

## Formulation And Evaluation Of Fast Dissolving Tablets Of Albendazole By Enhancing Solubility With Solid Dispersion Technique

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**Abstract:** In the current research, fast dissolving tablets of Albendazole (ABZ) by enhancing solubility with solid dispersion technique was prepared. Albendazole is used for the treatment of a variety of parasitic worm infestations. It is a poorly water soluble drug and Solubility is a significant physiochemical factor which affects the absorption of drug and therapeutic effectiveness. So solubility of ABZ was enhanced by preparing solid dispersion using solvent evaporation method. The prepared solid dispersion was evaluated for Solubility studies, Dissolution and kinetic drug release models and it was found that solubility of formulation has a maximum solubility & Dissolution has a maximum value **249.38( $\mu\text{g/ml}$ )** and it follows First order kinetic drug release models. Tablets were evaluated for Weight variation, Hardness, Friability, Water Absorption Ratio, Wetting Time, Content of uniformity and In-vitro disintegration time testing of tablets and it was found that tablets has a Weight Variation was found  $1.2 \pm 0.74$ , Hardness was found  **$2.3 \pm 0.05$** , Friability was found  $0.59 \pm 0.1$ , wetting time was found  $2.3 \pm 0.05$ , Content of uniformity was found  $96.97 \pm 0.89$  and In-vitro disintegration time was found  $99.97 \pm 0.89$ . The tablets were formulated successfully. Thus it can be concluded that urea enhances solubility more than other ingredients and sodium starch glycolate was found best super disintegrating agent.

**Key Words-** Albendazole (ABZ), solubility enhancement, mouth dissolving tablets (MDT), solid dispersion.

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### I. Introduction

#### Introduction

Albendazole is a benzimidazole unoriginal which is used for the treatment of a diversity of parasitic worm infestations. It is a broad-spectrum anti-hermitic and is efficacious antagonistic towards roundworms, tapeworms and flukes "Solubility" is the principal circumstance in pharmaceutical formulation that plays very functional role in the formulation of diverse dosage forms. Solubility of a complex in a specific solvent is entitled as the concentration of a solute in a saturated solution at a certain temperature. Solid dispersion can be prepared by many methods; here we use solvents evaporation method. These are novel types of tablets that dissolve/ disintegrate/ disperse in saliva within few seconds without water.<sup>[1, 2, 3]</sup>

#### ADVANTAGES OF FAST DISSOLVING TABLETS<sup>[4, 5]</sup>:

1. Those patients who cannot swallow, like the elderly, stroke victims and house-bound patients can smoothly swallow these tablets.
2. Patient's acceptance for those patients who are disabled, house-bound and for those who are travelling and busy people who do not have ready access to water.
3. Fast dissolving drug delivery system helps to change the taste of bitter drugs and give a acceptable feeling to mouth.
4. By this formulation exact dosing can be done as differentiate to liquid formulations.
5. Liquid medication can be incorporated in the form of solid preparation.
6. Drug absorption from the pre-gastric area is more rapid i.e. mouth, pharynx and esophagus which may produce fast onset of action.
7. Pre-gastric absorption can result in upgraded bioavailability, depleted dose and diminishing side effects.

#### LIMITATIONS OF FAST DISSOLVING TABLETS<sup>[6]</sup>:

1. This tablets have ordinarily inadequate mechanical strength. Hence, extra care for handling is required.
2. The tablets can leave obnoxious taste or grittiness in mouth if these not formulated properly.

