Lubrication	
Magnesium stearate	9.5
Enteric coating	
Hydroxy propyl methyl cellulose	25.00
Propylene glycol	3.75
Talc	11.25
Purified water	Q. S.

drug after the stability period and no interaction between the drug and the excipients [10].

Table 5: Results of pre-compression parameters of the optimized formula

Parameter	Observation
Angle of repose (0°)	39.41±0.49
Bulk density (g/mL)	0.489±0.18
Tap density (g/mL)	0.590±0.012
Compressibility index (%)	19.62±0.85
Hausner ratio	1.24

Values are expressed as mean±standard deviation, n=3

Table 6: Results of post-compression parameters of final formulation

Parameter	Observation
Weight (mg)	540
Thickness (mm)	5.69±0.04
Hardness (n)	9.3±0.5
Friability (%)	0.29±0.01
Disintegration time (min)	9–11 min
Assay	97
Content uniformity	99.7

Values are expressed as mean±standard deviation, n=3

Differential Scanning Calorimeter (DSC)

DSC thermograph of the active pharmaceutical ingredient (API) exhibited a sharp endothermic peak at 377.06°C. Physical mixture of Acamprosate calcium with excipients, such as microcrystalline cellulose, sodium starch glycolate, magnesium silicate, crospovidone, polyvinyl pyrrolidone, crospovidone, colloidal silicon dioxide, talc, and magnesium stearate exhibited endothermic peak of a at nearly similar

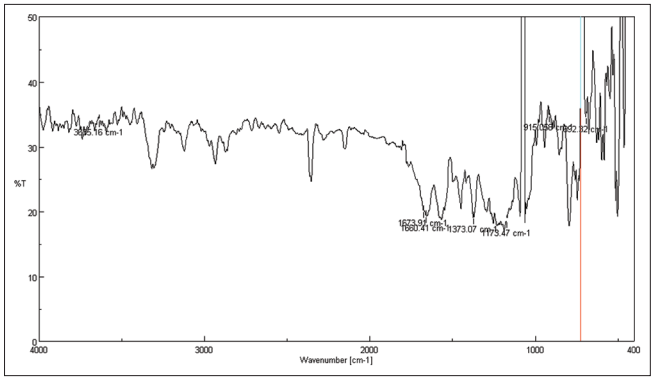

Fig. 1: Fourier transform infrared spectra of blend containing the drug and excipients

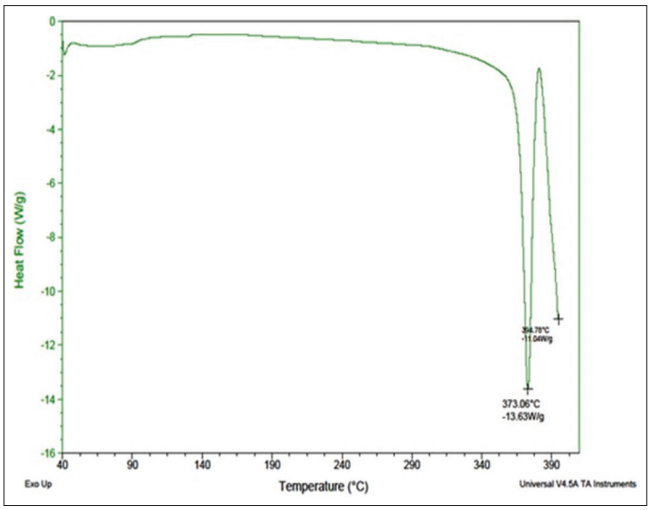

Fig. 2: Differential scanning calorimeter thermogram of a blend containing the drug and the excipient

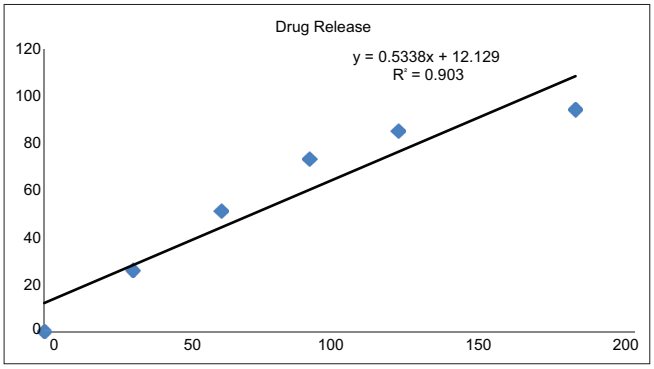

Fig. 3: Dissolution profile

place and with intensity (Fig. 2). This indicates that there was no interaction between the API and excipients, and onset of peak was start from 350°C, and sharp peak observed at 370°C [11].

