JOURNAL OF CRITICAL REVIEWS

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Research : Formulation and Evaluation of Albendazole Jelly using Heating Method for Anthelmintic Activity

Snehal Bhagat, Dr Sachin B. Dudhe,Urwashi Lanjewar,Savitha Wasake

Maharastra institute of pharmacy Betala (Bramhapuri) - 441206

Abstract : Albendazole was found to be considerably more active than other benzimidazoles. This was because it was metabolized to albendazole sulphoxide which was also an active anthelminthic, while almost all other benzimidazoles were metabolized to inactive compounds. Preliminary batches of albendazole jelly were prepared using physical appearance, stickiness and grittiness using gum acacia, Tragacanth, sodium alginate and gelatin as viscosity agent, glycerin as a humectant protector, propyl paraben and methyl paraben as a preservatives, sucrose as a sweetening agent and citric acid as a antioxidant. From the evaluation study, it was observed that, as the concentration of polymer was increased, stickiness of jelly was decreased and as the concentration of polymer was decreased, stickiness and grittiness of jelly was increased.

Keyword : Anthelmintic Activity, Albendazole Jelly.

INTRODUCTION

Albendazole is a benzimidazole carbamate (methyl-5-propyl thio-1H-benzimidazole-2-yl carbamate). It is a broad spectrum anthelmintic used. The drug was synthesized by Gyurik and Theodorides in 1975. And its anthelmintic activity was reported by Theodorides(1976).the first benzimidazole carbamate to make it into humans was mebendazole, followed by flubendazole. Smith kline & French animal health were working on albendazole, which was first marketed as valbazen, an animal an animal anthelminth, in the UK in November of 1977. Albendazole was found to be considerably more active than other benzimidazoles. This was because it was metabolized to albendazole sulphoxide which was also an active anthelminthic, while almost all other benzimidazoles were metabolized to inactive compounds. Albendazole was eventually approved for human use and marketing in 1987 (Horton J)[1] .

Helminth infestation mainly caused due to soil transmitted helminths, hookworms, tapeworms, roundworms, ascaris. These helminth infections have serious economic consequences to the affected populations. According to World Health Organization (WHO) Intestinal and extra-Intestinal worm infestations affect more than two billion people in the world. Hemithiasis is prevalent globally, but it is more common in developing countries with poorer personal and environmental hygiene. In human body GIT is the adobe of many helminths, but some also live in tissues, or their larvae migrate into tissue. They harm the host by depriving him of food, causing blood loss, injury to organs, intestinal or lymphatic obstruction and by secreting toxins. helminthiasis is rarely fatal, but is a major cause of ill health. development of resistance has not been a problem in the clinical use of anthelmintics. They affect people mostly pediatric, geriatric, bedridden, disabled and mentally ill people. Extra-intestinal worm infestation has particularly affects on tissues and organs such as liver, muscles, brain, blood vessels and lymphatic system. There are several types of worms which cause helmiths infection. These are as follows.

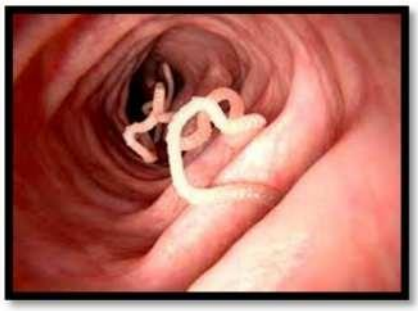
ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Worms

1.Cestodes	2.Nematodes	3.Termatodes
-Tape worm	-Round worm	-Fluke worm
- Flat worm	-Hook worm	

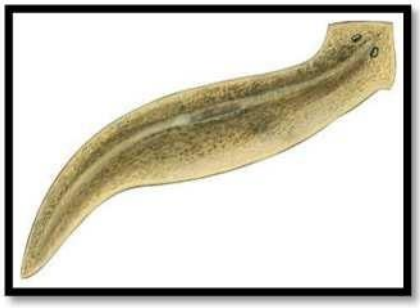
TAPE WORM

Tape worm are the class cestode. They are normally found in Off the truck meat which means that they need another larger Creature as an animal or human to be host. Tape worm can be Up to 30 or 36 feet (10-12 meters) long. They eat by absorbingMaterial directly through their epidermis(outside layer). The Head of a tape worm has four suckers and two rings of hooks.



FLAT WORM

Flat worm also called platyhelminth. A number of flat worm Species are free living, but about 80 percent of all flat wormsAre parasitic. They are bilaterally symmetrical and lack Specialized respiratory, skeletal and circulatory systems; no Body cavity is present. The body is not segmented; spongy Connective tissue (mesenchyme) constitutes the so-called Parenchyma and fills the space between organs.



ROUND WORM

Round worms are also known as nematodes. They are worms with a long

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

round body. They vary in length from several Millimeters to up to two metres. They are live in the intestines The eggs of the roundworm usually enter the body through Contaminated water or food. The symptoms of roundworm Infections include fatigue, weight loss, irritability, poor appetite,abdominal

pain and diarrhea.

HOOK WORM

Hook worms are intestinal, blood-feeding, parasitic worms. That causes types of infection known as helminthiasis. In Humans, hookworm infections caused by two main species Of worms belonging to the genera Ancylostoma and Necator.

FLUKE WORM-

Flukes are parasitic worms that live in the bile duct and the Liver of infected animals. These parasites causes a disease Called fascioliasis in people, cattle and sheep. They are most Prevalent in developing countries. It can caused by drinking Contaminated water, washing vegetables or fruits with Contaminated water.

