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Design Development and Evaluation of Anthelmintic Candy for Paediatric Use

Sanjana S[*1], Sneha H.C [2]
Department of Pharmaceutics, Ikon Pharmacy College Bheemanahalli, Bidadi, Ramanagara District, Karnataka, India.

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ABSTRACT
There was a need for innovative dosage forms that would both minimize first pass metabolism and boost bioavailability despite the wide variety of dosage forms already on the market. The goal of the enhanced research effort was to decrease first pass metabolism and increase bioavailability. Due to its simplicity of swallowing, ability to prevent pain, and most importantly patient compliance, the oral route of medication administration was a very popular form of drug administration. Candy was designed to dissolve gradually in the tongue and was a solid dose form that contained medication in a foundation that was sweetened and flavoured. Candies are pharmaceutical dose forms that are meant to be given to children. They contain albendazole in order for the candy to melt readily in the child's mouth. After boiling sugar and water to make candy, the medication albendazole was added and thoroughly blended. The prepared liquid was poured into the calibrated mold, and it was left outside to dry for a few hours. The made candy was stored in desiccators, wrapped in aluminium foil to keep moisture out.
Keywords: Albendazole, Medicated candy.

I. INTRODUCTION

Helminthic infection, also referred to as worm infection, is a severe health issue that affects hundreds of millions of pediatric. The helminthic transmitted secondary illness symptoms range widely, from respiratory issues to malnourishment. Growth retardation and severe morbidity in children are likely to result from iron deficiency anaemia and protein energy malnutrition.

A broad-spectrum anthelmintic is albendazole. It has a strong affinity for the parasite's β tubulin and prevents microtubule synthesis from occurring. The parasite several metabolic functions depend on these microtubules. These cause the parasite to absorb less glucose, which ultimately results in the parasite dying because it is the easiest to take, it doesn't cause pain, and most importantly, patients comply, oral administration is the most widely used method. For young patients, traditional pills and capsules can be uncomfortable due to their problems swallowing or the flavour of the liquid dosage forms more patient-friendly and compliant dose forms have become more and more in demand during the last ten years. Consequently, there has been a daily increase in the need for creating new technologies. [1]

In these cases, oral mucosal drug delivery is most preferred, oral mucosal medication administration is the recommended method in these situations. Candy is a solid dose form that dissolves gradually in the tongue. It contains medication in a foundation that has been sweetened and flavoured. The primary ingredients of candy are flavouring, colouring, opacifiers, stabilizing agents, and sweeteners. Patients who are unable to take solid oral dose forms are given candy.

Advantage of medicated candy

- Candy can be given to those patients who have difficulty in swallowing.
- Keeping the drug in contact with the oral cavity for an extended period of time.
- Easy to prepare with minimum amount of equipment and time.
- Do not require water intake for administration. Technique is non-invasive, as is the case of parental. [2]

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II. MATERIALS AND METHODS

MATERIALS

Table 1: Materials used in the formulations

S.NO	CHEMICALS	SUPPLIERS
1	Albendazole	Embiotic laboratories, Bangalore
2	Sucrose	TTK Pharma Ltd, Chennai.
3	Dextrose	Pharmafabrikon, Madurai.
4	Methyl cellulose	Pharmafabrikon, Madurai.
5	Citric acid	Pharmafabrikon, Madurai.
6	Glycerine	SaimirraInnopharm, Chennai

Table 2: Instruments utilized for formulations

S.NO	INSTRUMENTS	SUPPLIERS
1	Weighing balance	Asha Scientific Company
2	pH meter	MC Dalal, india
3	FT-IR	Shimadzu,Japan
4	Vernier caliper	Mitutoyo, Japan
5	Monsanto hardness tester	Campbell Electronics

PREFORMULATION STUDIES

Pre-formulation studies were the first step in the rational development of any formulation. It can be defined as "investigation of physical and chemical properties of the drug substance alone and combined with the excipients". These studies focus on those physiochemical properties of the new compound that could affect drug performance and development of an efficacious formulation.

