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Research Article

PREPARATION OF ORODISPERSIBLE TABLETS (ODT) OF ARIPIPRAZOLE WITH MICROCRYSTALLINE CELLULOSE BY MICRONIZATION

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A R T I C L E I N F O

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A B S T R A C T

Aripiprazole active substance is a white crystalline powder and is practically insoluble in water and its solubility is pH dependent. Therefore, a particle size effect on dissolution of the tablets can be expected. In order to ensure batch-to-batch consistency of the product, and to ensure adequate bioavailability, aripiprazole is subject to milling [7.] Though direct compression is the easiest way of preparing oral dispersible tablets but from the rheology study of the powder blend it was concluded that the blend (direct compression) B1 having no good flow property, which ultimately leads to nonuniformity of the drug in the compressed tablet. So as to enhance the flow property in the further study wet granulation technique was implemented in this research work. The dissolution (B2) concluded that the solubility,% release as well as bioavailability of the drug was enhanced up to a certain mark by means of the micronisation of the drug. So in the further study of this work, only micronised drug was used for better bioavailability. Solubility enhancement of aripiprazole ODT (B2) was resulted. Direct. Dissolution study of micronized formulation B2 concluded that the solubility, % release as well as bioavailability of the drug were enhanced up to a certain mark. So in the further study of this research work only micronized drug can be used for better bioavailability of prepared ODTs.

INTRODUCTION

Aripiprazole is a psychotropic drug that is available as ABILIFY® (aripiprazole) tablets, ABILIFY® DISCMELT™ (aripiprazole) orally disintegrating tablets, and in solution for Oral administration. Aripiprazole is 7-[4-[4-(2, 3-dichlorophenyl)-1-piperazinyl] butoxy] - 3, 4-dihydrocarbostyril. The empirical formula is C23H27Cl2N3O2 and its molecular Weight is 448.39[8]. It is postulated that Aripiprazle's mechanism of action is novel as it involves a combination of partial agonist action(agonist/antagonism) at dopamine D2 & serotonin 5-HT1A receptors and antagonism at serotonin 5-HT2A receptors[6]. Aripiprazole is a" quinolone" (carbostyril)" derivative atypical antipsychotic drug. It is well suited for the treatment of Schizophrenia because it affects both the positive & negative symptoms of schizophrenia. Aripiprazole is a BCS class-II drug i.e. the drug having low solubility & high permeability. This behaviour plays an important role or significantly affects its oral bioavailability. Aripiprazole active substance, is a white crystalline powder and is practically insoluble in water and its solubility is pH dependent. Therefore, a particle size effect on dissolution of the tablets can be expected. In order to ensure batch-to-batch consistency of the product, and to ensure adequate bioavailability, aripiprazole is subject to milling [7.] Direct compression *is* the easiest way of preparing oral dispersible tablets. In this process conventional equipment, commonly used excipients & limited number of steps are used, In this direct compression technique disintegration & solubilization of the dosage form depends upon the concentration of superdisintegrants & the applied compression force. With increase in the concentration of superdisintegrants the tablets disintegrates faster. To achieve a good disintegration properties a best possible superdisintegrant of optimum concentration was selected. Disintegration efficiency is based on force equivalent concept, which is the combined measurement of swelling force development and amount of water absorption. Force equivalent expresses the capability of disintegrant to transform absorbed water into swelling force. The optimisation of tablet disintegration was defined by means of disintegrant critical concentration. Below this concentration, the tablet disintegration time is inversely proportional to disintegrant concentration and above that disintegration time remains approximately constant or even increases. Bietal.[28] and Watanbe *et al*. [29] used microcrystalline cellulose (MCC) and low substituted hydroxyl propyl cellulose (HPC) to manufacture rapidly disintegrating tablets. The ratios of MCC to HPC varied from 8:2 to 9:1. Micronization involves the reduction of the size of the solid drug particle to 1 to 10 microns commonly by spray drying or by use of air jet mill. Surface area of drug particle is another parameter that influences drug dissolution, & in turn drug absorption. Small particles with greater surface area dissolves more rapidly than larger particles, even though both have the

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same intrinsic solubility. Particle size impacts a little influence on the absorption of drugs with high aqueous solubility, but it causes a pronounced effect on the absorption of drug with low aqueous solubility. **Hunter; Edward A *et al.,*** prepared directly compressed solid pharmaceutical dosage forms containing: a) acetaminophen, a direct compression vehicle comprising microcrystalline cellulose; and a pharmaceutically-acceptable lubricant. The acetaminophen and direct compression vehicle are combined under high shear conditions which are sufficient to transform acetaminophen and direct compression vehicle into a homogenous granulate without degradation[78] Schizophrenia is a major psychotic disorder. It's essential features consist of a mixture of characteristics signs and symptoms that have been present for a significant length of time during a 1-month period (or for a shorter time if successfully treated), with some signs of the disorder persisting for at least 6 months. Signs &Symptoms of schizophrenia includes two types of symptoms i.e positive, Negative