Following are the drugs used in treatment of anthelmintic infection[3];

-Piperazines : Diethylcarbamazine citrate (DEC), piperazine citrate.

-Benzimidazoles : Albendazole, Mebendazole, Thiabendazole.

-Heterocyclics : oxamniquine, praziquantel.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

-Natural products : Ivermectin, Avermectin.

-Vinyl pyrimidines: pyrantel, oxantel.

-Amides : Niclosamide.

-Nitro derivatives : Niridazole.

-Imidazo thiazole : Levamisole.

*Oral drug delivery system

* Jelly

Despite tremendous advancement in drug delivery, oral route remains the preferred route for the administration of therapeutic agents, low cost of therapy and ease of administration leads to patient compliance. The jelly has through the years gained increasing acceptance as a drug delivery system. Several ingredients are now incorporated in jelly, chlorhexidine as local disinfectant, nicotine, aspirin as an analgesic, and caffeine as a stay alert preparation, drug which required fast onset of action drug which have major absorption site is stomach and small intestine, children in particular may consider jelly as more preferred method of drug administration compared with oral liquids or tablets.

It is now know so far that a medicated preparation for oral administration is used in a jellied dosage form. Jellies are semisolid to thick viscous fluids that consist of sub microscopic particles in a somewhat rigid or plastic vehicle. They are transparent or translucent, non-greasy and mucilage type products. The jelly dosage form can be swallowed easily without water. Edible jellied composition include sweet jellies used in food industry, which are prepared usually used as a base one are two or more of excipient and the like. Their appearances are secured usually for about one year under preservation at room temperature is in cool place. However, none of them can keep preservation stability in terms of pH and the contents of the components at the medical level tests[10].

Advantages of jelly

- Jellies are transparent or translucent non greasy, semisolid preparation and contain more water than gels.
- It is convenient to administer- anywhere, anytime, doesn’ t required water.
- It may prove to be particularly suitable for the systemic delivery of drugs, which are susceptible to metabolism in the gut wall or liver.
- The treatment can, if required, be terminated at any time.
- In addition, the drugs that are released from jelly and swallowed, will be introduced in the gastrointestinal tract either dissolved or suspended in saliva and thus will be present in a readily bioavailability form.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Process of preparation of albendazole jelly

Albendazole jelly prepared by heating process

Albendazole jelly was prepared by heating method. Firstly gelatin was dissolved in required amount of water by heating, then the required quantity of glycerine, colour and essence was added in this prepared solution with continuous stirring for few time. Weigh accurately sufficient quantity of albendazole, gum acacia, sodium alginate, tragacanth, methyl paraben, propyl paraben, sucrose and citric acid were mixed properly and triturate in mortar pestle. The powder was added in prepared solution with continuous stirring for few minutes. Finally the prepared solution of jelly was transferred in moulds and then allow it, for cooling and setting.

Justification for selection of drug

- Albendazole was found to be considerably more active than other benzimidazoles. This was because it was metabolized to albendazole sulphoxide which was also an active anthelminthic, while almost all other benzimidazoles were metabolized to inactive compounds.
- Albendazole work against the all type of worm infestation.
- Another reason to recommended the albendazole for helminth infection is it is safe and cure the helminth infection.
- Albendazole has mode of action in treatment of helminth infestation.

Justification of selection polymer

1. gum acacia

- It has the high swell ability, which has a significant effect on the release kinetics of an incorporated drug.
- It is widely used as a binder, thickening agent, emulsifying agent or suspending agent, viscosity increasing agent.
- It is suitable for sustained release drug delivery system.
- Safety is established.
- Compatible with drug.

2. Sodium alginate

- it is used as a thickening agent and as an gelling agent.
- It is used as a rate-controlling polymer for sustained release.
- It is widely used in the preparations of oral formulations.
- It is inert and nontoxic.

3. Tragacanth

- It is used as a emulsifier, thickener, stabilizer and binder.
- It absorb water and convert as a gel.

4. Gelatin

- It is commonly used as gelling agent
- It absorb large quantity of water.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

It is also used as thickener, stabilizer, emulsifier and gives cream like consistency.

Materials and method

Table no 12.1 : list of equipment/instrument

Sr. No.	List of equipment and Instrument	Make	Model
1.	Analytical balance	LALCO	-
2.	Digital pH meter	LALCO	-
3.	Dissolution apparatus	LALCO	-
4.	Precision weighing balance	LALCO	-
5.	Brookfield viscometer	LALCO	-
6.	UV visible spectrophotometer	LALCO	-
7.	Sonicator	LALCO	-
8.	Stability chamber	LALCO	-
9.	freeze	LG	-

Table no 12.2 : list of chemicals and reagents used

Sr. No.	Name of drug / excipient	Name of manufacturer/ supplier And address
1.	Albendazole	Zim laboratory, kalmeshwar Nagpur.
2.	Gum acacia	Samar chemicals, M.I.D.C Hingna Nagpur.
3.	tragacanth	Samar chemicals, M.I.D.C Hingna Nagpur.
4.	Gelatin	Samar chemicals, M.I.D.C Hingna Nagpur.
5.	Methyl paraben	Samar chemicals, M.I.D.C Hingna Nagpur.
6.	Propyl paraben	Samar chemicals, M.I.D.C Hingna Nagpur.
7.	Sucrose	Samar chemicals, M.I.D.C Hingna Nagpur.
8.	Citric acid	Samar chemicals, M.I.D.C Hingna Nagpur.
9.	Glycerin	Samar chemicals, M.I.D.C Hingna Nagpur.
10.	Colour	Dayal food products, indore
11.	Essence	-

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

12.	Water	-

List of software

Table no 12.3 : list of software

Sr. No.	Name of software	Owner	purpose
1.	›soft office, excel200	Microsoft corporation	manage rawdata
2.	Intas	———	To calculate standard deviations

Experimental and results

Evaluation of raw material

Prior to development of a new dosage form with a drug candidate, it is Essential that certain fundamentalphysical and chemical properties of the drug candidate And excipient are to be determined.
The procedure for various test are given below,

identification test

- **Organoleptic properties**

About 1.0 g of sample was placed in watch glass and was subjectively assessed forAppearance, colour, odour and taste.

