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# FORMULATION DEVELOPMENT AND EVALUATION OF MEDICATED CHOCOLATE OF ALBENDAZOLE

**Amol Babasaheb Kolpe* and Prof. Rajendra K. Surawase**

Department of Pharmaceutics, LN Dr. J D Pawar College of Pharmacy Manur, Kalwan, Maharashtra.

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***Corresponding Author**
**Amol Babasaheb Kolpe**
Department of Pharmaceutics, LN Dr. J D Pawar College of Pharmacy Manur, Kalwan, Maharashtra.

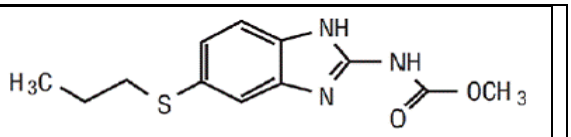
## ABSTRACT

Formulation of Medicated Chocolate of Albendazole is formulated by using cocoa butter and cocoa powder. Mostly Pediatric patient have fear to take the Medicine as Albendazole formulation or any other formulation. with the help of this formulation we will provide most palatable and acceptable formulation for pediatric patient and minimize the fear about medicine. So we prepared formulation and evaluate with different parameter such as Drug release, Compatibility of Drug and Excipient, safety and organoleptic properties by using UV-spectroscopy, IR Spectroscopy, DSC. After Evaluation of all parameter we found satisfactory results with all parameter and conclude that this developed formulation is successfully Developed and Evaluated.

**KEYWORD:** Albendazole (ALB), Coca powder, Coca Butter. Icing Sugar, Sodium Benzoate.

## INTRODUCTION

Chocolate is highly sophisticated a versatile food that is combined to create totally likable taste and texture sensations. Chocolate is also an anhydrous medium and is therefore it is resistant to micro organism growth and to hydrolysis of water sensitive active agents. Chocolate is good vehicle for delivering active agents in many aspects. Chocolate is one of the most tasty, acceptable and favorite in children. Anthelmintics are the drugs that are used for the treatment against the infections caused by the worms, flukes, nematodes, round worms, tapeworms etc. Albendazole (ALB) is a benzimidazole carbamate with a broad spectrum anti-parasitic. In general, most ascariasis, trichuriasis, enterobiasis and hookworm, Tapeworm infections can be successfully treated with single dose ALB.

| | | |
|---|---|---|
| Structure **Albendazole:** | : |  |

Chocolate is one of the most Tasty, likable palatable and favorite in children, so we have developed Albendazole Medicated chocolate. Hence, an attempt will be made to improve the patient compliance and palatability.

## MATERIAL AND METHOD

### Procurement of Drug and Excipients

The following drug, excipients and chemicals were used for the formulation and evaluation of chocolates of Albendazole.

**Materials:** The drug and excipients used in this work are given in Table no. 1.

**Table 1: List of Chemicals.**

| S.N. | Drug and excipients | Supplier/Gifted by |
|---|---|---|
| **1.** | Albendazole | Medriech ltd. (Meiji seika pharma), Bangalore |
| **2.** | Cocoa butter | Pruthvi foods Pvt. Ltd, Ahmedabad |
| **3.** | Cocoa powder | Pruthvi foods Pvt. Ltd, Ahmedabad |
| **4.** | Milk Powder | Pruthvi foods Pvt. Ltd, Ahmedabad |
| **5.** | Icing sugar | Loba Chemie, Mumbai |
| **6.** | Sodium benzoate | Loba Chemie, Mumbai |

*Note: All the other chemicals like icing sugar, Dicalcium phosphate used are of analytical grade (AR).*

**Instruments and Equipments:** The following equipments and instruments have been used in present research work.

**Table 2: List of Equipments and Instruments.**

| S.N. | Name of Equipment and Instrument | Model | Make |
|---|---|---|---|
| **1.** | Digital electronic balance | BL-220H | Shimadzu |
| **2.** | UV-Visible Double Beam Spectrophotometer. | 1601 | Shimadzu |
| **3.** | Fourier transform infrared spectrophotometer | 8400S | Shimadzu |
| **4.** | Hot Air Oven | __ | Lab Hosp |
| **5.** | Differential Scanning Colorimeter | DSC 60 | Shimadzu |
| **6.** | Vernier Caliper | __ | Aerospace |
| **7.** | Magnetic Stirrer | __ | Aerospace |
| **8.** | USP Tablet Dissolution Test Apparatus Type-II | DISSO 2000 | Lab India |
| **9.** | Stability Chamber | __ | Science Lab |

**Preparation of medicated chocolates**

For the formulation of each chocolate form drug, cocoa butter, cocoa powder, milk powder, icing sugar and sodium benzoate were used. All ingredients were weighed accurately.