Positive symptoms tends to be exaggerated of normal functioning, while negative symptoms involves loss of normal functioning.& include blunted effect, reduced ability to related to others, lack of motivation, narrowing of ideation, poverty of speech[3]. The onset of Schizophrenia typically occurs during adolescence or early adulthood. It affects men & women with equal frequency. The illness is chronic & less then 20% of patients recover fully from a single episode of psychosis. Schizophrenia accounts for approximately 10% of all suicides .Now a days Schizophrenia is a growing disease in India also in the western countries. Generally an accountability of 20 % of the prescribed drugs belongs to antipsychotic, or anti depressant, etc [4]. The US Food and Drug Administration Center for Drug Evaluation and Research (CDER) defines in the Orange Book an ODT as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue" [10.] The European Pharmacopoeia however defines a similar term, orodisperse, as a tablet that can be placed in the mouth where it disperses rapidly before swallowing [11.] Recent market studies indicate that more than half of the patient population prefers ODTs to other dosage forms [12] and most consumers would ask their doctors for ODTs (70%), purchase ODTs (70%), or prefer ODTs to regular tablets or liquids (>80%) . At present, ODTs are the only quick-dissolving dosage form recognized by FDA and listed in Approved Drug Products with Therapeutic Equivalence Evaluations (also called the Orange Book) [13,14]. ODT products have been developed for numerous indications ranging from migraines (for which a rapid onset of action is important) to mental illness (for which patient compliance is important for treating chronic indications such as depression and schizophrenia) [13]An orally disintegrating tablets is a solid dosage form that contains medicinal substances & that rapidly disintegrates rapidly without water (within a fraction of seconds) when placed on the tongue, drug is released, dissolved, dispersed in saliva. Then the drug is swallowed & absorbed across the GIT. A quick dissolving tablet(also known as fast dissolving tablet, fast dissolving multiparticulate, rapid dissolving, mouth dissolving, fast melting, or orodispersing tablets)is an oral tablet that doesn't require water for swallowing. The tablet dissolves within 60 sec when placed in the mouth. The active ingredients are absorbed through the mucos membranes in the mouth & GIT & enter the blood stream. A fraction of pregastric drug absorption may bypass the digestive system & metabolism by the stomach acids & enzymes. Following the above advantages of fast dissolving dosage forms, are increasingly being recognized in both industry & academia which encourages of such formulation.

MATERIAL AND METHODS

Material

Aripiperazole I.P, cross caramellose sodium, magnesium stearate, ferric oxide red, aerosil, citric acid, MCC(C KG 802) was obtained as a gift sample from Matrix Laboratories Ltd. Hyderabad.,. All other chemicals and solvents were of analytical grade and used as received. Distilled water was prepared in laboratory using all glass distillation apparatus.

Methods

Preparation of orally disintegrating tablets of aripiprazole with microcrystalline cellulose by direct compression technique:

From the rheology study of the powder blend it was concluded that the blend (direct compression) having no good flow property, which ultimately leads to no nuniformity of the drug in the compressed tablet. So as to enhance the flow property in the further study wet granulation technique was implemented in this research work. Aripiprazole along with other ingredients were passed through suitable sieve. Microcrystalline cellulose & ferric oxide red were passed through suitable sieve & mixed to aripiperazole for 5 min in a poybag. Then the dry mix was lubricated properly by means of this Mg. stearate & aerosil passed through suitable sieve. Then the dry blend was mixed for 5 - 10 min & then compressed into tablet with the help of a cadmach rotary punch machine by using 7.8 mm flat faced bevelled edge punch with break line on one side. The tablets were evaluated for crushing strength, friability, DT. dissolution study etc., which also not up to the in-house specification. Particularly from the dissolution study & from the comparison of disso profile to the innovator product it clearly indicates that the drug having poor solubility & poor oral bioavailability, so to enhance the bioavailability of the concerned drug following measures were taken.

Particle size reduction or micronisation of the drug by air jet mill., Solid dispersion with suitable polymers (carriers) like PVP $K_{30,}$ PEG 4000 etc., Complexation with β-cyclodextrin.