- **Loss on drying**

It was determined as per LOD testing designed to measure the amount of water andVolatile matter in the drug when dried in specific condition.

Accurately about 1g of drug weighed and powder was kept in oven for 1h at 180^{o}C or6h at 105 ^{o}C.

- **pH**

pH of test sample was determined by 2.0 per cent w/v dispersion in carbon free water.

- **Determination of melting range**

Glass capillary method was used to determined the melting point. Sample filled in a glass capillary tube.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

The capillary tube was tied with a thermometer and immersed in Thiele' s tube (containing liquid paraffin as a heating medium) which was heated slowly. The temperature at which drug started melting and temperature at which it melted completely was noted.

- **Solubility study**

The solubility study of sample was carried out to select the solvent in which the sample is soluble.
Method: in each selected solvent viz; water, methanol, ethanol, acetone, hydrochloric acid, isopropyl alcohol, diethyl ether, phosphate buffer 6.8, accurately weighed 10 mg of sample was placed and solubility was visually observed.

- **Flow properties of drug (albendazole)**

Bulk density and tapped densityHausner' s ratio
Carr' s index Angle of repose

A. Bulk density

Bulk density or apparent density is defined as the ratio of mass of powder to the bulk volume.
Bulk density and tapped density values of blend powder were determined.

Procedure- A quantity of 2.0 g of powder was first passed through 40# sieve to break any agglomerates formed during the storage. This powder was then introduced into 10 ml of measuring cylinder and the volume occupied by the powder was noted. The bulk density values werecalculated using following formula;

B. Tapped density

Procedure – A quantity of 2.0 g of powder was first passed through 40# sieve to break any agglomerates formed during the storage. This powder was then introduced into 10 ml measuring cylinder. The cylinder containing the powder sample manually tapped by raising the cylinder and allowed it to drop under its own weight from constant height. Cylinder was tapped for 500 times initially and the tapped volume (V1) was measured to the nearest graduated units, the tapping was repeated for additional 750 times and the tapped volume (V2) was measured to the nearest graduated units. If the difference between the two volumes is less than 2% then volume (V2) is taken rather againtapping for additional 1250 times. The tapped density values were calculated using following formula;

C. Hausner' s ratio

Hausner' s ratio was calculated by the following formula and the values were interpreted as pertable,

Table no- 13.1 : correlation of hausner' s ratio with flow properties of powder

Sr.no.	Hausner' s ratio	Quality of flow
1.	1.00-1.11	Excellent

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

2.	1.12-1.18	Good
3.	1.19-1.25	Fair
4.	1.26-1.34	Passable
5.	1.35-1.45	Poor
6.	1.46-1.59	Very poor
7.	>1.60	Very poor

D. Carr' s index (compressibility index)

The compressibility indices of individual blend were calculated using following formula andfindings were imterpreted as per table,

Table no- 13.2 : correlation of compressibility index and quality of flow

Sr. No.	Carr' s index	Quality of flow
1.	<10	Excellent
2.	11-15	Good
3.	16-20	Fair
4.	21-25	Passable
5.	26-31	Poor
6.	32-37	Very poor
7.	>38	Very very poor

E. Angle of repose

The angle of repose of individual blend was determined by funnel method. The height of funnel was adjusted from surface of graph paper. The accurately weight quantity of powder was allowed to flow through the funnel on a graph paper in such a way that the tip of funnel just touched the heap of powder. The diameter of the powder cone was measured and and angle of repose was calculated using the following equations,

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

$$\tan\theta = 2h/D$$

Where, θ = angle of repose, h = height of heap, D = diameter of heap
The flow pattern was interpreted using the following correlation.

Table no- 13.3 : correlation of angle of repose and powder flow

Sr. No.	Type of flow	Value of angle of repose
1.	Excellent	<25
2.	Good	25-30
3.	Passable	30-40
4.	Poor	>40

Evaluations of albendazole

Table no 14.1 : evaluation of drug (albendazole)

Sr. No.	Test		Reported	Observed
1.	Organoleptic properties	appearance	Crystalline powder	Crystalline powder
		Taste	Sweet taste	Sweet taste
		Odour	characteristic	characteristic
		colour	white	white
2.	Melting point	Melting range	208-210°C	210 °C

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

3.	Identification Test	pH	1.2 – 7.5	7.2
4.	)lubility Study	Distilled water	Practically insoluble	Practically insoluble
		Ethanol	Slightly soluble	Slightly soluble
		0.1N HCL	Slightly soluble	Slightly soluble
		Chloroform	Slightly soluble	Slightly soluble
		Acetone	Slightly soluble	Slightly soluble

Table no 14.2 : flow characteristics of drug (albendazole)

Sr. No.	Bulk density	Tapped density	Hausner' s ratio	Compressibility index	Angle of repose
1.	0.52±0.03	0.60±0.01	1.15±0.02	13.33±0.42	27.48±0.50

Evaluation of pharmaceutical excipient used in jelly

a) Gum acacia

it is widely used as a binder, thickening agent, emulsifying agent, Suspending agent and viscosity increasing agent.