The overall objective of pre-formulation testing is to generate information useful to the formulator in developing stable and bio available dosage forms that can be

- To establish physical characteristics.
- To establish its compatibility with the excipient. [3]

Solubility

To assess the solubility of a little amount of albendazole, several solvents such as acetonitrile, methanol, ethyl acetate, and chloroform were introduced individually. [4]

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FORMULATION TABLE FOR ALBENDAZOLE MEDICATED CANDY [5]

Table 3: Formulation table

S.NO	INGREDIENTS	F1	F2	F3
1	Albendazole	0.2gm	0.2gm	0.2gm
2	Sucrose	3gm	3gm	2.5gm
3	Dextrose	1.5gm	1.5gm	1gm
4	Methyl cellulose	0.1g	0.1gm	0.15gm
5	Citric acid	0.12g	0.9gm	0.1gm
6	Glycerin	3%	4%	6%

PREPARATION OF ALBENDAZOL HARD MEDICATED CANDY [6]

The necessary amount of sugar syrup was made by mixing the water. A tiny quantity of dextrose was dissolved in water, and the resulting combination was heated to 110 °C to completely dissolve the dextrose and produce a transparent, viscous syrup. Subsequently, the sugar syrup was mixed with the dextrose syrup and cooked to 160^0C until a golden yellow colour was achieved. The medication, polymer, and other chemicals were added after the temperature was lowered to 90^0C, and the taste was added between120^0 and 135^0C. After filling the calibrated mold with the prepared mixture, it was allowed to dry outside for a few hours. Wrapped in aluminium foil, the prepared candy was kept in desiccators to prevent it from absorbing moisture.

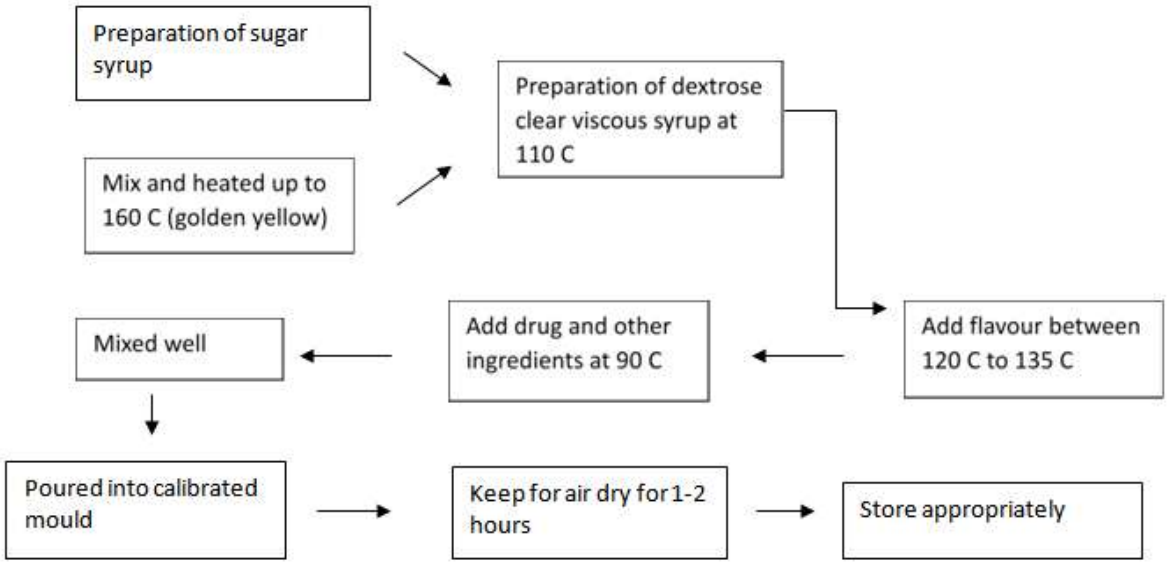

Figure 1: Preparation of Albendazole hard candy

EVALUATION PARAMETERS [7-11]

1. Physical parameters

In order to examine the surface properties and shape, ten medicated candy were weighed and examined.