**APPROACHES FOR FAST DISSOLVING TABLET:**

The fast-dissolving property of any tablet is imputable to a quick incursion of water into the tablet matrix which results in unpleasant tablet rapid disintegration. Technologies used in the fabrication of Fast dissolving tablets include<sup>[7, 8 & 9]</sup>:

- 1) Melt granulation
- 2) Phase transition process
- 3) Sublimation
- 4) Three-dimensional Printing (3DP)
- 5) Mass Extrusion
- 6) Spray drying
- 7) Tablet Molding
- 8) Lyophilization or Freeze-Drying
- 9) Direct compression

**1. Melt granulation:**

The approach by which pharmaceutical powders are competently clustered by a meltable binder is called as Melt Granulation. The advantage of this approach estimated to a ordinary granulation is that it does not required water or organic solvents. This technique is universally used to enhance the dissolution rate of poorly water-soluble drugs, like Albendazole, Ibuprofen, Diclofenac, etc.<sup>[10]</sup>

**2. Phase transition process:**

Conjugation of low and high melting point sugar alcohols, and a phase transition in the manufacturing process, is important guideline for preparing FDTs without any special equipment. FDT can prepare by compressing the powder containing erythritol which has a melting point: 122 °C and xylitol with the melting point: 93-95 °C, and then heated at about 93 °C for 15 min. After heating, the median pore size and hardness of the tablets will also increase.<sup>[11]</sup>

**3. Sublimation:**

Volatile ingredients are used to generate permeable matrix, and later subjected to a process of sublimation. In studies inert solid ingredients which exhibits high volatility will compressed with the other excipients into a tablet. Then the volatile material is removed by sublimation, leave a permeable matrix. Solvents such as cyclohexane and benzene can be also recommended to initiate the permeability in the matrix.<sup>[12]</sup>

**4. Three-dimensional Printing (3DP):**

A novel fast dissolving drug delivery device with loose powders in it can be fabricated by using the three dimensional printing (3DP) process. This is based on computer-aided design models, the drug delivery device which contain the drug like acetaminophen can be prepared undoubtedly by 3DP system.<sup>[13]</sup>

**5. Mass Extrusion:**

By the use of solvent mixture of water soluble polyethylene glycol and methanol this technology comprises tempering of the active blend and expulsion of tempered mass through the extruder or syringe by which the cylindrical shaped extrude which are finally cut into even components by the use of heated blade which forms the tablets. This process can also be used for the coated granules of bitter drugs to mask their taste.<sup>[14,15]</sup>

**6. Spray drying:**

Technique by which highly permeable, fine powders can be produced is called as Spray drying. Spray-dryers are occasionally used in the pharmaceutical industry for producing highly permeable powders. The formulations for the matrix that can produce which contained hydrolysable and non-hydrolysable gelatin as a assisting agent, mannitol as a bulking agent, and sodium starch glycolate or crosscarmellose as a super disintegrate.<sup>[16]</sup>

**7. Tablet Molding:**

Molding process is of two type's first solvent method and second heat method. In solvent method moistening of the powder blend with a hydro alcoholic solvent is carried out and then compression is carried out at low pressures in molded plates to form a wetted mass. Removal of the solvent is done by air-drying. These tablets are less compact than the compressed tablets.<sup>[16]</sup>

**8. Lyophilization or Freeze-Drying:**

The process in which water is sublimed from the product after it is frozen is known as Freeze drying. In this technique creation of an amorphous porous structure which can dissolve rapidly is carried out. This procedure involved in the manufacturing of Fast dissolving tablets used is that the active drug is dissolved or dispersed in an aqueous solution of a carrier or a polymer. <sup>[17]</sup>

**9. Direct compression:**

It is more easiest way of manufacturing of tablets. By this method high doses may be accommodated and gross weight of tablet can easily exceed then that of other production methods. This technique is now applied for manufacturing of fast dissolving tablets because of the availability of tablet bulking agents, especially the disintegrating agents and sugar-based bulking agents. These super disintegrating agents used in fast dissolving tablets, because they give a quick disintegration of tablets and thus it improves dissolution. <sup>[17]</sup>

**II. Solubility**

“Solubility” is the principal circumstance in pharmaceutical formulation that plays very functional role in the formulation of diverse dosage forms. Solubility of a complex in a specific solvent is entitled as the concentration of a solute in a saturated solution at a certain temperature. <sup>[18]</sup>

