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DEVELOPMENT AMITRIPTYLINE FAST DISSOLVING TABLET BY USING ISAPGHULA HUSK SUPERDISINTEGRANT

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ABSTRACT

OBJECTIVE: - The effect of a natural superdisintegrant was compared to that of synthetic and conventional superdisintegrants in the Fast Dissolving tablet formulation of amitriptyline in the project study that is now being reported. The new dihydropyridine calcium antagonist amitriptyline has longer-lasting calcium antagonistic effects than nifedipine and nicotriptyline. Amitriptyline has been used to treat vascular diseases associated with hypertension as well as any form of hypertension. Amitriptyline is a BCS Class-II medicine with very low solubility and high permeability. It also consistently has very poor medication compliance. The solubility of the medication is directly correlated with the dissolution rate.

METHODS: In the current study, nine fast-dissolving amitriptyline tablet formulations made with natural superdisintegrants were assessed and compiled in accordance with the guidelines, requirements, and criteria set forth by the authorities. By adopting the direct compression method, three different types of superdisintegrants—Isapghula Husk, sodium starch glycolate, and Crospovidone sodium—with three concentrations (2%, 4%, and 6%) were used to generate various formulations.

RESULT:- Angle of repose, bulk density, tapped density, and other pre-compression parameters were assessed for the blend. Next, post-compression parameters such as thickness, drug content, hardness, weight variation, wetting time, friability, disintegration time, dissolution time, and drug release study were assessed for the tablet. In vitro dissolution experiments revealed that formulation ST8 had the lowest disintegration time and that, after three minutes, formulation ST had better drug release.

CONCLUSION: - The best formulations were also found to be stable and optimized formulations were subjected to the stability studies as per ICH guideline and standards.

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INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
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Vol 12,Issuse 2. June 2022

Keywords:-

Fast Dissolving tablet, Amitriptyline, Co-proceed, sodium starch glycolate, Natural, Isapghula Husk direct compression, dissolution time.

INTRODUCTION:-

Due to its exact drug dosage, compact size, ease of manufacture, and ease of self-administration, tablets are the most commonly used dosage form. One disadvantage of traditional tablets is that they might be difficult for elderly and pediatric patients to swallow.1, 2, The Fast Dissolving tablet is a unique medicine delivery mechanism that scientists have created to overcome these challenges. Fast dissolving tablets are those that, when combined with contact saline, dissolve in the mouth in a matter of seconds without the need for additional water. FDT offers three benefits: faster start of action, better patient acceptability, and improved bioavailability.3, 4, Amitriptyline is a new and different kind of calcium channel blocker called dihydropyridine that has a long-lasting, gradual dilation of the blood vessels. It belongs to the fourth generation of dihydropyridines (DHP).[5, 6,7,8,9]

MATERIAL AND METHOD:-

MATERIAL:-

Amitriptyline was a gift sample from Emcure Pharmaceuticals Pvt. Ltd. Pune, Isapghula Husk was gifted by Krishna Herbals , Delhi, Aspartame used was procured from Sweetener India, Delhi, and other reagents and chemicals used were of analytical grade.

METHOD:-

Amitriptyline fast-dissolving tablets were made using the direct compression technique. Excipients and pure API medication were passed through #60 No. mesh. For each formulation, the necessary amount of medication and excipients was taken in accordance with Table No. 1. Using a mortar and pestle, the powdered pure medication, mannitol, and lactose were thoroughly combined while triturating continuously. After adding the necessary amount of aspartame and super disintegrates to each recipe, and thoroughly mixing them, magnesium stearate and talc powder were added.10–12. The medication and excipient mixture was compacted using a tablet punching machine with seven stations. (Shakti Health Care) 4 mm of punch. For every intended formulation, a batch of 100 tablets of each formulation was made. Prior to the manufacture of the tablets, mix the mixture thoroughly.[13-15]

Pre-formulation studies:-

Angle of Repose (θ):

Angle of repose is the maximum possible angle between the surface of the pile of the powder and the horizontal plane of the powder. When more quantity powder is added to the pile, it slides down, until the mutual friction of the particles producing a surface angle θ, is equilibrium with the gravitational force.[15, 16, 17]

The angle of repose was determined by the funnel method suggested by the scientist Newman. Angle of repose is determined by the following formula

$\tan \theta = h/r$

$\theta = \tan^{-1} h/r$ Where θ = Angle of repose, r = Radius of the cone, h = height of the cone

Bulk Density:

INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
IJPAST

ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

Density is weight mass per unit volume. Bulk density is defined as the mass of the powder is divided by the bulk volume of powder and is expressed as gm/ cm^3.The bulk density of a powder primarily depends on its, particle shape, particle size, distribution and the tendency of particles to adhere together. There are two types of bulk density.[18-21]

Low bulk density

The particles are pack in such a way so as to leave large gaps between their surfaces resulting up in light powder of low bulk density.