2. Weight Variation Test

An automatic balance can be used to weigh medicated candy and determine the weight of ten medicated candies.

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3. Thickness Test

Using a Vernier caliper, the dosage form's diameter thickness.were measured. Each unit's variation from the mean diameter is calculated, and it should not be more than ± 5%.

4. Hardness Test

A Monsanto Hardness Tester was used to determine the candy's level of hardness.

5. Moisture Content

One-gram sample is weighed using the gravimetric method, and it is then kept in a desiccator for a full day. After deducting the final weight from the start, the moisture content difference is computed % Moisture content = Initial weight – Final weight /Initial weight × 100

6. Mouth dissolving Time

Using a mechanical stirrer at 50 rpm and 100 ml of phosphate buffer pH 6.8, each candy was placed in a separate beaker, and the time it took for the candy to dissolve fully was recorded at 37°.

III. RESULTS AND DISCUSSION

PREFORMULATION STUDIES: CHARACTERIZATION OF THE DRUG

Melting point of Albendazole

Melting point was measured by the capillary method and it was found to be 208ºC.

Determination of λ max of Albendazole

The maximum absorbance of the Metoclopramide hydrochloride was studied and found to be 295 nm. Hence the wavelength of 295 nm was selected for the analysis of the drug in dissolution media.

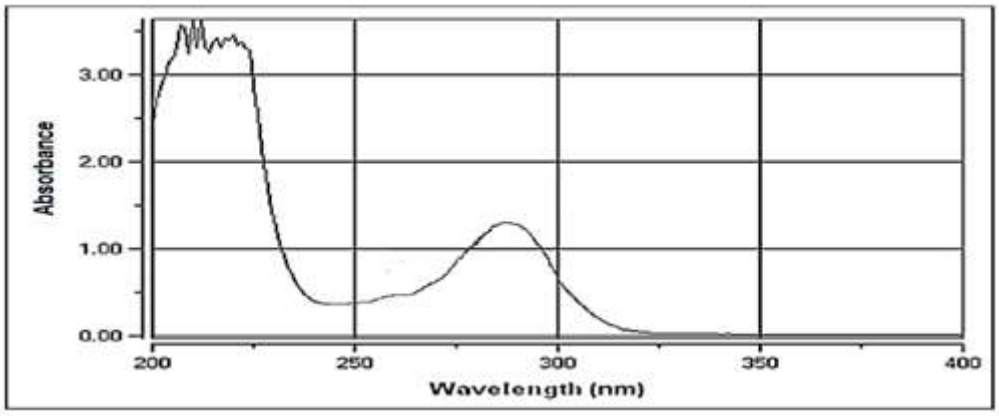

Figure 2: The UV spectrum of Albendazole in phosphate buffer

CHEMICAL COMPATIBILITY STUDY

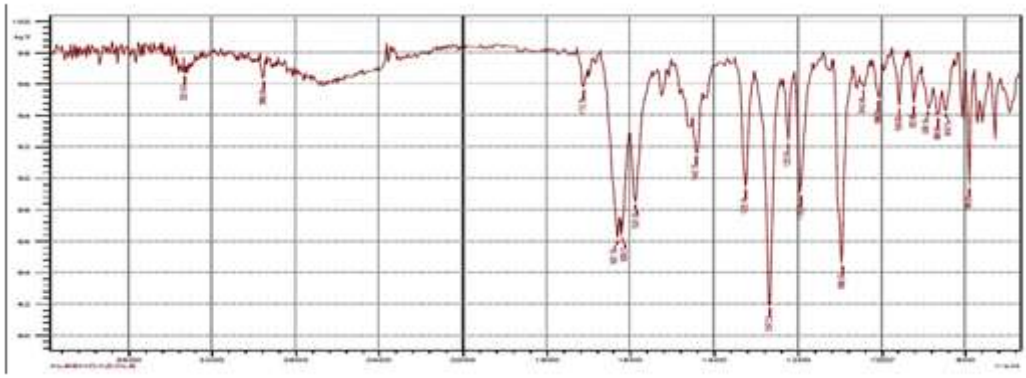

Figure 3: FTIR spectrum of albendazole

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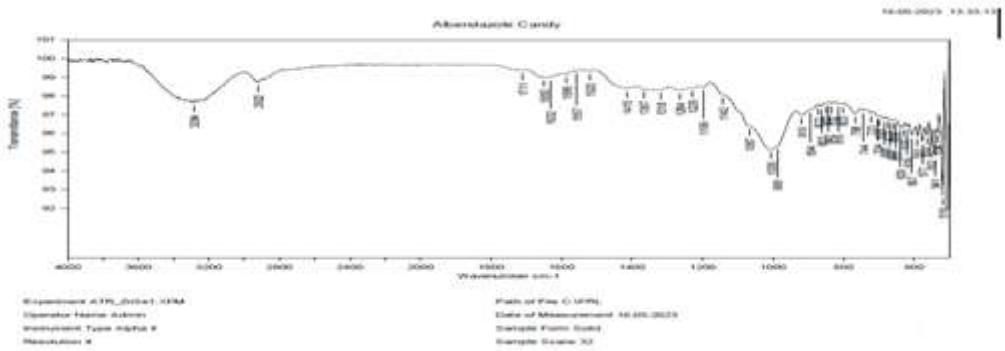

Figure 4: FTIR spectral interpretation of the Optimized formulation