Micronized batch (b2) preparation

Around 40 gm of pure API of aripiprazole was weighed &micronized by means of air jet mill at the rate of 2 Psi. Then the required amt. of micronized aripiprazole was taken & same procedure followed as per batch1.After the preparation of dry blend, binder solution was prepared by taking required amt.(2.625gm)of kolidone K30(binder) in a beaker containing 10-20 ml of isopropyl alcohol. A uniform binder solution was prepared by means of a magnetic stirrer. Then the dry blend was granulated by means of slowly adding the binder solution & thorough kneading, till the required granules were achieved. Then the wet granules were dried by means of a rapid dryer till L.O.D comes to below 1.Then the dried granules were sieved by using 30sieves (#). Then it was lubricated by means of aerosil & Mg.stearate & compressed into tablets. Then the compressed tablets were evaluated for different parameter

like, crushing strength, friability, disintegration time, and dissolution etc

Tablet Evaluation

Evaluation of lubricated blend

The lubricated blend was subjected to Angle of repose, Hausner's ratio, Carr's index by Fixed funnel method, Specification for Hausner Ratio, Specification for Carr's compressibility index specification respectively.

Crushing strength

A Crushing strength tester (Schleuniger Hardness tester–Dr Schleuniger, Pharmatron) was used to determine the load (N) required to diametrically break the tablets into two equal halves. The crushing strength of tablets was determined after compression. Tablets with sign of lamination or capping were not used.

Determinations were made in triplicate, and the mean values are reported with 5-7kp shown in **table:8** [10,12,15]

% Friability

The Crushing strength test may not be the best measure of the potential tablet behaviour during handling and packaging. The resistance to surface abrasion may be more relevant parameter in such cases. In some formulation when compressed into very hard tablets, tend to "cap" on attrition, losing their crown portions. So in that case tablet's strength can be measured by means of its friability and found in between 1.2 %. **(table: 3)** The percent friability of the tablets was determined using Roche friabilator operated at 25 revolutions per minute (RPM) for 4 minutes.[10,12,15] Twenty tablets tumbled in the friabilator after weighing them accurately. The tablets were then dedusting by soft muslin cloth and the loss in weight caused by facture or abrasion was recorded as percentage weight loss.

$$\text{Percentage Friability} = 100 \times \frac{\text{Loss in weight}}{\text{Initial weight}}$$

Disintegration Time

The time required for disintegration of six tablets , placed in each tube of disintegration test apparatus, was measured at 37 ± 2^{o} C using 900 ml distilled water recorded as 120 seconds for dry blend and 140 seconds for micronized batch.**(table:3). [9,10,12,15]**

Dissolution study

In vitro dissolution study of the tablet of the prepared batch B1 was conducted from which the % release & bio availability of the tablet can easily be predicted; also the dissolution study was compared with the dissolution study of the innovator product **(Fig 1,2,)**;. From the dissolution it was concluded that the solubility, % release as well as bioavailability of the drug was enhanced up to a certain mark by means of the micronisation of the drug **(Fig:3).** So in the further study of this thesis work only micronised drug was used for better bioavailability. Dissolution profile are shown in **fig 4,5,6** in graph for dry blend tablet, innovator's product and micronized tablet respectively.

Table-1 Formula for (B1)

Ingredient	Mg/Tab	% wt/wt	For 500 tab(gm)
Aripiprazole	10	6.67	5
Crosscarmelose sodium	14.5	10	7.25
MCC(C KG 802)	120.235	80.15	54.867
Mg.stearate	1.5	1	0.75
Aerosil	0.75	0.5	0.375
Citric acid	3.0	2.0	1.5
Ferric oxide(red)	0.015	0.01	0.0075

RESULT AND DISCUSSION

From the Rheology study of the powder blend it was concluded that the blend (direct compression) having no good flow property, which ultimately leads to no uniformity of the drug in the compressed tablet. So as to enhance the flow property in the further study wet granulation technique was implemented in this research work. Wet granulation technique was implemented due to following reasons eg. Poor flow property of the drug, Poor content uniformity of the drug in the compressed tablet.

Difference in particle size of dry blend & bulk density between the drug & diluents leads to stratification within the granulation. This stratification leads to poor content uniformity of the drug in the compressed tablet.The stratification & the resulted content uniformity problems are of special concern in case of this low dose drug.Also due to this dry nature of direct compression, static charges build up can occur on the drug during routine screening & mixing which may prevent uniform distribution of the drug in the granulation.