**Formulation of chocolate Base**

The sugar syrup prepared by heating the sugar (Pharmaceutical Grade)with Water in a beaker using a heating mantle at 50°C for 5-6 minute. The coca base is prepared by melt down the coca butter in a beaker for 2 minute and adding the above prepared sugar syrup then add milk powder and coca powder in it. This mixture is get cooled upto semisolid consistency and then add flavouring agent and mix it.

**Formulation of medicated chocolate**

Oven was preheated at 50°C. Then chocolate base was melted to obtained free pourable liquid. Albendazole and Sodium benzoate was added in chocolate base for uniform mixing. Above mixture was filled into pre calibrated polycarbonate set mould and refrigerated for 15 min till it become solid. Figure no. 1 showing the preparation of medicated chocolate. This solidified content was removed from mould carefully and evaluated using various evaluation parameters.

**Figure 1: Preparation of medicated chocolate.**

**Table 3: Composition of medicated chocolates of Albendazole.**

| Sr. No. | Ingredients (gm) | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|---|
| **1.** | Albendazole | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.2 |
| **2.** | Cocoa Butter | 2.25 | 2 | 1.75 | 1.5 | 1.25 | 1 |
| **3.** | Cocoa Powder | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| **4.** | Milk powder | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 | 1.2 |
| **5.** | Icing Sugar | 3.75 | 3.5 | 3.25 | 3 | 2.75 | 2.5 |
| **6.** | Sodium Benzoate | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 | 0.05 |
| | **Total Weight** | **7.95** | **7.45** | **6.95** | **6.45** | **5.95** | **5.45** |

## RESULTS AND DISCUSSION

### Preformulation Study of Albendazole

### Organoleptic properties and description, Melting Point, Solubility:

**Table 4: Organoleptic properties and description.**

| Property | Observation |
|---|---|
| Organoleptic properties | Slightly white to pale buff colored powder. |
| Melting Point | 209$^{o}$C, which matches with the reported value. |
| Solubility | freely soluble dimethylsulfoxide,HCL,NaOH |