**FACTORS AFFECTING SOLUBILIZATION <sup>[19]:</sup>**

The solubility based on the nature and composition of solvent medium, the physical form of the solid along with temperature and pressure of system. Factors that affect the solubility are as follows-

**A) Particle Size:**

The particle size of the solid impacts the solubility since when the particle size is decreased the surface area will be increased. The larger surface area enables a greater interaction between the solvent and the solute. The effect of particle size on solubility can be catalogued

$$\log \frac{S}{S_0} = \frac{2 \gamma V}{2.303 R T r}$$

Where, S<sub>0</sub> is the solubility of unbelievably large particles, S is the solubility of fine particles, V is molar volume, r is the radius of the fine particle and D is the surface tension of the solid.

**B) Pressure**

Modification in pressure have practically no outcome on solubility of any solid or liquid solute but for gaseous solutes, when pressure is increased, there is increase in solubility and a decrease in pressure causes the decrease in solubility. <sup>[20]</sup>

**Step 1: Holes opens in the solvent**



**Step2: Molecules of the solid breaks away from the bulk**



**Step 3: The freed solid molecule is intergrated into the hole in the solvent**



**Fig. 1 Process of solubilisation**

**C) Temperature:**

When temperature is increased the solution process absorbs the energy and the solubility will be increased but if the process releases energy that is the process is exothermic so the solubility will decrease while increasing the temperature. A few solid solutes are less soluble in warm solutions. <sup>[21]</sup>

**D) Molecular size:**

The molecules have higher molecular weight and higher molecular size is less soluble because larger molecules are more difficult to surround with solvent molecules in order to dissolve the substance. In the case of organic

compounds the amount of carbon branching will increase the solubility since more branching will reduce the size (or volume) of the molecule and make it easier to solvate the molecules with solvent. [22]

**DRUG PROFILE:**

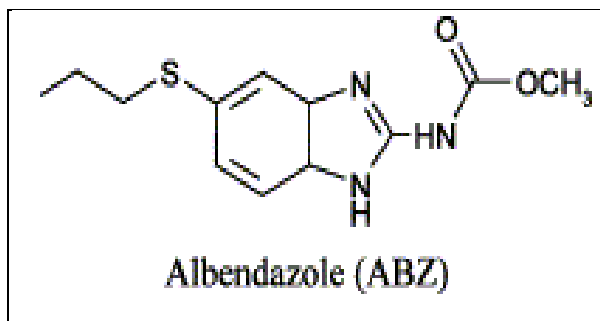
**Albendazole** [23, 24, 25, 26]

**Generic name:** Albendazole **IUPAC Name:** Methyl [5-(propylthio)-1H-benzimidazol-2-yl] carbamate.

Molecular Formula:  $C_{12}H_{15}N_3O_2S$

Molecular Weight: 265.3314 g/mol

**Structure:**



**Melting point:** 208°-210° C

**Solubility:** Insoluble in water.  
Soluble in strong acids and bases.  
Soluble in Glacial acetic acid.

**Medical uses:**

It is effective first-line of treatment against:

- Flatworms
- ❖ **Flukes/trematodes**
- Fasciolosis
- ❖ **Tapeworm/cestodes**
- Cysticercosis
- Echinococcosis
- Nematodes
- ❖ Enterobiasis (pinworm infection)
- ❖ Trichuriasis (whipworm infection)
- ❖ Toxocariasis
- ❖ Ascariasis
- ❖ Hookworm
- ❖ Cutaneous larva migrans (caused by Ancylostoma)
- ❖ Filariasis
- ❖ Myiasis
- Albendazole may cause abdominal pain, dizziness, headache, fever, nausea, vomiting, or temporary hair loss.
- **How to use Albendazole:**
- Take this medication by mouth with meals, usually 1 to 2 times daily or as directed by your doctor.
- Dosage is based on your weight, medical condition, and response to treatment. Take this medication exactly as prescribed by your doctor.
- Use this medication regularly in order to get the most benefit from it. To help you remember, take it at the same time(s) each day.
- Continue to take this medication until the full prescribed amount is finished, even if symptoms disappear after a few days.

