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Design and Evaluation of Albendazole Sustained Release Tablets

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Abstract: The current research work deals with the development of sustained release tablets of albendazole using a blend of natural and synthetic polymers. Three formulations were prepared (A1-A3) by varying the composition of polymers in a ratio of 1:1 and alternating the polymer combinations. All the prepared formulations were evaluated for various parameters like hardness, weight variation, friability, content uniformity, disintegration time, in-vitro drug release study and also stability study. The study reveals optimum formulation blends and good in-vitro release profile showing rapid disintegration and rapid dissolution profile. Sustained release tablets are ideally suited for drug delivery of BCS class II drugs which have half life in the range of 2-8 hours. Albendazole is used for the treatment of infections caused by microbes in human intestine and the formulation can be used for effective germicidal treatment. The prepared formulations showed t50% of average 6-7 hours with t80% of 10-12 hours with zero order release profile in some formulations. All other parameters of the batches were found to be optimum and within acceptance criteria. The formulation AF3 was found to be the best formulation on the basis of evaluation parameters. The prepared formulations can be further developed and optimized to give better results.

Key words: albendazole, sustained release, tablets.

1. Introduction

Conventional drug delivery system has been characterized by immediate release and repeated dosing of the drug which might lead to the risk of dose fluctuation, this arises the need of a formulation with control release that maintain a near-constant or uniform blood level. The desire to maintain a near-constant or uniform blood level of a drug often translates into better patient compliance, as well as enhanced clinical efficacy of the drug for its intended use. [1,2]

Sustained release, sustained action, prolong action, controlled release, extended action, depot are terms used to identify drug delivery systems that are designed to achieve prolong therapeutic effect by continuously releasing medication over an extended period of time after administration of single dose. In the case of orally administer this period is measured in hours while in the case of injectables this period varies from days to months.

Advantages of sustained release dosage forms:- [3]

1. Control of drug therapy is achieved.

2. Rate and extent of drug absorption can be is modified

3. Frequency of drug administration is reduced.

4. Patient compliance can be improved.

5. Drug administration can be made convenient

6. Maximizing the availability of drug with minimum dose.

7. The safety margin of high potency drug can be increased.

He oral route administration is mostly adopted route because of its comfortable dosage form, design and patient care. Several parameters should be kept in mind before formulating sustain release dosage form which includes various pH in GIT, the gastrointestinal motility, the enzyme system and its effect on the dosage form and the drug. Most of sustained release dosage form follows the mechanism of diffusion, dissolution or combination of both, to produce slow release of drug at predetermined

rate. Hypothetically, a sustained release dosage form should release the drug by a zero-order mechanism which maintains drug plasma level time similar to intravenous infusion. [5,6,7]

2. Materials and methods

2.1 Materials

All materials procured were of pharmaceutical grade and good quality. The drug was procured from tirupati pharmaceuticals pvt. Ltd. Paonta sahib.

2.2 Methods

Standard curve of the drug was prepared in buffer 1.2, 7.4 and the beer lamberts range was established. Preformulation studies of the drug were also conducted including particle size, partition coefficient, solubility analysis. [8-11]

The formulations were prepared by optimizing the formulation blends and finally three ratios of polymers were selected. Three polymers were identified including HPMCK4M, Carbopol 934 and hydroxyl ethyl cellulose. The ratio was 1:1 between polymers and the drug using varying polymer combinations as given in table no.. the tablets were prepared by direct compression methods. [12-15]

The prepared formulations were evaluated for various parameters like hardness, weight variation, friability, content uniformity, disintegration time, in-vitro release and kinetics of release. [16-18]

Table No. 1 Formulation Composition

	Formulation code		
Ingredient/quantity	**A1**	**A2**	**A3**
Drug	100	100	100
MCC	50	50	50
HPMC K4M	50	-	50
Carbopol 934	-	50	50
Hydroxyl ethyl cellulose	50	50	-
Lactose	50	50	50
Talc	1	1	1
Magnesium stearate	2	2	2

Results and discussion

The results of the prepared formulations are given in table no:. the formulations showed optimum results with satisfactory release profile. The hardness was found to be in the range of 9.6-10.2kg/cm^2, weight variation in the range of 1.2-2.8% which was well within the official limits, content uniformity was found to be from 96.4% - 98.4% which was within the acceptance criteria for tablets. Friability was within the limit of 1%. The disintegration time showed that the tablets show good sustained release profile with in-vitro release showing t 80% data of more than 12 hours.