Table no- 15.1 : evaluation of gum acacia

Sr. No.	Test		Reported	Observed
1	Organoleptic Properties	Appearance	Yellowish-white	Yellowish-white
		Taste	bland	bland
		Odour	Odourless	Odourless
		Colour	Yellowish-white	Yellowish-white
2.	Melting point	Melting range	>250^{o}C	245^{o}C
3.	Identification Taste	pH	Near 4.1-4.8	4.5

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

4.	Solubility Study	Water	Soluble	soluble
		Methanol	Insoluble	Insoluble
		Ethanol	Insoluble	Insoluble

b) Sodium alginate

It is used as a stabilizer, as a thickener and emulsifier and as a gelling Agent.

Table No -15.2 : evaluation of sodium alginate

Sr. No.	Test		Reported	Observed
1.	rganoleptic Properties	Appearance	White to yellow Fibrous powder	White to yellow Fibrous powder
		Taste	Tasteless	Tasteless
		Odour	Odourless	Odourless
		Colour	White-yellow	White-yellow
2.	Melting point	Melting range	>300 ^{o}C	288 ^{o}C
3.	Identification Taste	pH	5.0 – 11.0	10
4.	lubilityStudy	Water	Freely soluble	Freely soluble
		Methanol	Insoluble	Insoluble
		Ethanol	Insoluble	Insoluble

c) Tragacanth

It is used as emulsifier, thickener & stabilizer.

Table No- 15.3 : evaluation of tragacanth

Sr. No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	White to yellow crystalline powder	White to yellow crystalline powder

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

		Taste	Tasteless	Tasteless
		Odour	Odourless	Odourless
		Colour	White-yellow	White-yellow
2.	Melting point	Melting range	84 °C	83 °C
3.	Identification	pH	5 - 6	5
4.	olubilityStudy	Water	Soluble	soluble
		Methanol	Insoluble	Insoluble
		Ethanol	Insoluble	Insoluble

d) Gelatin

It is used as gelling agent & film forming agent.

Table No- 15.4 : evaluation of gelatin

Sr. No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	int-yellow colour brittle crystals.	int-yellow colour brittle crystals.
		Taste	Tasteless	Tasteless
		Odour	Odourless	Odourless
		Colour	Faint-yellow	Faint-yellow
2.	Melting point	Melting range	32 °C	31 °C
3.	Identification Taste	pH	4.5 – 5.0	4.8
4.	olubilityStudy	Water	Soluble	soluble
		Methanol	Precipitated	Precipitated
		Ethanol	Precipitated	Precipitated

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

e) Methyl paraben

It is used as anti-fungal & as a preservative.

Table No- 15.5 : evaluation of methyl paraben

Sr. No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	te crystalline powder.	te crystallinepowder.
		Taste	Slight burning taste	Slight burning taste
		Odour	odourless	odourless
		Colour	White	White
2.	leltingpoint	Melting range	125 – 128 °C	127 °C
3.	Identification Taste	pH	5.8	5.6
4.	lubilityStudy	Water	Slightly Soluble	Slightly soluble
		Methanol	Soluble	Soluble
		Ethanol	Soluble	Soluble

f) Propyl paraben

It is used as anti-fungal & as a preservative.

Table No- 15.6 : evaluation of propyl paraben

Sr.No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	Fine white crystalline powder.	hite crystallinepowder.
		Taste	Tasteless	Tasteless

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

		Odour	Odourless	Odourless
		Colour	White	White
2.	Melting point	Melting range	96 – 99 °C	98 °C
3.	Identification Taste	pH	6 - 7	7
4.	lubilityStudy	Water	Slightly Soluble	Slightly soluble
		Methanol	Soluble	Soluble
		Ethanol	Soluble	Soluble

g) Citric acid

It used as antioxidant, as a preservative, as a acidifier and chelating used.

Table No- 15.7 : evaluation of citric acid.

Sr. No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	crystallinesolid.	crystallinesolid.
		Taste	Sour salt	Sour salt
		Odour	Odourless	Odourless
		Colour	White	White
2.	Melting point	Melting range	156 °C	155 °C
3.	Identification Taste	pH	4.7	4.5
4.	lubilityStudy	Water	Soluble	soluble

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

		Methanol	Soluble	Soluble
		Ethanol	Soluble	Soluble

h) Sucrose

It is used as a sweetening agent.

Table No- 15.8 : evaluation of sucrose.

Sr. No.	Test		Reported	Observed
1	rganoleptic Properties	Appearance	crystallinesolid.	crystallinesolid.
		Taste	Sweet	Sweet
		Odour	Odourless	Odourless
		Colour	White	White
2.	Melting point	Melting range	186 °C	185 °C
3.	Identification Taste	pH	6 – 8.5	7
4.	lubilityStudy	Water	Soluble	soluble
		Methanol	Insoluble	Insoluble
		Ethanol	Insoluble	Insoluble

i) Glycerin

It is used as Antimicrobial preservative, co solvent, emollient, Humectants, plasticizer, solvent, sweetening agent, tonicity agent.

Table No- 15.9 : evaluation of glycerin.

