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FORMULATION,DEVELOPMENT AND EVALUATION OF ALBENDAZOLE ORAL JELLIES.

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Abstract:

Albendazole oral jellies using suitable natural and synthetic polymer as gelling agent with different concentrations. The benefits of these prepared jellies are increased bioavailability by-passing first pass metabolism. jellies were prepared by dispersing the gelling agent in water. Physical characteristics, pH, in vitro % drug release kinetics, content uniformity, spreadability, viscosity, IR spectral analysis, and stability studies were conducted.The prepared jellies of Albendazole found to be stable and there has no significant change in physical appearance, pH, viscosity etc. Thus, the study confirmed that the Albendazole oral jelly can be used as a possible alternative to recently available oral formulations. The prepared formulations are free from sugar crystals. Among the prepared formulation, formulation F2 (96.21%) and F10 (98.44%) respectively released in 30 min. was found to be promising. Stability studies, pH, viscosity, spreadability, on the promising. IR spectroscopic studies indicate that there were no drug-excipients interactions.

keywords: *Albendazole jellies, gelling agents , etc.*

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INTRODUCTION:

The oral route is most popular route for the administration of various drugs. The ease of administration leads to high levels of patient compliance. Helminthiasis also known as helminth infection or worm infection is any macroparasitic disease of humans and other animals in which a part of the body is infected with parasitic worms (helminths). These parasites are broadly classified into tapeworms, flukes and roundworms. They often live in the gastrointestinal tract of their hosts, but may also burrow into other organs, where they induce physiological damage. Soil-transmitted helminthiasis (SHT) and schistosomiasis are the most important group of helminthiases, collectively belonging to the "neglected tropical diseases".[5,6] Therefore some researchers has prepared and reported formulation such as tablets like chewable tablet, matrix tablet, microcapsules, microsphere, suspensions, etc. The present investigation is designed to improve patient compliance and ease of administration. Advantages of the Albendazole oral jellies as a dosage form include increase in bioavailability, helps to bypass extensive hepatic first pass metabolism, reduction of dosage wastage, and etc. the present work is aimed at preparing a formulation of Albendazole oral jellies, for treatment of worm infestation.[7,10]

Criteria To Be Met By Drug Proposed To Be Formulated In Albendazole Oral Jellies

Some physicochemical parameters for selecting of drug to be formulated in a Albendazole oral Jellies as follows.

- The Drug should have Pleasant taste.
- It should be partially Unionized at the pH of oral cavity
- Drug should not affect the natural microbial flora of the mouth.
- Good solubility in water as well as in saliva and also good stability
- The drug should have high solubility and high permeability (BCS Class-I)
- The drug have extensive first pass metabolism.
- It should have quick onset of action

MATERIALS AND METHODS:

Material:

Albendazole[11] was received as a gift sample from Glenmark Pharmaceuticals Ltd, Nashik. Gelling agents like Pectin[9], Xanthum gum[9], Sodium alginate[9], Gelatin[9], HPMC[12], and HP-β-CD etc. were brought from Modern Science, Nashik. All other chemicals and solvents used were of analytical grade..

Method:

The Albendazole and HP-β-CD (1:1.5, 1:2, and 1:2.5) were prepared by kneading method. In this method HP-β-CD was taken in a glass mortar, little water was added mixed to obtain homogenous paste. The drug was added slowly while grinding. The mixture was ground for 1 hour and during this process approximate quantity of water was added to maintain suitable consistency.

Preparation of Medicated Oral Jellies 4,5

All the formulations were prepared using freshly boiled and cooled distilled water as per the composition listed in **Table No. 1.** Albendazole jellies were prepared by dispersion of gelling agent in water. All the powdered materials were mixed in each other. The required quantity of propylene glycol and sugar syrup were added into it. This mixture was added into freshly boiled distilled water and mix thoroughly by using magnetic stirrer (1 MLH, REMI Equipment Pvt. Ltd) for 30 minutes to facilitate hydration of gelling agent. Albendazole with HP-β-CD complex was added to the above solution under continuous stirring. Color and flavor was added to this under continuous stirring at 60ºC. This whole solution is transferred into moulds and then allows it for cooling and settling undisturbed by proper covering the moulds to avoid exposure to outer environment. After settling of jellies, wrapped into the gelatin paper and stored in cool place.