Acamprosate calcium+physical mixture

Pure form of API, that is, Acamprosate calcium, showed the endothermic peak at 377°C while the physical mixture, including all excipient containing Acamprosate calcium, showed the endothermic peak at 373.06°C, which shows the compatibility between Acamprosate and selected excipient for formulation.

In these batches effect of different fillers (Avicel 101andAvicel102) on drug release was studied. Dissolution studies of F1 and F2 batches were not carried out. From post-compression parameters such as thickness, hardness, and friability, it was cleared that trial batch F2, which contains Avicel 101, was finalized for further trials. Because batch F1and F2 showed much lower hardness, which was not acceptable for coating purposes. (Table 2) F3–F8 batches have different concentration of crospovidone and hydroxypropyl methylcellulose to get desired release pattern [12,14-17].

Table 7: Dissolution profile of optimized formulation

Dissolution profile in 0.1 NHCl followed by pH 6.8 citrate-sodium hydroxide buffer, 900 mL, 180 rpm, USP Type-I (Basket)		
Dissolution media	**Time (min)**	**% Drug release**
		Optimized formula
Acid stage	120	0
Buffer stage	30	26
	60	51
	90	73
	120	85
	180	94

Based on the formulation and development of the prototype formulation, and their data reflect that the following prototype formula is proposed for batches. The F6 batch is considered as optimized batch for film-coated tablets (333 mg) (Table 4).

The angle of repose was found to be 39.41° this value is between 32 and 45, which shows the good flow property of powder blend (Table 5).

The disintegration of the core tablet was found to be satisfactory, which ensured the opening pattern and hardness [21-23].

Optimized formulation showed similar to ideal film coated formulation [13].

As per the recent trend, alcohol dependence was commonly observed, to help the patient and encourage for recovery, antialcoholic agent have high importance. In addition, very few competitors are available in the market, so it means it has high commercial value.

For drug confirmation, FTIR and DSC tests were carried out. In DSC at 377.06°C endothermic peak was observed, which matches with drug Acamprosate calcium melting point 375°C confirm the drug purity. FTIR functional group confirms the API moiety as well as the stability of drug.

Compatibility study was done to ensure the acceptability of excipients in the powder blend. This was confirmed by cross-check with API and Physical mixture FTIR, DSC results.

In initial trials, Trail batch F1 had hardness problem was observed and overcome by changing the diluent grade from Avicel 101 to Avicel 102 (trial batch F2).

On the basis of hardness, drug content, disintegration, and dissolution profile of Acamprosate calcium Trial batch F6 considered as optimized batch. F6 optimized batch showed dissolution of drug at 180 min, about 94% (Table 7). Drug content of optimized batch was 99.7% (Table 6), Hardness and thickness of optimized batch (F6) were found to be 7N and 5.58 mm, respectively.

CONCLUSION

A film-coating tablet containing Acamprosate calcium was prepared by the direct compression method successfully. Based on hardness, disintegrate on time, drug content, and *in vitro* drug release profile, formulation batch (F6) was selected as the optimized batch, which was found to be 94.00% release after 180 min, respectively. In conclusion,

prepared Film coated tablets of Acamprosate calcium has delayed release as expected.

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AUTHORS' CONTRIBUTIONS

The coauthors Ankita Pardeshi, Dr. Sachin Rane, and Dr. Jesika Ranehave made a substantial contribution to the conception, acquisition of data, interpretation of results, and in the drafting of the article.

CONFLICTS OF INTEREST

The authors declare no conflicts of interest.

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