**Experimental Methods**

**A) Formulation of calibration curve:** [27]

**a) Standard Reserved Solution:** Standard reserved solution was prepared by dissolving 10 mg of Albendazole in 100 ml of Glacial acetic acid to get concentration of 100 µg/ml.

**b) Procedure for calibration curve:** Standard reserved solution was moreover mixed with distilled water to prepare solution of different concentration 5-25 µg/ml. Eventually, the developed standards was measured at the wavelength 254 nm and recorded.

**Enhancement of Solubility:**

**(B)Formulation of solid dispersions**

Solid dispersions was developed by the solvent evaporation technique, in this technique drug (Albendazole) and carrier (Urea, PVPK-30) were diffused in organic solvent (methanol) after the diffusion, the solvent was evaporated by utilizing a water bath. The solid mass achieved were ground. Sieved through # 80 and dried.

**Table no. 1 formulae for solid dispersion**

S. No.	Ingredients	F 1	F 2	F 3	F 4
1	Albendazole(gm)	1	1	1	1
2	PVP K-30(gm)	1	-	2	-
3	Urea(gm)	-	1	-	2
4	Methanol(ml)	5	5	5	5

**(C) Evaluation of solid dispersion**

**(i) Solubility studies**

**(ii) Dissolution Studies**

**(iii) Kinetic Models for Drug Release**

**(i) Solubility studies**

Solubility studies of ABZ were moved out to know the possible solubilizing effect of the carrier by adding drug (20 mg) to 10 ml of aqueous solutions contained increasing concentration of carrier (1:0, 1:1, 1:2) and glass containers were sealed maintained under stirring at constant temperature (20°C) for (2 days). And the prepared solid dispersions were also subjected to solubility study; drug concentration was determined spectrophotometrically at 254nm

**(ii) Dissolution studies-**

Dissolution studies were conducted using USP paddle dissolution technique by dispersed powder technique, for this reason in 900 ml of 0.1N HCl, at a stable temperature  $37 \pm 0.5^\circ\text{C}$ , with a speed of paddle rotation is 50 rpm. 50mg powdered samples of each formulation (solid dispersion of ABZ) were added to the dissolution medium. At a time interval of 15 minutes, 5 ml of the mixture was withdrawn, filtered and inspected for ABZ content by UV spectrophotometer at 254 nm. Percent dissolution efficiency (%DE) was evaluated to compare the respective presentation of dissimilar carriers in solid dispersion formulations. The greatness of %DE (%DE t min) for each formulation was computed as the percent ratio of area under the dissolution curve up to the time (t) to that of the area of the rectangle narrated by 100% dissolution at the same time.

**(iii) Kinetic modelling of drug release-**

**(a)Zero order kinetics models**

Drug dissolution from dosage forms that do not disintegrates and deliver the drug slowly can be illustrated by the equation:

$Q_0 - Q_t = K_0T$
$Q_t = Q_0 + K_0T$

Reposition the above equation,

Where,

$Q_t$  is the amount of drug dissolved in time t,

$Q_0$  is the initial amount of drug in the solution (most times,  $Q_0 = 0$ ) and

$K_0$  is the zero order release constant expressed in units of concentration/time.

To study the release kinetics, data obtained from in vitro drug release studies, are plotted as cumulative amount of drug released versus time.

**(b)First order kinetics model**

This model is used to describe absorption and elimination of some drugs, although it is difficult to conceptualize this mechanism on a theoretical basis.

The data obtained are plotted as log cumulative percentage of drug remaining vs. time which would yield a straight line with a slope of  $-K/2.303$ .