Sr. No.	Test		Reported	Observed
1	rganoleptic	Appearance	Viscous liquid	Viscous liquid

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

	Properties	Taste	Sweet taste	Sweet taste
		Odour	odourless	Odourless
		Colour	Clear	clear
2.	oilingpoint	Boiling point	288-290 °C	290 °C
3.	tificationTaste	Assay	99.0-101.0%	99.0%
		Heavy metals	5ppm	5ppm
4.	olubilityStudy	Water	Soluble	soluble
		chloroform	Practically insoluble	Practically insoluble
		Ethanol	soluble	soluble

2. Formulation and development

Albendazole jelly was prepared by heating process

Firstly gelatin was dissolved in required amount of water by heating, then the required quantity of glycerine, colour and essence was added in this prepared solution with continuous stirring for few time. Weigh accurately sufficient quantity of albendazole, gum acacia, sodium alginate, tragacanth, methyl paraben, propyl paraben, sucrose and citric acid were mixed properly and triturate in mortar pestle. The powder was added in prepared solution with continuous stirring for few minutes. Finally the prepared solution of jelly was transferred in moulds and then allow it, for cooling and setting.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Fig no- 16.1 Albendazole jelly.

Table No- 16.1 : formulation of albendazole jelly preliminary batches

Ingredients	**Quality %**						
	S1	S2	S3	S4	S5	S6	S7
Albendazole(mg)	400	400	400	400	400	400	400
Gum acacia	0.3	0.2	0.3	0.4	0.3	0.3	0.4
Sodium alginate	0.2	0.3	0.3	0.3	0.2	0.2	0.2
Tragacanth	0.3	0.2	0.3	0.3	0.3	0.2	0.2
Gelatin	0.5	0.7	0.6	0.7	0.7	0.7	0.7
Methyl paraben	0.3	0.2	0.3	0.2	0.3	0.3	0.3
Propyl paraben	0.3	0.3	0.2	0.2	0.2	0.2	0.3
Citric acid	0.3	0.3	0.2	0.2	0.3	0.2	0.2
Sucrose	0.6	0.4	0.5	0.5	0.5	0.5	0.4
Glycerin	3	5	4	3	3	5	4
Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Essense	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Colour	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Table No- 16.2 : evaluation of preliminary batches.

Batch	Clarity	Texture	Consistency	Stickiness	Grittiness
S1	Turbid form	Smooth	Fluid like	Sticky	More gritty
S2	Turbid form	Smooth	Fluid like	Sticky	More gritty
S3	Turbid form	Smooth	Fluid like	Sticky	More gritty
S4	Turbid form	Smooth	Fluid like	Sticky	More gritty
S5	Turbid form	Smooth	Thick	Slightly sticky	Slightly gritty
S6	Turbid form	Smooth	Thick	Non-sticky	Less gritty
S7	Turbid form	Smooth	Thick	Non-sticky	Less gritty

Albendazole jelly was prepared by using gum acacia, sodium alginate, tragacanth, and gelatin different concentration viz; 1%, 2%, 3% and 10% were carried out for albendazole jelly as discussed in table respectively.

The results shows in table stickiness and grittiness indicates the jelly with polymers concentration shows acceptable jelly formulation. As the concentration of polymer was increased, stickiness of jelly was decreased, and the concentration of polymer was decreased, stickiness and grittiness of jelly was increased.

Table no- 16.3 : formulation of selected batches of albendazole jelly.

Ingredients	Quantity %								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Albendazole(mg)	400	400	400	400	400	400	400	400	400
Gum acacia	0.3	0.2	0.3	0.4	0.2	0.3	0.3	0.4	0.5
Sodium alginate	0.2	0.3	0.3	0.3	0.3	0.2	0.2	0.2	0.3
Tragacanth	0.3	0.2	0.3	0.3	0.2	0.2	0.3	0.2	0.3
Gelatin	0.5	0.7	0.6	0.7	0.8	0.7	0.7	0.7	0.7
Methyl paraben	0.3	0.2	0.3	0.2	0.3	0.3	0.3	0.3	0.2
Propyl paraben	0.3	0.3	0.2	0.2	0.3	0.2	0.2	0.3	0.3
Citric acid	0.3	0.3	0.2	0.2	0.2	0.2	0.3	0.2	0.2

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Sucrose	0.6	0.4	0.5	0.5	0.4	0.5	0.5	0.4	0.4
Glycerin	3ml	5ml	4ml	3ml	4ml	5ml	3ml	4ml	2ml
Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Essence	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
colour	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

Evaluation of albendazole jelly

The albendazole jelly were evaluated for following parameters,

1. physical appearance
2. stickiness ang grittiness
3. pH
4. viscosity
5. drug content %
6. drug release study (in-vitro)
7. stability study

17.1. physical appearance

The albendazole jelly was examined for physical appearance in terms of clarity, texture andconsistency.

17.2. stickiness and grittiness

Texture of the albendazole jelly in term of stickiness and grittiness had been evaluated by visual inspection of the product after mildly rubbing the jelly sample between two fingers.

17.3. determination of pH

The pH value of 1% aqueous solutions of the prepared jellies were checked by using a calibrated digital pH meter at constant temperature. For the purpose 1g of the weighed formulation was dispersed in 100ml of distilled water and pH was noted. The standard pH of jelly was 2.00-6.05

17.4. determination of viscosity

Viscosity of the jelly was carried out by using Brookfield viscometer. As the system is non- Newtonian spindle was used. Viscosity was measured for the fixed time 2 min at 50 rpm. Viscosity determination of jelly was done by Brookfield viscometer.

17.5. drug content (%)

Accurately weighed of jelly formulation was crushed in mortor pestle. A quantity of powder equivalent to 400 mg albendazole was accurately weighed and transferred in 100 ml volumetric flask containing small volume (10 ml) of 0.1 N HCL. The solution was sonicate for 15 min, to disperse the contents and filtered through

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

whatman filter paper. Appropriate dilutions of filtrate were made and the drug content was estimated by using UV-Visible spectrophotometer at 308 nm.