### FTIR studies of Albendazole

**Figure 2: Shows the IR spectra of pure drug.**

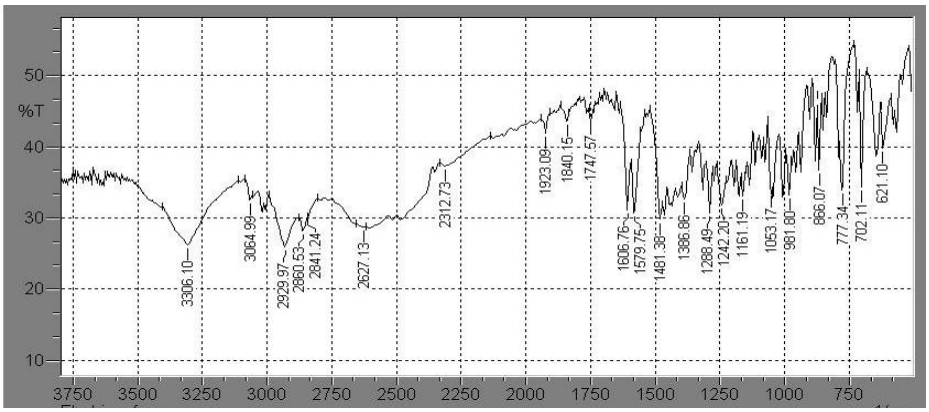



**Figure 2: FTIR spectra for the drug Albendazole.**

**Table 5: The functional groups detection by using wave numbers.**

| Functional groups | Wave numbers ($cm^{-1}$) | Standard frequency range |
|---|---|---|
| CH3/CH2 C-H stretching | 2929.77 | 2850-3000 |
| C=O Stretch. | 1747.57 | 1680-1880 |
| CH3/CH2 C-H stretching | 2860.53 | 2850-3000 |
| -C=N | 1579.75 | 1375-1500 |
| N-H stretch of amido gr. | 3064.99 | 3500-3100 |
| C-O Stretch. | 1053.17 | 1000-1350 |
| C=O Stretch. | 1747.57 | 1680-1880 |
| C-S-C stretch. | 961.60 | 800-1000 |

### Interpretation

Table No. 5 Shows the interpretation of the peaks obtained in the Infra Red spectra along with their corresponding functional groups.

**DSC Studies of Albendazole**

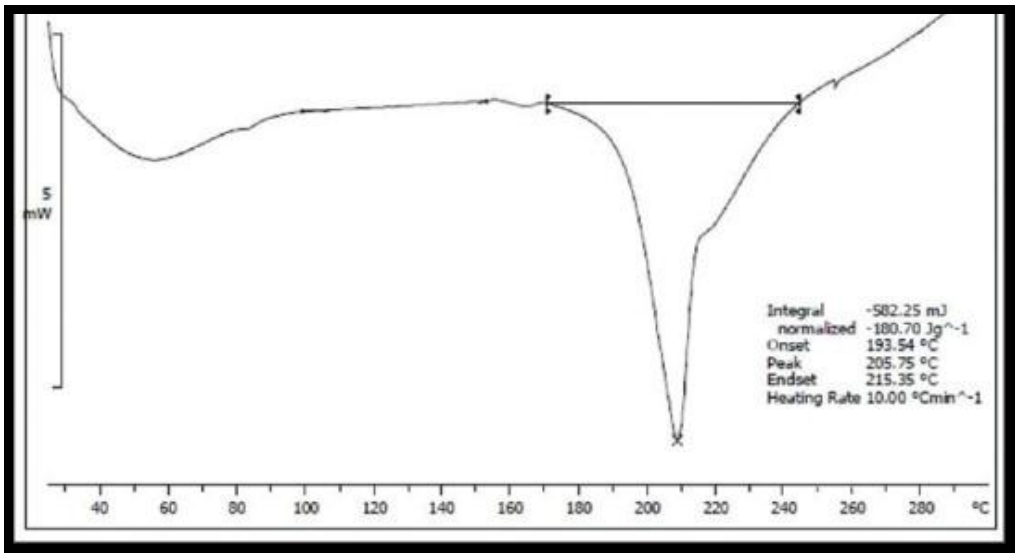



**Figure 3: DSC thermogram of Albendazole.**

**Table 6: DSC peaks of Albendazole.**

| Drug | Melting point | Interpretation | | |
|---|---|---|---|---|
| | | Onset | Peak | End set |
| Albendazole | $208^0$ -$210^0$ C | 193.54°C | 205.75°C | 215.35°C |

**Spectroscopic studies (Determination of λmax) of Albendazole**

The UV spectrum, obtained after the proper dilution of the drug shown in Figure No. 10. The drug solution was scanned and wavelength was found to be 291 nm. The spectrum was showing λmax at 291 nm, hence all further analysis was done by using the wavelength 291 nm.