Table 4: FTIR Interpretation for Medicated Candy formulation

S.NO	Functional Group	Wave Number	Observed Frequency	
			Albendazole	Medicated Candy
1	C_6H_6	1450-1600	1442.75	1415
2	N-H	3300-3500	3331.07	3284
3	C-H	2850-2950	2956.87	2922
4	C=O	1780-1650	1712.79	1711
5	C=C	1680-1600	1631.78	1650
6	C=N	1650-1550	1620.21	1632
7	C-N	1230-1020	1095.57	1067
8	CH_3	1370-1250	1267.23	1264

PHYSICAL APPEARANCE OF ALBENDAZOLE MEDICATED CANDY.

PHYSICAL OBSERVATION

The general appearance of a candy formulation, its visual identity and overall elegance is essential for consumer acceptance and to control lot to lot uniformity. The control of the general appearance of a candy involve the measurement of number of attributes such as candy's colour, presence or absence of an odor, taste, surface texture and physical flaws. Randomly selected ten medicated candies were inspected visually and the results were listed in Table 5.

Table 5: Physical Observation of Medicated Candy

S.NO	CHARACTERISTICS	RESULTS
1	Color	Dark Brown
2	Odor	Pleasant
3	Taste	Sweet
4	Texture	Smooth
5	Appearance	Glossy
6	Shape	Artin

In physical appearance evaluation all the formulations were smooth in nature. F2 formulation shows slightly thick and sticky in nature. F3 formulation shows slightly bitterness and F1 formulation was good and acceptable.

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WEIGHT VARIATION OF ALBENDAZOLE MEDICATED HARD CANDIES

Uniformity of weight is an in-process test parameter which ensures consistency of dosage units during moulding. The average weight was calculated by weighing 10 medicated candy and results were listed in Table 6. Results indicate that none of the individual candy weight deviates from the average weight by more than the 5% and it complies with IP standard for tablet.