The release kinetics shows that the formulations follow zero order or higuchi kinetics with linear profile and also supercase II transport mechanism which suggests for swelling and erosion mechanism of srug release from the matrix tablets. [19-21]

Table No.2 Evaluation Parameters

Evaluation parameter	**Formulation code**		
	A1	A2	A3
Hardness (Kg/Cm^2)	9.6	9.4	10.2

Friability (%)	0.5	0.3	0.46
Weight Variation (%)	±1.3	±2.5	±2.8
Content Uniformity (%)	98.4%	96.4%	97.8%
Disintegration Time (Sec)	More than 2 hours	More than 2 hours	More than 2 hours
T 80% (Mins)	>12 hours	>12 hours	>12 hours

Figure No:1 Hardness Of Formulations

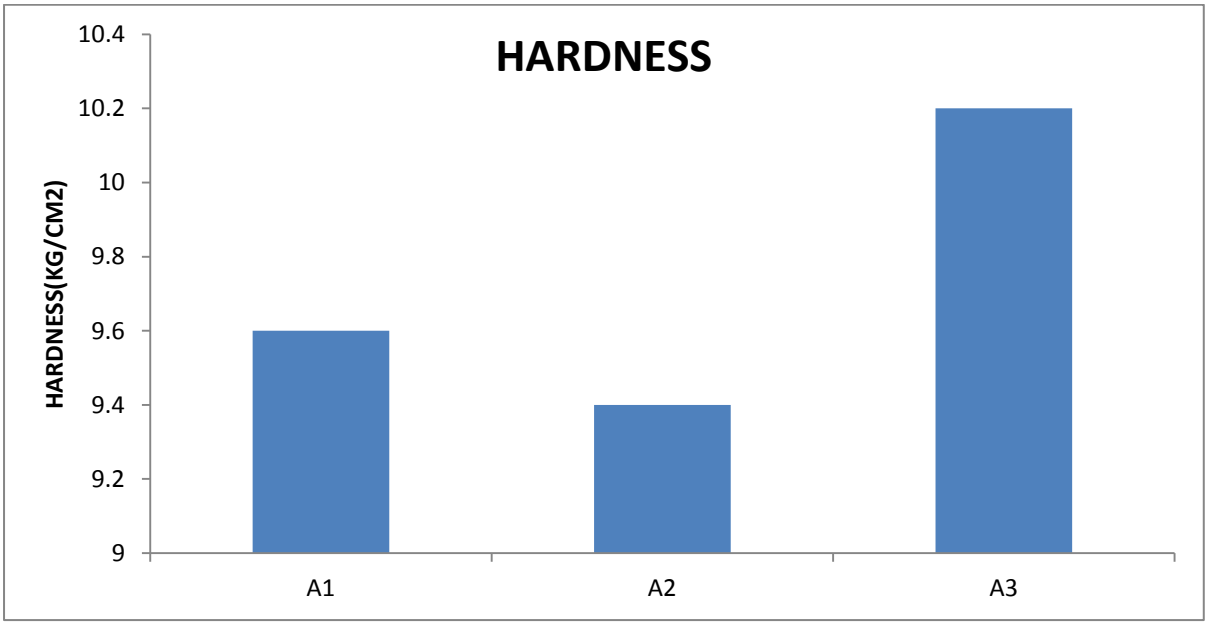

Figure No:2 % Weight Variation Of Formulations

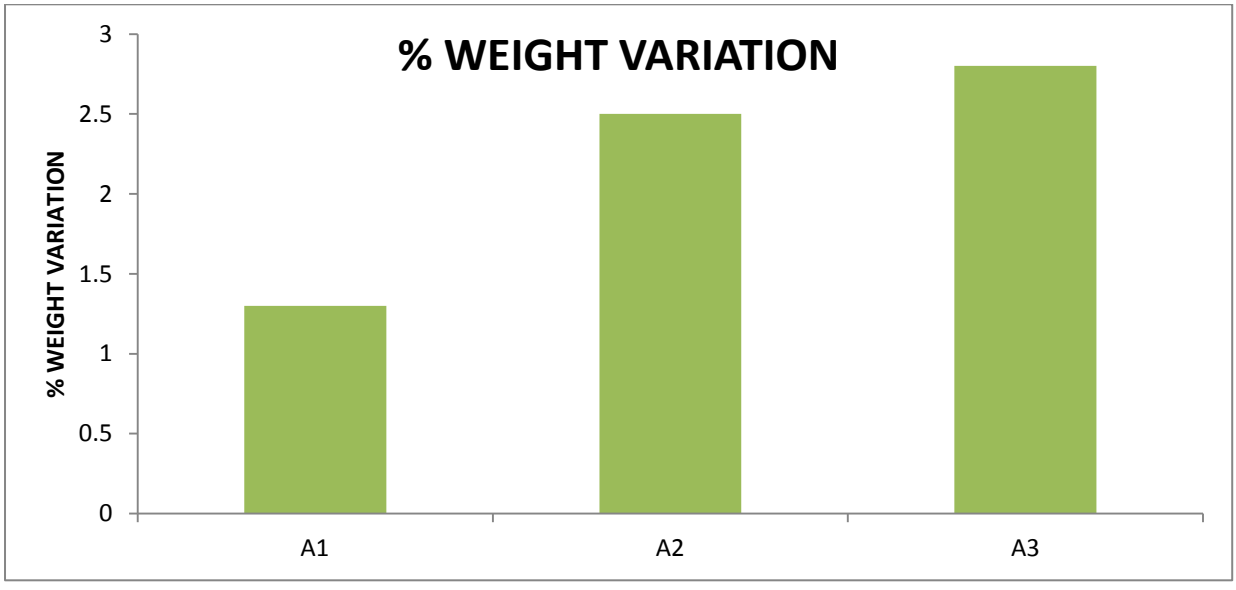

Figure No:3 % Content Uniformity Of Formulations

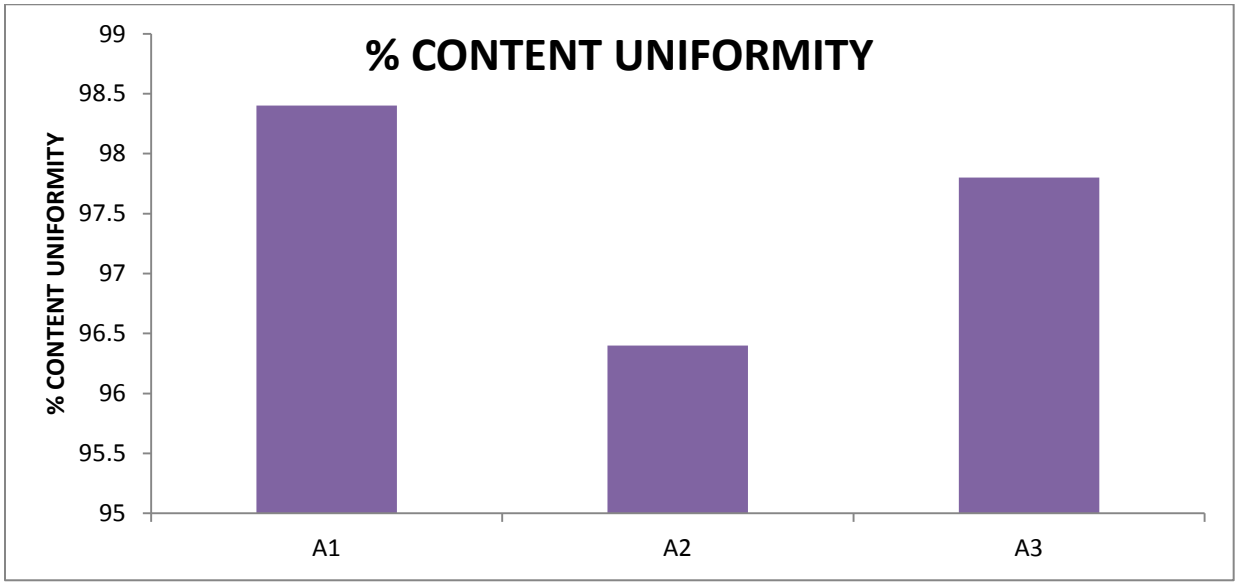

Figure No:4 % Friability Of Formulations

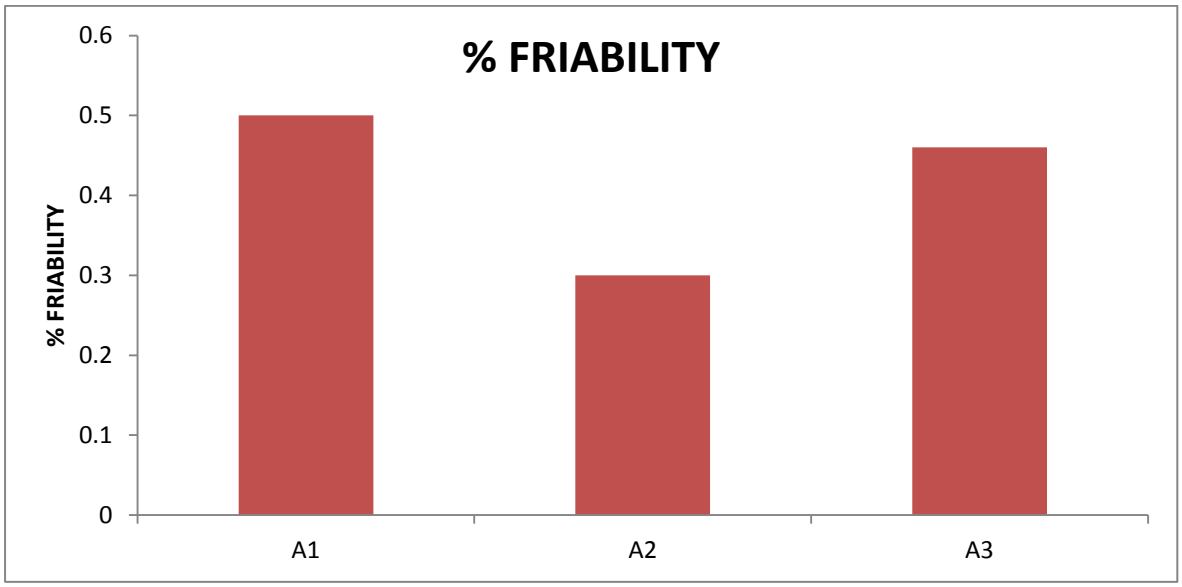

Figure no:5 % in-vitro drug release

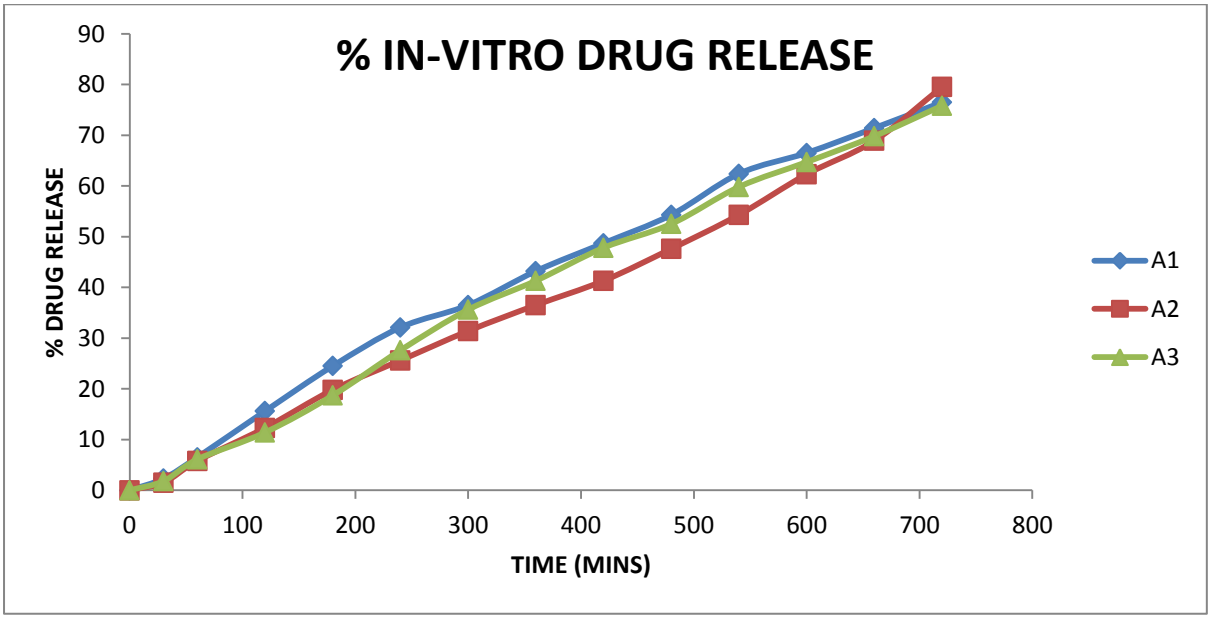

Table No. 3 Release Kinetics Of Formulations A1

Model Fitting	**R^2**	**k**
Zero order	0.9917	0.1077
1st order	0.9853	-0.0019
Higuchi Matrix	0.9350	9.2553
Peppas	0.9835	0.3396
Hix.Crow.	0.9962	0.0005
Parameters for		
Korsmeyer-Peppas Equation		
n =	1.0567	