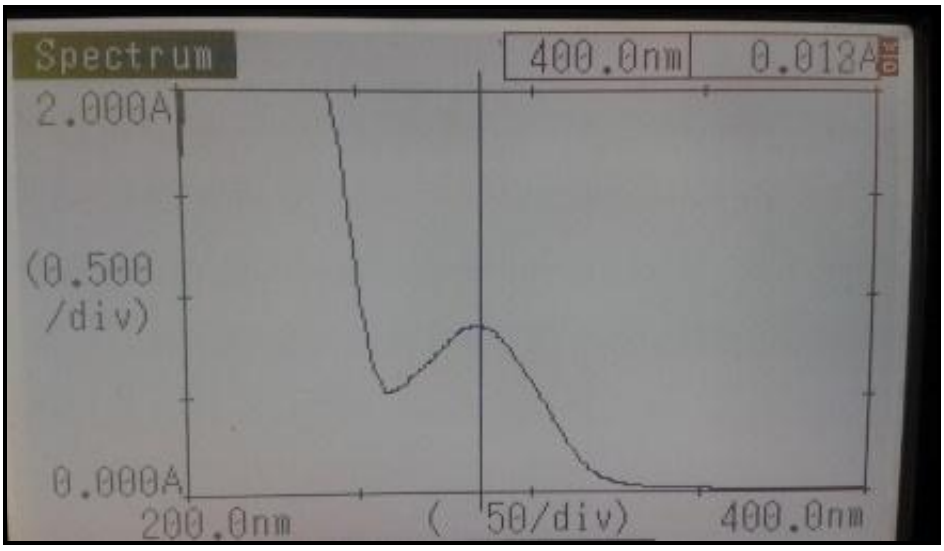



**Figure 4: The UV-spectra of pure Albendazole in phosphate buffer pH 6.8.**

**Evaluation parameters for formulated Albendazole Medicated chocolates.**

| Sr. No. | Formulation code | Appearance /Texture | Colour | Taste | Odour | Shape | Weight variation (gm)* | Thickness (mm)** |
|---|---|---|---|---|---|---|---|---|
| **1.** | F1 | Glossy, even shine, no streaks | Dark brown | Semi-sweet | Pleasant and fresh chocolaty | Round shape | 7.96±0.24 | 9.18± 0.04 |
| **2.** | F2 | Glossy, even shine, no streaks | Dark brown | Sweet, good after taste | Pleasant and fresh chocolaty | Round shape | 7.48±0.26 | 8.99+ 0.03 |
| **3.** | F3 | Glossy, even shine, no streaks | Dark brown | Neither bitter nor sweet | Pleasant and fresh chocolaty | Round shape | 6.96 ±0.32 | 8.75+ 0.01 |
| **4.** | F4 | Glossy, even shine, no streaks | Dark brown | Semi-sweet | Pleasant and fresh chocolaty | Round shape | 6.46 ±0.30 | 8.50+ 0.11 |
| **5.** | F5 | Glossy, even shine, no streaks | Dark brown | Neither bitter nor sweet | Pleasant and fresh chocolaty | Round shape | 5.95 ±0.44 | 8.15+ 0.13 |
| **6.** | F6 | Glossy, even shine, no streaks | Dark brown | Bitter | Pleasant and fresh chocolaty | Round shape | 5.44±0.27 | 8.03+ 0.12 |

**Evaluation parameters for formulated Albendazole Medicated chocolates**

| Sr. No. | Formulation code | Drug content (%)** | Melting point (˚C) | % moisture content |
|---|---|---|---|---|
| 1. | F1 | 100.06+0.04 | 36.0˚C | 8.36 |
| 2. | F2 | 99.56+0.04 | 34.0˚C | 6.28 |
| 3. | F3 | 99.36+0.08 | 34.5˚C | 7.90 |
| 4. | F4 | 99.97+0.08 | 35.0˚C | 10.27 |
| 5. | F5 | 99.21+0.08 | 34.5˚C | 8.99 |
| 6. | F6 | 99.06+0.04 | 35.5˚C | 8.20 |

### 6.1.1.Blooming test

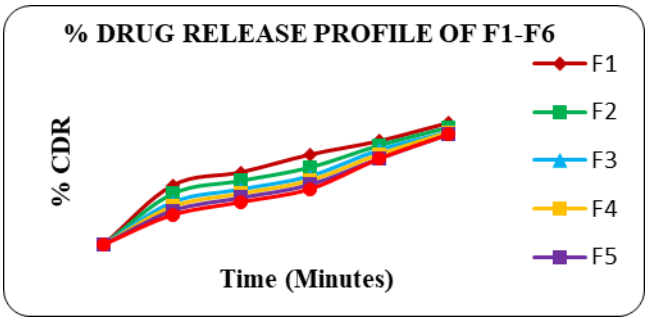
**Table 6: Blooming test of Albendazole chocolate (Optimized batch F1).**

| Sr. No. | Storage Condition | Evaluated Condition | Fat Bloom | Sugar Bloom |
|---|---|---|---|---|
| 1. | Refrigerated Condition (2-8°C) for 24 hr. | At Room Temperature | No Blooming | No Blooming |
| 2. | Room Temperature (25°C) for 24 hr. | At Refrigerated Condition | No Blooming | No Blooming |