**(c)Higuchi model**

Higuchi proposed this model in 1961 to describe the drug release from matrix system. Higuchi model is based on the hypotheses that:

(i) initial drug concentration in the matrix is much higher than drug solubility

- (ii) drug diffusion takes place only in one dimension (edge effect must be negligible)
  - (iii) drug particles are much smaller than system thickness
  - (iv) matrix swelling and dissolution are negligible
  - (v) drug diffusivity is constant and
  - (vi) perfect sink conditions are always attained in the release environment.
- The data obtained were plotted as cumulative percentage drug release versus square root of time.

**(d) Korsmeyer–Peppas Model (The power law)**

A simple relationship which described drug release from a polymeric system equation was derived by Korsmeyer et al. in 1983.

The following assumptions were made in this model:

- i. The generic equation is applicable for small values of t or short times and the portion of release curve where  $M_t/M_\infty < 0.6$  should only be used to determine the exponent n.
- ii. Drug release occurs in a one dimensional way.
- iii. The system's length to thickness ratio should be at least 10.

To study the release kinetics, data obtained from in vitro drug release studies were plotted as log cumulative percentage drug release versus log time.

**(D) Formulation of tablets**

**(i) Pre-formulation studies of Bulk:** <sup>[28]</sup>

- a) Bulk Density
- b) Tapped Density
- c) Angle of Repose
- d) Carr's Compressibility Index
- e) Hausner's Ratio

**(ii) Formulation of tablets**

Fast dissolving tablets of Albendazole were prepared using direct compression method incorporating Microcrystalline cellulose (MCC) and Sodium alginate (SA) as disintegrants. Cross carmellose Sodium (CCS) and Sodium starch glycolate (SSG) as super disintegrants. The Albendazole solid dispersion equivalent to 200mg, Mannitol, Polyvinyl pyrrolidone K-30(PVP K-30) and Aspartame were mixed thoroughly in glass mortar using a pestle. Disintegrants or Super disintegrants were incorporated in the powder mixture according to each formulation in the tablets and finally Magnesium stearate were added. The whole mixture will be passed through Sieve No. 60 twice. Tablets will be prepared using tablet machine.

**Table no. 2 formulae for tablets**

S. No.	Ingredients	F1(in mg)	F2(in mg)	F3(in mg)	F4(in mg)
1	Solid dispersion of ABZ equivalent to	200	200	200	200
2	PVP K-30	33	33	33	33
3	Magnesium stearate	11	11	11	11
4	Mannitol	500	500	500	500
5	Aspartame	22	22	22	22
6	Sodium alginate	55	-	-	-
7	Micro crystalline cellulose	-	55	-	-
8	Sodium starch glycolate	-	-	55	-
9	Cross carmellose sodium	-	-	-	55

:

**E) Evaluation of Tablets:** <sup>[29]</sup>

- 1. Hardness
- 2. Weight Variation
- 3. Friability
- 4. Disintegration
- 5. Wetting Time
- 6. Content of Uniformity