Then the compressed tablets were evaluated for different parameter like, crushing strength, friability, disintegration time, and dissolution etc, shown in **table:(2,3,4)** which also not up to the in-house specification. Particularly from the dissolution study & from the comparison of disso profile to the innovator product it clearly indicates that the drug having poor solubility & poor oral bioavailability, so to enhance the bioavailability of the concerned drug following measures could be taken like Particle size reduction or micronisation of the drug by air jet mill, Solid dispersion with suitable polymers (carriers) like PVP $K_{30,}$ PEG 4000, Complexation with β-cyclodextrin etc. In vitro dissolution study of the tablet of the prepared batch B1 was conducted from which the % release & bio availability of the tablet can easily be predicted; also the dissolution study was compared with the dissolution study of the innovator product. From the dissolution it was concluded that the solubility, % release as well as bioavailability of the drug was enhanced upto a certain mark by means of the micronisation of the drug. So in the further study of this thesis work only micronised drug was used for better bioavailability.

Table 2 evaluation for lubricated blend

Batch code	Angle of repose	Hausner's ratio	Carr's index
B1	45	1.6	35

Table 3 Evaluation for Tablet

Batch code	Hardness (kP)	Friability (%)	D.T(sec)
B1	5.9	1.2	120

Table 4 Dissolution Profile of Batch No-B (D.C WITH MCC)

STD abs	0.598	0.598	0.598
Factor	99	99	99

Dissolution Profile of Batch No-B!(D.C With MCC)

Time	**Absorbance**			**%RELEASE**			**AVg.**	**MIN.**	**MAX.**	**%RSD**
	UNIT -01	UNIT-02	UNIT-03	UNIT-01	UNIT-02	UNIT-03				
0	0	0	0	0	0	0	0	0	0	0
10 MIN	0.374	0.349	0.324	61.92	57.78	53.64	57.78	53.64	61.92	4.14
20 MIN	0.381	0.383	0.359	63.08	63.41	59.43	61.97	59.43	63.41	2.20
30 MIN	0.4	0.397	0.402	66.22	65.72	66.55	66.17	65.72	66.55	0.42
45 MIN	0.462	0.465	0.449	76.48	76.98	74.33	75.93	74.33	76.98	1.41
60 MIN	0.481	0.481	0.461	79.63	79.63	76.32	78.53	76.32	79.63	1.91

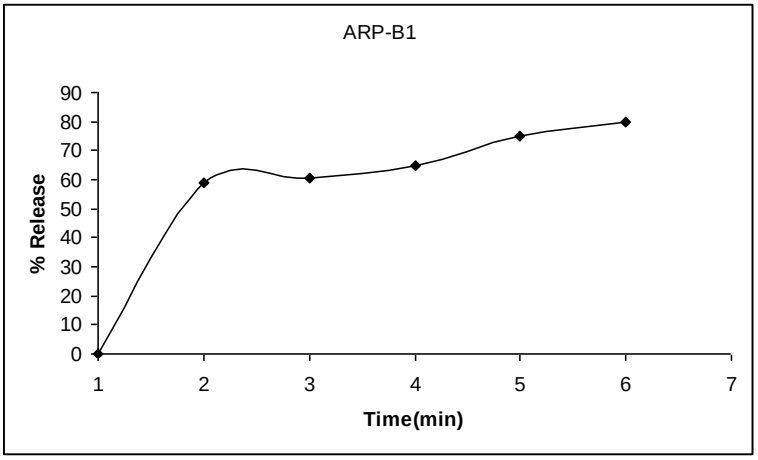


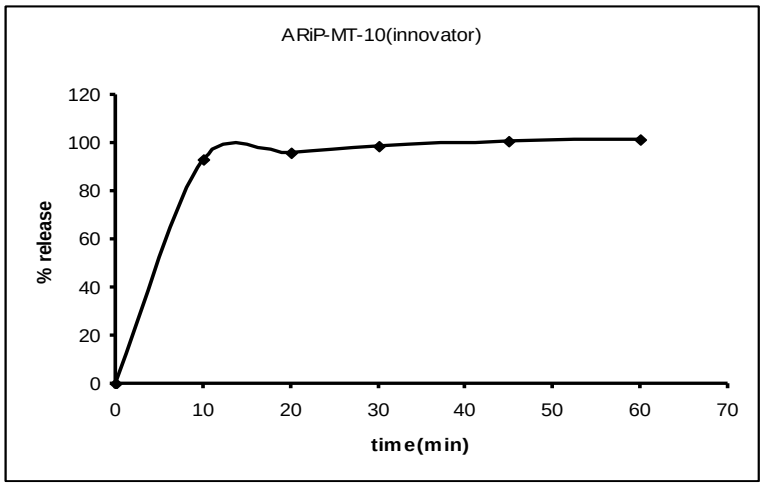
Figure 1 Graph For (B1)