### 6.1.2. In-vitro dissolution study

**Table 7: % Cumulative drug release of Albendazole chocolate.**

| Formulation Code | Time (Min.) | | | | |
|---|---|---|---|---|---|
| | 4 | 8 | 12 | 16 | 20 |
| **F1** | 48.46 | 59.33 | 73.76 | 84.87 | 99.55 |
| **F2** | 41.53 | 52.33 | 63.24 | 81.17 | 95.81 |
| **F3** | 34.61 | 45.34 | 56.18 | 77.5 | 92.11 |
| **F4** | 31.15 | 41.85 | 52.65 | 73.93 | 91.97 |
| **F5** | 27.69 | 38.35 | 49.11 | 70.37 | 90.1 |
| **F6** | 24.23 | 34.85 | 45.58 | 70.26 | 90 |




### 6.1.3.Stability Studies

Table no. 18 showing the data of short-term stability study of optimize batch

**Table 8: Stability Studies of Formulation F1.**

| Code | % Drug Release Data | | | | Drug Content | Melting point | Appearance |
|---|---|---|---|---|---|---|---|
| | Initial | 10th day | 20th day | 30th day | | | |
| **F1** | 99.5 | 99.16 | 98.76 | 98.70 | 99.99 | 34.5°C | Acceptable |

### 6.2. Drug release kinetics- model fitting of the dissolution data

The release rate constant (k) of mathematical models for *in vitro* drug release of all formulations are Shown below in table no. 19.

Release rate constant (k) = Slope* 2.303

**Table 9: Results of drug release kinetics model.**

| Code | Zero order | | First order | | Higuchi Equation | | Korsemeyer-Peppas | | | Mechanism of drug release |
|---|---|---|---|---|---|---|---|---|---|---|
| | $R^2$ | K | $R^2$ | K | $R^2$ | K | $R^2$ | K | N | |
| **F1** | 0.997 | 7.35 | 0.843 | 0.17 | 0.978 | 47.3 | 0.976 | 1 | 0.43 | Non-fickian transport |
| **F2** | 0.989 | 7.91 | 0.844 | 0.15 | 0.956 | 50.52 | 0.960 | 1.2 | 0.52 | Non-fickian transport |
| **F3** | 0.982 | 8.47 | 0.877 | 0.12 | 0.946 | 54 | 0.954 | 1.4 | 0.61 | Non-fickian transport |
| **F4** | 0.977 | 8.85 | 0.853 | 0.12 | 0.935 | 56.23 | 0.955 | 1.52 | 0.66 | Non-fickian transport |
| **F5** | 0.973 | 9.03 | 0.849 | 0.11 | 0.929 | 57.27 | 0.954 | 1.65 | 0.71 | Non-fickian transport |
| **F6** | 0.968 | 9.61 | 0.851 | 0.11 | 0.921 | 60.89 | 0.95 | 1.85 | 0.80 | Non-fickian transport |

## CONCLUSION

In present dissertation work, an attempt was made to formulate medicated chocolate of Albendazole using cocoa butter, cocoa powder and milk powder for the treatment of helminth infection. The aim of this research work was to formulate and evaluate medicated chocolate of Albendazole for pediatric patient, in view to improve patient compliance. The medicated chocolates were evaluated for shape, colour, texture, fragrance, dimension, taste, weight, blooming test, melting point, % drug content and dissolution study. Each chocolate of Albendazole contains 200mg drug. All the data of in-vitro drug release studies was fitted into various models like zero order, first order, Higuchi, and Korsmeyer-Peppas model. The formulation batch F1 shows the maximum correlation coefficient. Hence it can be concluded that the formulation F1 will be useful for treatment of helminths infection.

"So, the medicated chocolates of Albendazole is a best choice to bypass the hepatic first pass metabolism with an improvement in the bioavailability of Albendazole."

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