17.6. In-vitro drug release study

Dissolution test parameters		
Dissolution test apparatus	:	USP XXII type II (paddle)
Dissolution medium	:	pH 1.2
Volume of dissolution medium	:	900 ml
Temperature of medium	:	$37 \pm 0.5^{o}C$
Speed of rotating paddle	:	50 rpm
Sampling volume	:	1 ml
Sampling time	:	60 min
Duration of test	:	8 hr.

The test was carried out at above mentioned test conditions. In vitro drug release study of albendazole jelly was performed using USP apparatus II fitted with a paddle (50 rpm) at 37 ± 0.5℃ using a stimulated gastric fluid without enzymes (pH 1.2; 900 ml) as a dissolution medium. A quantity of albendazole jelly equivalent to 400 mg was accurately weighed and inserted in jelly was small pieces (2.5 mm) and then placed into the dissolution medium. At predetermined time intervals, 1 ml samples were withdrawn filtered through 0.45 µ membrane filter and analysed at 308 nm using UV-Visible spectrophotometer.

17.7. stability studies

Stability studies of the optimized formulations were carried out to know

1. whether the chemical change or degradation of the active ingredient has occurred this may lower the therapeutic potency of active ingredient over storage period.
2. whether any toxic degradation product has formed which may be undesirable.

3. whether gross changes in the physical form of the dosage form have occurred implying poor or substandard quality of ingredients.

In any rational design and evaluation of dosage forms for drugs, the stability of the active components must be major criteria in determining their acceptance or rejection. During the stability studies of the product is exposed to normal conditions of temperature and humidity however the studies will take a longer time and hence it would be convenient to carry out the accelerated stability studies where the product is stored under extreme conditions of temperature and humidity.

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

To assess the drug and formulation stability studies were done according to ICH guidelines. Optimized formulation sealed in aluminium packaging coated inside with polyethene and various replicates were kept in the environmental chamber maintained at 40℃ and 75% RH for 3 months.

At the end of studies, sample were analysed for the

1) physical appearance

2) drug content

3) cumulative % drug release studies.

no- 17.1 : evaluation test of physical appearance, stickiness, grittiness, pH, viscosity, % drugContent of albendazole jelly.

Batches	Clarity	Texture	Consistency	Stickiness	Grittiness	pH	Viscosity (cPs)	%Drug content
F1	Turbid Form	Smooth	Fluid like	Sticky	More Gritty	4.24 ±0.092	4800 ±692	71.35 ±0.54
F2	Turbid Form	Smooth	Fluid like	Sticky	Gritty	4.30 ±0.020	5333 ±611	72.62 ±0.61
F3	Turbid Form	Smooth	Thin	Sticky	Gritty	4.64 ±0.031	6133 ±230	78.54 ±0.63
F4	Turbid Form	Smooth	Thin	Slightly Sticky	Slightly Gritty	4.96 ±0.078	6400 ±400	88.83 ±0.59
F5	Turbid Form	Smooth	Thin	Slightly Sticky	Slightly Gritty	4.97 ±0.115	6933 ±230	82.13 ±0.64
F6	Turbid Form	Smooth	Thick	Non-Sticky	Less Gritty	6.01 ±0.020	9600 ±400	91.45 ±0.65
F7	Turbid Form	Smooth	Thick	Non-Sticky	Less Gritty	5.80 ±0.025	8266 ±832	83.10 ±0.57
F8	Turbid Form	Smooth	Thick	Non-Sticky	Less Gritty	5.92 ±0.066	8533 ±230	84.56 ±0.54
F9	Turbid Form	Smooth	Thick	Non-Sticky	Less Gritty	5.91 ±0.081	8000 ±400	76.60 ±0.62

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Table no- 17.2 : cumulative % drug release in buffer pH 1.2

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
10	21.35 ±0.69	27.18 ±0.63	24.27 ±0.61	17.47 ±0.80	22.33 ±0.62	18.44 ±0.54	20.38 ±0.60	17.47 ±0.52	21.35 ±0.40
20	32.03 ±0.51	33.98 ±0.56	30.09 ±0.63	25.29 ±0.44	30.09 ±0.42	22.33 ±0.68	28.15 ±0.57	20.87 ±0.55	22.23 ±0.63
30	34.95 ±0.66	39.80 ±0.62	36.89 ±0.59	31.06 ±0.54	36.89 ±0.49	26.21 ±0.50	33.00 ±0.42	37.86 ±0.63	35.92 ±0.49
40	39.80 ±0.71	45.63 ±0.67	44.66 ±0.54	45.63 ±0.62	43.68 ±0.54	30.09 ±0.75	47.57 ±0.76	49.51 ±0.64	45.63 ±0.57
50	45.63 ±0.68	51.45 ±0.69	59.51 ±0.74	54.36 ±0.71	57.28 ±0.51	45.63 ±0.50	54.36 ±0.43	56.31 ±0.40	57.21 ±0.39
60	48.54 ±0.65	56.31 ±0.54	59.22 ±0.55	61.16 ±0.67	61.16 ±0.68	50.48 ±0.62	66.99 ±0.61	65.04 ±0.53	64.07 ±0.59
90	61.16 ±0.66	63.10 ±0.54	61.16 ±0.57	66.01 ±0.59	70.87 ±0.61	66.01 ±0.39	83.49 ±0.76	80.58 ±0.43	86.40 ±0.47
120	56.31 ±0.71	57.88 ±0.69	56.31 ±0.39	68.93 ±0.73	75.72 ±0.71	80.58 ±0.49	68.93 ±0.58	73.78 ±0.59	70.87 ±0.65

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

180	59.22 ±0.54	61.16 ±0.59	50.48 ±0.63	61.16 ±0.61	70.87 ±0.59	91.26 ±0.62	61.16 ±0.64	68.93 ±0.57	66.01 ±0.69

Stability studies

The stability studies were carried out on optimized formulation. The formulation was stored at 40 ± 2℃/75 ± 5% RH (climate zone IV condition for accelerated testing) for 45 days to access its stability. After 0, 15 and 30 days samples were withdrawn and retested for physical appearance, % drug release as shown in table and the results indicated that the formulation was able to retain its stability for 30 days.