Table 6: Weight Variation of Medicated Candy

S.NO	Weight of medicated candy (gm)		
	F1	F2	F3
1	4.9	4.1	3.6
2	4.8	4.3	3.8
3	4.7	4.2	3.6
4	4.8	4.4	3.5
5	4.9	4.2	3.4
6	4.8	4.3	3.6
7	4.6	4.1	3.6
8	4.7	4.4	3.8
9	4.9	4.5	3.9
10	4.8	4.1	3.7
Average Weight	**4.79**	**4.26**	**3.65**

THICKNESS OF MEDICATED CANDIES

Six medicated toffee were used to evaluate the average thickness by measuring Vernier callipers

S.NO	Thickness of medicated candy (mm)		
	F1	F2	F3
1	8.99	8.36	9.18
2	8.97	8.35	9.16
3	8.96	8.40	9.12
4	8.99	8.36	9.14
5	8.96	8.35	9.18
6	8.96	8.34	9.19
Average Thickness	**8.97**	**8.36**	**9.16**

Table 7: Thickness of Medicated candy

HARDNESS OF MEDICATED LOZENGES

Table 8: Hardness of formulated Medicated Candies Mean±SD (n=3)

S.NO	FORMULATION CODE	HARDNESS OF CANDY (kg/cm^2)
1	F1	10.65 ± 0.57
2	F2	9.65 ±0.56
3	F3	7.3 ± 0.42

The hardness of all formulated lozenges was found within the range up to 7.3 kg/cm2 to 10.65 kg/cm2.Among the ten formulations of lozenges, the lowest value for hardness was noted for F3 (i.e., 7.3 kg/cm2) and highest i.e., 10.65

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kg/cm2 for F1. The hardness of the lozenges is due to the presence of methyl cellulose.

MOISTURE CONTENT OF MEDICATED CANDIES

Table 9: Moisture Content of formulated Medicated Candies

S.NO	Formulation Code	Moisture Content Of Candy (%)
1	F1	0.72
2	F2	1.1
3	F3	1.3

Moisture content determination is a critical parameter of candies quality.The standard limits of moisture content should be in the range of 0.5 to 1.5 %. As per the result obtained that moisture content in the prepared candies was found in the range of 0.5 to 1.5 % which is within the standard limit

MOUTH DISSOLVING TIME OF MEDICATED CANDIES

Table 10: Mouth dissolving time of medicated candies

Formulation Code	Mouth Dissolving Time (Mins)	Average
F1	12.53	12:50±0.19
	12.17	
	12.8	
F2	10.58	10.16±0.51
	10.32	
	9.59	
F3	7.16	7.06±0.43
	7.54	
	6.49	

Mouth dissolving time of medicated candies was found to be within the range upto 7:06 to 12:50 minutes. The addition of plasticizer was increases the mouth dissolving time of the formulations. F1 formulation shows the highest mouth dissolving time.

FORMULATED ALBENDAZOLE MEDICATED CANDIES

Figure 5: Optimized formulation of Medicated candy

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IV. CONCLUSION

The goal of the current study was to create and assess medicated candies containing albendazole that would operate as an anthelmintic by way of buccal absorption with the addition of a polymer. FT-IR spectroscopy was used to perform a chemical compatibility analysis. The formulation uses 20% liquid glucose to smooth out the sugar basis, make it look better, and keep it from crystallizing. The candies maintained their good look and hard candy type even with a reduced glycerin concentration. The duration of buccal retention was extended by further methylcellulose addition. Physical appearance, weight variation, thickness, hardness, moisture content, and oral dissolving time were all assessed when preparing each formulation. The duration taken by medicated lozenges to dissolve in the mouth was determined to be between 7:06 and 12:50 minutes. The maximum time to dissolve in a medium was displayed by the F1 formulation. The range of 0.5 to 1.5% should be the standard limits for moisture content. According to the results, the prepared candies moisture content was found to be within the standard limits, ranging from 0.5% to 1.5%. The slow dissolution of albendazole candies in the mouth effectively alleviates dysphagia, a common complication of worm infestation in juvenile and geriatric patients as well as adult patients experiencing difficulty swallowing tablets. It has been discovered that medicinal lozenges made of candy will provide an alternate dosage type. These will also benefit from lower doses, faster onset of action, shorter dosage regimens, and economy in addition to patient compliance, convenience, and comfort for effective therapy.

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