**III. Result**

**(A) Evaluation of solid dispersion**

**(i) Solubility studies**

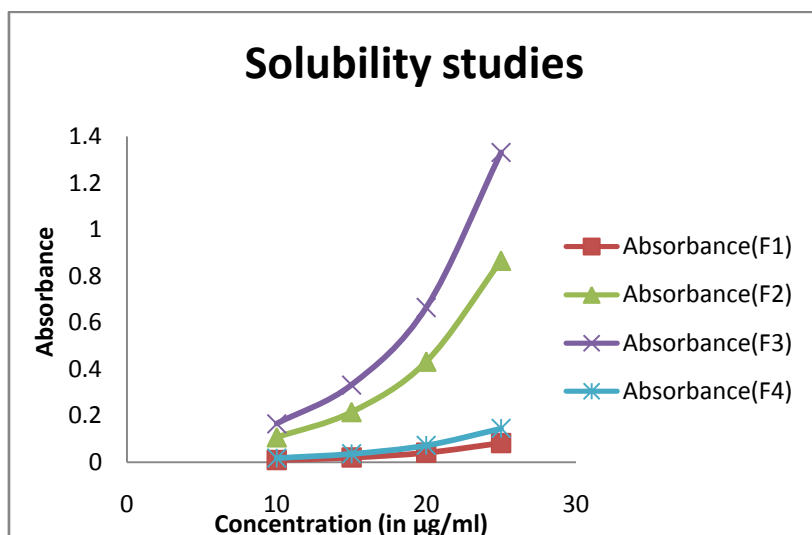


Figure No. 1 Phase solubility study

## (ii) Dissolution Studies and Kinetic Models for Drug Release

Table no. 3 Evaluation of solid dispersion

S.No.	formulation	Dissolution studies drug release (in90 min.)	First order	Zero order	Higuchi model	Korsmeyer-Peppas model
1	F1	129.69(µg/ml)	0.936	0.856	0.770	0.318
2	F2	86.3(µg/ml)	0.929	0.947	0.837	0.749
3	F3	78.6(µg/ml)	0.916	0.954	0.827	0.728
4	F4	249.38(µg/ml)	0.991	0.969	0.886	0.847

## (B) Pre-formulation studies of Bulk

Table no. 4 Pre-formulation studies of Bulk

S. No.	F	Angle of repose	Bulk density	Tapped density	Carr's index	Hausner's ratio
1	F1	27.62±0.39	0.44±0.025	0.66±0.025	10.89±0.71	1.54±0.009
2	F2	28.97±0.59	0.42±0.018	0.61±0.057	09.75±0.77	1.57±0.014
3	F3	25.71±0.35	0.38±0.029	0.54±0.036	07.95±0.81	1.42±0.027
4	F4	29.65±0.46	0.42±0.019	0.62±0.029	14.60±0.99	1.2 4±0.081

## (C) Evaluation of Tablets

Table no.5 Evaluation parameter of tablets

F	Hardness	Weight variation	Friability	Disintegration time	Wetting time	Content of uniformity
F1	3.5±0.5	3.5±1.5	0.96±0.5	4.85±1.50	4.15±0.25	96.28±0.75
F2	3.8±0.5	2.9±1.4	0.68±0.15	5.31±0.30	3.1±0.25	95.81±0.37
F3	2.3±0.05	1.2±0.74	0.59±0.1	1.45±0.25	2.3±0.05	99.97±0.89
F4	4.2±2.0.5	2.4±1.30	0.72±0.2	2.96±1.60	3.4±1.9	94.64±0.29

## IV. Discussion

Albendazole(ABZ) is a poorly water soluble drug, for increasing its solubility. Solid dispersions were prepared. Solid dispersions are set of products which comprises of two different components namely a hydrophilic matrix and a hydrophobic drug. The matrix may be in a crystalline or amorphous form. Here, the possible reason for increase in solubility is that, in solid dispersion Albendazole can be dispersed molecularly, in amorphous particles or in crystalline particles. In this work PVP K-30 and Urea were used to prepare solid dispersion. PVP K-30 and Urea were used in four formulations in a ratio of ABZ: PVP K30 to be 1:1 and 1:2 & ABZ : Urea to be 1:1 and 1:2. From the observation Urea proved more convenient for enhancing the solubility of Albendazole. After solubility enhancement tablets were formulated using two different disintegrants namely Microcrystalline cellulose (MCC) and Sodium alginate (SA) & two different super disintegrants namely Sodium starch glycolate (SSG) and Cross carmellose sodium(CCS). At the time of measurement of dispersion time and disintegration time, it was proved that Sodium starch glycolate (SSG) increases the solubility and thus decreases the dispersion time disintegration time.

## V. Conclusion

In this work, From the observation Urea proved more convenient for enhancing the solubility of Albendazole. After solubility enhancement tablets were formulated using four different super disintegrants. At the time of measurement of dispersion time and disintegration time, it was proved that Sodium starch glycolate (SSG) increases the solubility and thus decreases the dispersion time disintegration time.

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