Table no- 17.3 : stability data of selected formulation

Parameter	Stability study		
	0 day	15 day	30 day
Physical appearance			
Clarity	Turbid form	Turbid form	Turbid form
Texture	Smooth	Smooth	Smooth
Consistency	Thick	Thick	Thick
Stickiness	Non-sticky	Non-sticky	Non-sticky
Grittiness	Less gritty	Less gritty	Less gritty
Drug content (%)	91.45±0.65	91.25±0.45	91.20±0.42
e interval(min)	Cumulative drug release (%)		
	0 day	15 days	30 days
0	0	0	0
10	18.44±0.54	18.15±0.53	17.78±0.57
20	22.33±0.68	22.11±0.71	21.84±0.62
30	26.21±0.50	26.10±0.52	25.67±0.58
40	30.09±0.75	30.01±0.79	30.00±0.71
50	45.63±0.50	45.47±0.55	45.18±0.53
60	50.48±0.62	50.39±0.69	50.13±0.69
90	66.01±0.39	66.00±0.38	66.01±039
120	80.58±0.49	80.27±0.52	80.33±0.47
180	91.26±0.62	91.13±0.73	91.14±0.71

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

Discussion

Discussion

Albendazole is used for antihelminth activity. The main objective of study was to formulation and evaluation of albendazole jelly for antihelminth activity. Formulation of albendazole jelly are control release drug delivery.

Appearance, melting point, loss on drying, $\lambda_{max,}$ of drug albendazole were carry out as per specification of USP, BP and IP. It was observed that obtained sample of albendazole complies with the standard quality of quality mentioned in USP, BP and IP.

Preliminary batches of albendazole jelly were prepared using physical appearance, stickiness and grittiness using gum acacia, Tragacanth, sodium alginate and gelatin as viscosity agent, glycerin as a humectant protector, propyl paraben and methyl paraben as a preservatives, sucrose as a sweetening agent and citric acid as a antioxidant. It was observed that polymer concentration was important parameter in the formulation of jelly.

As the polymer concentration was increased stickiness, grittiness and viscosity for jelly increased. On the basis of screening gum acacia, sodium alginate, tragacanth, gelatin, glycerin was independent. Where stickiness, grittiness and viscosity are dependent. Formulations F1 to F9 were prepared using gum acacia, tragacanth, sodium alginate, gelatin concentration at different levels.

From the evaluation study, it was observed that, as the concentration of polymer was increased, stickiness of jelly was decreased and as the concentration of polymer was decreased, stickiness and grittiness of jelly was increased.

At high level of gum acacia, tragacanth, sodium alginate and gelatin (batch F6), viscosity was increased as compared to F1 batch because of the drug was properly bound with the polymer. At medium level of polymers (batch F4), viscosity was decreased and at low level of polymers (batch 1), viscosity of gel was developed.

From the stability studies, it is clear that the formulation was stable for thirty days resulting in no significant changes observed on physical appearance, stickiness, grittiness, drug content(%) and cumulative % drug release studies.

Overall results indicate that batch F6 containing 400 mg albendazole of jelly was better one to prepare drug jelly. From the observed study, albendazole jelly were prepared control release drug delivery system are better result of albendazole jelly.

Summary and conclusion

Summary

The present work deal with the albendazole and its formulation as control release jelly by heating process by powder adding method. Preformulation studies were carried out to check the physical appearance, stickiness and grittiness properties of drugs and formulation components.

For the preparation preliminary batches of jelly, concentration of drug 400 mg were selected. The one batch selected and preparation of selection batches of jelly. The ten batches were formulated of jelly.

Among studies batches batch F6 (400 mg of albendazole) give higher % drug release in dissolution media, viscosity and higher drug content as compared to other formulation and thus, selected as optimized formulation. From the above discussion it was concluded that the stable albendazole loaded jelly can be formulated by selecting appropriate ratios of different concentration of polymer. Overall results indicated that batch F6 containing 400 mg albendazole of jelly was better one to prepare drug loaded jelly.

Conclusion

From the stability studied, it was clear that the formulation was stable for thirty days resulting in no significant changes observed on drug release studies. It can be concluded that the jelly of albendazole can be

successfully prepared by using different concentration of polymer and thus, the problems of high half biological life, high bioavailability, lower clearance and lower elimination half-life can be overcome by formulating control release jelly. Hence control release drug delivery system is a useful dosage form for oral delivery of albendazole.