Evaluation Parameters of Albendazole Oral Jellies:

Physical Appearances

The texture of soft jelly was evaluated in terms of stickiness and grittiness by mildly rubbing the gel between two fingers. Color and odor were also evaluated by physical appearances.

Determination of pH

The pH of the final jelly had got influenced not only stability, but also on the taste. The pH of soft jelly was measured using Digital pH meter at room temperature. For this purpose 0.5 gm of jelly was dispersed in 50 mL of distilled water to make1% solution, and the pH was noted.

Viscosity

Viscosity of jelly was measured by Brookfield® viscometer using spindle DV-E-64. Viscosity was measured for the fixed time 2 minutes at the rotation of 3 RPM at room temperature (25ºC ± 5ºC).

Spreadability

Spreadability of jellies was determined by an apparatus which consist of two wooden blocks provided with two glass slides. Lower slide fixed on a wooden block and upper slide with one end tied to a glass slide and the other end tied weighing the pan. About 2.5 gm of jelly was placed between two slides, and 1000 gm weight was placed over it for 5 minutes to press the sample to a uniform thickness. 80 gm weight was added to the pan, and

the time (in seconds) required to separate the two slides was taken as a measure of spreadability. A shorter time interval to cover a distance of 7.5 cm considered as better spreadability and was calculated by the formula,

$$S = \frac{M \times L}{T}$$

Where, S is the spreadability,

M is the weight tide to upper slide,

L is the length of glass slide (7.5 cm),

T is the time taken to separate two slides

***In- vitro* drug release**

Literature shows that dissolution of jellies should be seen in 0.1 N HCl Solution. *In-vitro* drug release study of jellies was carried out by using the paddle apparatus method. The dissolution test was carried out using 900 mL of 0.1 N HCl solution, at 37 ± 0.5^0C and 100 RPM. A sample (5 mL) of the solution was withdrawn from the dissolution apparatus at 5, 10, 15, 20, 25, 30 min. and withdrawn volume was replaced with fresh dissolution media.

Following parameters were used for the dissolution study.

1. Apparatus : USP dissolution apparatus type II (paddle type)
2. Speed of the paddle : 100 RPM
3. Temperature : 37.5^0c ± 0.5^0c
4. Dissolution medium : 0.1 N HCl
5. Volume of fluid : 900 mL
6. Sampling time : 5, 10, 15, 20, 25 and 30 minutes

Content Uniformity

The jellies were taken out of the molds in beaker and weighed individually, pooled and mixed. The gel equivalent of 200 mg Albendazole was taken in 100 ml volumetric flask dissolved and made up to the volume using 0.1 N HCl. The content uniformity was estimated by UV-Vis Spectrophotometer at 228.8 nm after filtering the sample through filter paper.

Stability Study

Stability studies of prepared jelly at room temperature (25^OC±5°C, 75%±5% RH). The stability studies are carried out for 1 month and the formulations were analyzed for the changes in the physical parameters like appearance, pH, and viscosity.

RESULT AND DISCUSSION:

Jelly formulation consisting of Pectin, Gelatin, Xanthum Gum, Sodium Alginate and HPMC was successfully developed with increased dissolution rate and ultimately increased aqueous solubility of poorly water soluble drug, Albendazole. It can help to bypass extensive hepatic first pass metabolism and improved bioavailability of Albendazole. Many paediatric and geriatric patients are unwilling to take the solid dosage forms of higher dose; this disadvantage is overcome by jelly formulation. The formulation (**F2 & F10**) found to be stable in short term accelerated testing done for one month. There has been no significant change in physical appearance, pH, viscosity etc.