Table 5 Dissolution profile of innovator product

STD abs	0.598	0.598	0.598
Factor	99	99	99

Dissolution Profile of -Innovator

Time	**Absorbance**			**%Release**			**AVg.**	**MIN.**	**MAX.**	**%RSD**
	UNIT -01	**UNIT-02**	**UNIT-03**	**UNIT-01**	**UNIT-02**	**UNIT03**				
0	0	0	0	0	0	0	0	0	0	0
10	0.561	0.556	0.568	92.87	92.05	94.03	92.98	92.05	94.03	1.00
20	0.572	0.578	0.581	94.70	95.69	96.19	95.52	94.70	96.19	0.86
30	0.588	0.601	0.595	97.34	99.50	98.50	98.45	97.34	99.50	0.72
45	0.602	0.605	0.612	99.66	100.16	101.32	100.38	99.66	101.32	0.55
60	0.609	0.612	0.618	100.82	101.32	102.31	101.48	100.82	102.31	0.48



(Innovator product)

Evaluation of micronized batch (B2)

Evaluation of Tablet

Batch code	Hardness (kP)	Friability (%)	D.T(sec)
B2	6.7	1.2	140

Table 6 Dissolution profile of batch B2

STD abs	0.598	0.598	0.598
Factor	99	99	99

Dissolution Profile of Batch No-Arp-Odt-B2(Micronized)

TIME	Absorbance			%Release			AVg.	MIN.	MAX.	%RSD
	UNIT -01	UNIT-02	UNIT-03	UNIT-01	UNIT-02	UNIT03				
0	0	0	0	0	0	0	0	0	0	0
10	0.533	0.528	0.506	88.24	87.41	83.77	86.47	83.77	88.24	2.25
20	0.529	0.499	0.574	87.58	82.61	95.03	88.41	82.61	95.03	6.21
30	0.543	0.567	0.569	89.89	93.87	94.20	92.65	89.89	94.2	2.18
45	0.539	0.575	0.576	89.23	95.19	95.36	93.26	89.23	95.36	3.12
60	0.562	0.581	0.575	93.04	96.19	95.19	94.80	93.04	96.19	1.58

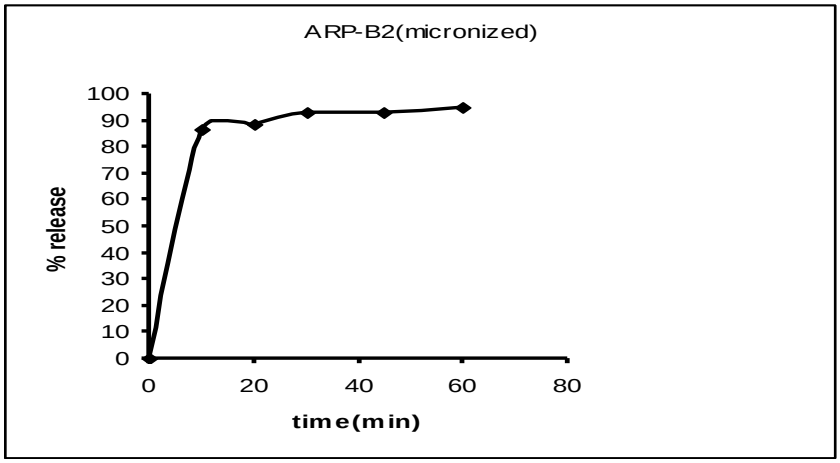


Figure 3 Graph For Arp Micronised Batch

CONCLUSION

The therapeutic effectiveness of a drug depends upon the ability of the dosage form to deliver the medicament to its site of action at a rate & amount to elicit the desired pharmacological response. The rate or rapidity with which a drug is absorbed is an important consideration in the treatment of acute condition like asthma. epilepsy, cardiac failure. pain. etc. Solubility of drug can be enhanced by various technique. In this research work the solubility of aripiprazole can be enhanced to the desired level

Future Prospects

Over the last decade, ODTs have grown steadily in demand & importance as a convenient, potentially safer alternative to conventional tablets & capsules.ODTs are more popular because of its greater patient compliance. With the rapid acceptance of ODTs by patient & pharmaceutical companies, the market for the dosage form is promising & the product pipeline continuous to grow rapidly. ODTs offer life-cycle management opportunities for pharmaceutical marketers. In contrast with other technologies, such as modified release & microencapsulation, ODT will continue to provide enhanced therapeutic& commercial benefits.

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