k =	0.3396	
Best fit model=	Hixon-Crowell	
Mechanism of release▼		
Supercase II Transport		

Table No.4 Release Kinetics Of Formulations A2

Model Fitting	**R^2**	**k**
Zero order	0.9955	0.1057
1st order	0.9248	-0.0019
Higuchi Matrix	0.9266	9.1213
Peppas	0.9830	0.2555
Hix.Crow.	0.9608	0.0005
Parameters for		
Korsmeyer-Peppas Equation		
n =	1.1460	
k =	0.2555	
Best fit model=	Zero order	
Mechanism of release▼		
Supercase II Transport		

Table No. 5 Release Kinetics Of Formulations A3

Model Fitting	**R^2**	**k**
Zero order	0.9958	0.1082
1st order	0.9811	-0.0019
Higuchi Matrix	0.9376	9.1902
Peppas	0.9889	0.2708
Hix.Crow.	0.9941	0.0005
Parameters for		
Korsmeyer-Peppas		

Equation	
n =	1.1326
k =	0.2708
Best fit model=	Zero order
Mechanism of release▼	
Supercase II Transport	

Conclusion

The prepared formulations show good release profile with good evaluation parameters. The formulation need to be further optimized and evaluated to show even better results. The polymeric combinations selected are ideal for sustained release profile of many drugs and can be used as a set formula for formulating sustained and controlled release products. All formulation are found to be consistent, stable and within the acceptance criteria.

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