18. Reference

1. Nagaraju Swamy, Kanakapura Basavaiah; simple and rapid spectrophotometric assay of albendazole in pharmaceuticals using iodine and picric acid as CT complexing agents; Brazilian journal of pharmaceutical sciences 2014, volume-50; page no. 840-850
2. Sung-Tae-Hong; Albendazole and Praziquantel: Review and Safety Monitoring in Korea https://doi.org/10.3947/ic.2018.50.1.1 Infect Chemother 2018;50(1);1-10 ISSN 2093-2340(print); page no. 1-10
3. Tripathi KD, Essential of medical pharmacology, seventh edition; page no. 849-851
4. Indian Pharmacopoeia, Family Health and Welfare Department Of Government of India
5. SUKHBIR LAL KHOKRA, BHARAT PARASHAR, HITESH KUMAR DHAMIJA, RAHUL PUROHIT, ABHISHEK CHANDEL; FORMULATION DEVELOPMENT AND EVALUATION OF CHEWABLE TABLET OF ALBENDAZOLE BY DIFFERENT TECHNIQUES; International Journal of Pharmacy and Pharmaceutical Sciences ISSN-0975- 1491; volume 4, Issue 1, 2012;page no,461-464
6. CHEROGONY ROBERT KIPLAGAT; PREFORMULATION STUDY TO ENHANCE SOLUBILITY OF ALBENDAZOLE; U53/81076/2015; page no. 1-49
7. S. Harish Kumar*, A. Sheikalisha, S. Chandra, R. Suresh, S. Sangeetha, Tamilselvan A; FORMULATION AND EVALUATION OF ORAL MEDICATED JELLIES OF CYPROHEPTADINE HCL, International Journal of Advanced Pharmaceutical Sciences, Volume 1, Issue 08, Page 07-41 ISSN:2456-8147
8. Mahendrakumar Dubey, Dr.Zankhana Sheth: Design and Development of Oral Medicated Jelly of Palonosetron Hydrochloride, Indian journal of Research ISSN- 2250-1991; volume- 4/Issue:4/June 2015; page no. 253-255
9. Arun Raj. R*, JibcyFeba Rachel John, Jyoti Harindran; Formulation and Evaluation of Domperidone Medicated Jelly Using Solvent Deposition Method for Solubility Enhancement, Research & Reviews: A Journal of Drug Formulation, Development and Production ISSN: 2394- 1944 (Online) Volume 4, Issue 2
10. Mangesh D Godbole1*, Debarshi Kar Mahapatra1, Priya D Khode; Fabrication and Characterization of Edible Jelly Formulation of Stevioside: A Nutraceutical or OTC Aid for the Diabetic Patients, Inventi Rapid: Nutraceuticals Vol. 2017, Issue 2 [ISSN 0976-3872]; page no. 1-9
11. Abitha, M., H.& Flowerlet Mathew (2015) Natural polymers in pharmaceutical formulation. International Journal of Institutional Pharmacy and Life Sciences, 5(1), 205-231.
12. Adedibu C.Tella*1, Ojeyemi M. Olabemiwo2, Musa O. Salawu3 and Gabriel K. Obiyenwa1; Developing a Spectrophotometric method for the estimation of Albendazole in solid and suspension forms, International Journal of the Physical Sciences Vol. 5 (4), pp. 379-382, April, 2010

ISSN- 2394-5125 VOL 07, ISSUE 19, 2020

13. N.L. PRASANTHI*, P. NANDINI, S.S. MANIKIRAN, N. RAMARAO; Design and Development of Herbal Pediatric Edible Jelly for Anthelmintic Infections, N.L. PRASANTHI et al /J. Pharm. Sci. & Res. Vol. 11(6), 2019, 2417-2421

14. Deshmuk M; Preparation and Evaluation of Paracetamol Jelly formulation for paediatrics. Inventi Journal. 2010:1-12.

15. Raja Manali M*1 , Dhiren P. Shah2; ORAL MEDICATED JELLY: A RECENT ADVANCEMENT IN FORMULATION, AN INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES; Pharma Science Monitor 7(2),Apr-Jun 2016; ISSN: 0978- 7908; page no. 13-20

16. Ibrahim, Khalid A.; Nawaz, Asma; Mumtaz, Shamim; Iqbal, Furqan Muhammad; Khan, Ahmad; Zaman, Shahiq uz; Abd El-Salam, Nasser M.; Ullah, Naseem; Hussain, Tajammal; Hussain Shah, Syed Nisar; Pakistan Journal of Pharmaceutical Sciences . 2017Supplement, Vol. 30, p579-583.

17. S. Sarojini* 1 , K. Anusha1 , Ch. Maneesha1 , M. A. Mufaquam1 , B. Deepika2 , Y. Krishna Reddy2 and Naga Raju Kandukoori; ORAL MEDICATED JELLIES – A REVIEW, World Journal of Pharmaceutical Research; Volume 7, Issue 6, 352-365.

18. The theory & practise of industrial pharmacy by LEON LACHMAN, HERBERT A. LIEBERMAN, JOSEPH L. KANIG; third edition; VARGHESE PUBLISHING HOUSE BOMBAY; page no. 548-563

19. PIYUSH YADAV*,RUPALI SINGH; A REVIEW ON ANTHELMINTIC DRUGS AND THEIR FUTURE SCOPE, International Journal of Pharmacy and Pharmaceutical Sciences; ISSN- 0975-1491 Vol 3, Issue 3, 2011 page no. 17-21

20. Katakam Prakash[1,3], Varanasi M. Satyanarayana[2,3], Hwisa T. Nagiat[1], Assaleh H. Fathi[1], Adiki K. Shanta[3] Avula R. Prameela[2]; Formulation development and evaluation of novel oral jellies of carbamazepine using pectin, guar gum, and gellan gum, Asian Journal of Pharmaceutics
- October-December 2014; page no. 241-249