CONCLUSION:

We concluded that the objective of this study is achieved. Thus, the study confirmed that the Albendazole oral jelly formulation can be used as a possible alternative to recently available oral formulation

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11.en.m.wikipedia.org/wiki/Helminthiasis
12.en.m.wikipedia.org/wiki/Albendazole

FIGURES:

Fig 1: Oral Jellies of Albendazole

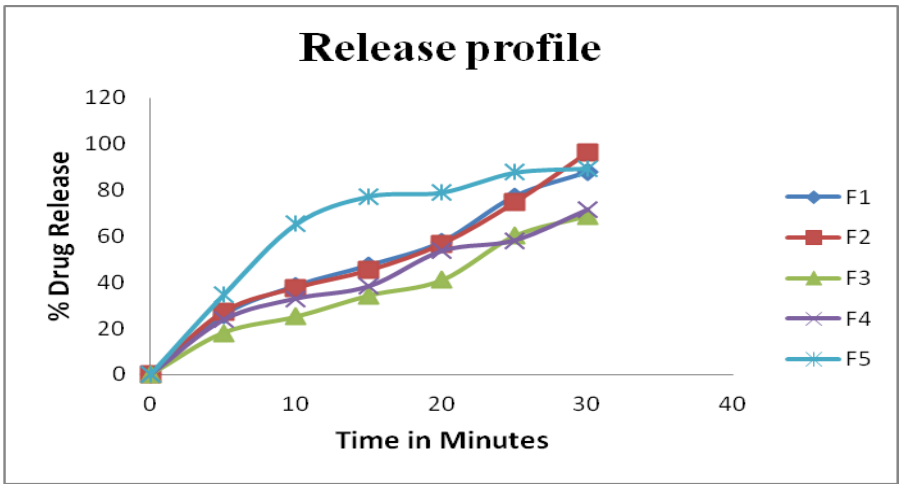

Fig 2: Percent Drug Release profile graph of Formulation F1 to F5

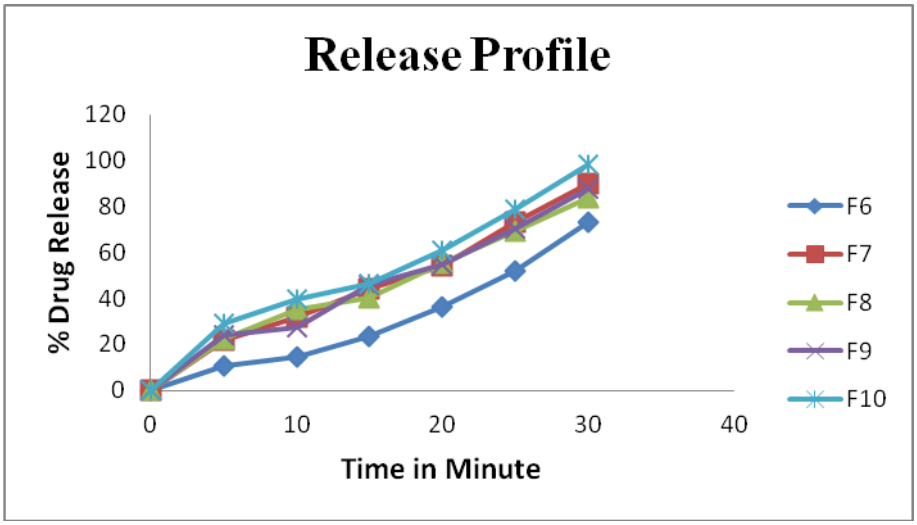

Fig 3: Percent Drug Release profile graph of Formulation F6 to F10

TABLES:

Table 1: Formulations of Albendazole Oral Jellies

Formulation Code	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Albendazole (mg)	200	200	200	200	200	200	200	200	200	200
Pectin	1%	3%	-----	-----	-----	-----	-----	-----	-----	-----
Xanthum gum	-----	-----	1%	2%	-----	-----	-----	-----	-----	-----
Gelatin	-----	-----	-----	-----	1%	3%	-----	-----	-----	-----
Sodium alginate	-----	-----	-----	-----	-----	-----	5%	10%	-----	-----
HPMC	-----	-----	-----	-----	-----	-----	-----	-----	5%	10%
Citric acid	1%	1%	1%	1%	1%	1%	1%	1%	1%	1%
Propylene Glycol	3%	3%	3%	3%	3%	3%	3%	3%	3%	3%
Sugar Syrup	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Methyl paraben	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Propyl paraben	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%	0.01%
Colouring agent (Tartrazine)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Flavouring agent (Pineapple)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Table 2:Solubility enhancement of Albendazole.

Obs. Code.	Method of Preparation	Ratio
A	Kneaded Product	1:1.5
B	Kneaded Product	1:2
C	Kneaded Product	1:2.5

Table 3:Physical Appearances of Albendazole oral jellies

Sr. No.	Formulation code	Texture	Colour	Flavour
1.	F1	Smooth	Orange	Orange
2.	F2	Smooth	Yellow	Pineapple
3.	F3	Smooth	Reddish Pink	Strawberry
4.	F4	Smooth	Yellow	Pineapple
5.	F5	Smooth	Reddish Pink	Strawberry
6.	F6	Smooth	Yellow	Pineapple
7.	F7	Smooth	Orange	Orange
8.	F8	Smooth	Yellow	Pineapple
9.	F9	Smooth	Reddish Pink	Strawberry
10.	F10	Smooth	Yellow	Pineapple

Table 4: *pH* of Albendazole oral Jellies

Sr. No.	Formulation Code	pH
1	F1	6.20±0.140
2	F2	6.62±0.115
3	F3	6.40±0.158
4	F4	6.66±0.109
5	F5	7.6±0.101
6	F6	7.6±0.101
7	F7	6.79±0.06
8	F8	6.93±0.055
9	F9	6.59±0.070
10	F10	6.76±0.075

Table 5: Viscosity of Albendazole oral jellies

Sr. No.	Formulation Code	Viscosity (cps)
1	F1	56700
2	F2	60600
3	F3	59600
4	F4	61800
5	F5	55200
6	F6	57000
7	F7	62500
8	F8	66100
9	F9	61230
10	F10	64500

Table 6: Spreadability of Albendazole oral jellies

Sr. No.	Formulation Code	Spreadability
1	F1	30
2	F2	28.84
3	F3	17.64
4	F4	30.99
5	F5	32.60
6	F6	25.86
7	F7	25.33
8	F8	26.78
9	F9	28.30
10	F10	28.73

Table 7: *In-vitro* % drug release kinetics data

Sr. No.	Formulation code	% Drug release after 30 min
1	F1	89.77
2	F2	96.21
3	F3	68.69
4	F4	71.43
5	F5	89.44
6	F6	73.21
7	F7	90.10
8	F8	83.59
9	F9	87.91
10	F10	98.44

Table 8: Content uniformity of Albendazole oral Jellies.

Sr. No.	Formulation code	% Drug content
1	F1	94.751 ±0.528
2	F2	97.659 ±0.399
3	F3	93.0892 ±0.287
4	F4	94.751 ±0.528
5	F5	99.417 ±0.507
6	F6	97.883 ±0.253
7	F7	100.791 ±0.241
8	F8	102.73 ±0.479
9	F9	97.659 ±0.399
10	F10	98.745 ±0.253

Table 9: Stability evaluation of Albendazole oral jellies.

Formulation code	Days	Appearance	pH	Viscosity (cps)
F2	1 month	Smooth	6.53±0.04	60540
	2 month	Smooth	6.47±0.04	59600
	3 month	Smooth	6.31±0.09	58190
F10	1 month	Smooth	6.6±0.08	64130
	2 month	Smooth	6.4±0.06	62200
	3 month	Smooth	6.3±0.07	61840