High bulk density

Here the smaller particles shift between the large particles resulting in heavy powder of high bulk density

Tapped Density (DT):

It was the ratio of total mass of the powder to tapped volume of the powder. Volume was reported by tapping the powder for 500 times and the tapped volume was observed, if the difference between these two volumes was less than 2%. If it more than 2%, then tapping was continued for 750 times and tapped volume was noted. Tapping was continued until the difference between volumes was less than 2% in bulk density apparatus. It was expressed in g/ml and was given as following,

DT= M/Vt

Where, M is the mass of powder

Vt is the tapped volume of the powder. [22-24]

Carr's index (or) % compressibility:

Carr's index indicates powder flow properties. It is expressed by percentage and is given by:

I=DT−Db/DT×100

Where, DT denotes the tapped density of the powder

And Db is the bulk density of the powder. [25-28]

Hausner ratio:

Hausner ratio is an indirect index of ease of powder flow properties. It is calculated by the following formula:

Hausner ratio=Dt/Db

Where, Dt show the tapped density., Db is the bulk density.

Lower hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25)

EVALUATATION OF TABLET:-

All prepared tablets of Amitriptyline were evaluated for the following parameters as per IP guideline and standards for all the calculations are represented in the table No.3

WEIGHT VARIATION:-

Twenty tablets of Amitriptyline formulation were selected randomly from each of the formulation and weighted individually using Windsar Digital Balance for their weight variation data. The average weight of the tablets as well as percentage deviation was calculated.[29-31]

HARDNESS:-

Hardness of the Amitriptyline tablets were measured with Monsanto tablet hardness

INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
IJPAST
ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

tester for evaluation the hardness of the tablets.

THICKNESS:-

The thickness of the tablet was measured in mm by the Vernier Calipers for all the designed formulation batches.

FRIABILITY:-

The Friability of the Amitriptyline tablet by a sample of twenty tablets was measured using USP type Roche Friabilator. The tablets were dusted reweighed and percentage weight-loss was calculated.

%Friability= Initial Weight−Final Weight * 100/ Initial Weight

Water absorption ratio:

A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in small Petri-plate (ID = 6.5 cm) containing 10 ml of water. A tablet was placed on the paper and time for complete wetting of the tablet was measured in seconds. Three trials for each batch were performed and the standard deviation was also determined. The wetted tablet was weighed and water absorption ratio R, was determined by following equation

$$R = \{(Wa - Wb) / Wa\} \times 100$$

Where, Wa and W_b were weights of the tablets after and before study.[33-35]

Wetting Time

A piece of tissue paper (12cmX10.75cm) folded twice was placed in a small Petri dish (ID = 9 cm) containing 5ml pH 6.8 phosphate buffer, A tablet was placed on the paper and the time taken for complete wetting was observed. Three tablets from each formulation were randomly selected and the average wetting time was noted.

DISINTEGRATION STUDY:-

Disintegration time study was carried out by selecting 6 tablets of Amitriptyline and performed disintegration test (Lab India) using 900 ml distilled water at temperature ($37^0C \pm 2^0C$) [36-37]

DISSOLUTION STUDY:-

The In-vitro for the dissolution study was carried out in the USP (United state pharmacopeia) dissolution test apparatus type II known as Paddle dissolution apparatus, used phosphate buffer as dissolution medium as 900 ml containing PH 6.8 was taken in vessel and the temperature maintained at 37 ± 0.5^0C. The speed of the paddle was set at RPM 50, then 5 ml dissolution medium was withdrawn and the same amount (5ml) of fresh medium was replenished to the dissolution medium. The calculations of the Concentration were calculated by absorbance base. The release of the drug was performed in replicates of three.[38]

Table No. 1:- Formulation of Fast dissolving tablet of Amitriptyline:

Ingredients(mg)	ST1	ST2	ST3	ST4	ST5	ST6	ST7	ST8	ST9
Amitriptyline	20	20	20	20	20	20	20	20	20
Crosspovidone	2	4	6	-	-	-	-	-	-
SodiumStarch Glycolate	-	-	-	2	4	6	-	-	-

INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
IJPAST
ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

Isapghula Husk	-	-	-	-	-	-	2	4	6
Aspartame	2	2	2	2	2	2	2	2	2
Flavour	2	2	2	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Mannitol	40	40	40	40	40	40	40	40	40
Lactose	30	28	26	30	28	26	30	28	26
TOTAL	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**	**100**

Table No. 2:- Pre-compression parameters of Amitriptyline Fast Dissolving tablet

Parameters / **Formulation**	**Bulk Density (mg/ml)**	**Tapped Density (mg/ml)**	**Hausners Ratio**	**Compressibility Index (%)**	**Angle of Repose**
ST1	0.389± 0.01	0.514±0.02	1.32±0.02	24.31± 0.02	20.43± 0.02
ST2	0.395± 0.03	0.529±0.01	1.32±0.01	24.61± 0.01	20.66± 0.03
ST3	0.394± 0.02	0.513±0.03	1.30±0.02	23.19± 0.02	20.22± 0.01
ST4	0.402± 0.04	0.488±0.02	1.21±0.03	17.62± 0.01	21.86 ± 0.03
ST5	0.415± 0.09	0.491±0.03	1.18±0.01	15.47± 0.03	21.11 ± 0.02
ST6	0.421± 0.03	0.489± 0.04	1.16±0.01	13.90± 0.02	20.44 ± 0.01
ST7	0.388± 0.06	0.494± 0.01	1.27±0.01	21.45± 0.01	23.09± 0.02
ST8	0.391± 0.05	0.495± 0.03	1.26±0.04	21.01± 0.03	24.61± 0.01
ST9	0.393± 0.02	0.499± 0.04	1.26±0.01	21.24± 0.01	22.04± 0.02

Table No. 3:- Post-Compression parameters of Amitriptyline Fast Dissolving tablet:

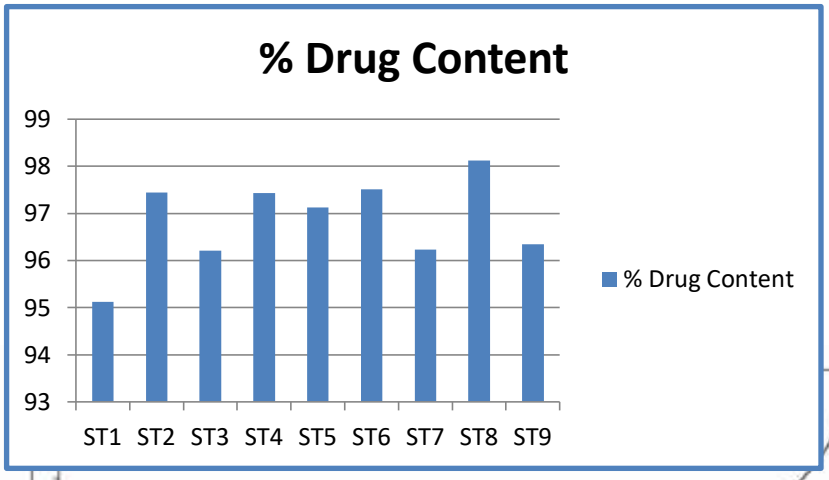
Parameters / **Formulation**	**Thickness (mm)**	**Weight (mg)**	**Hardness (Kg/cm^2)**	**Friability (%)**	**Disintegration Time (Sec)**	**Swelling Time (Sec)**
ST1	4	96.05±0.55	3.05±0.05	0.55±0.04	45±0.01	22±1
ST2	4	97.57±0.78	3.02±0.01	0.58±0.05	45±0.02	20±2
ST3	4	97.01±0.11	3.25±0.04	0.59±0.07	42±0.01	21±1

INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
IJPAST
ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

ST4	3	96.02±0.25	3.24±0.02	0.61±0.06	45±0.02	20±1
ST5	3	98.01±0.11	3.22±0.01	0.62±0.02	34±0.03	18±2
ST6	3	100.05±0.15	3.23±0.03	0.64±0.02	40±0.01	20±2
ST7	4	102.01±0.15	3.32±0.05	0.65±0.03	44±0.02	22±2
ST8	4	101.50±0.04	3.40±0.04	0.63±0.04	42±0.03	21±2
ST9	4	102.02±0.22	3.45±0.03	0.58±0.06	43±.0.04	22±1

Table No. 4:- Drug Content in the Fast Dissolving Tablet of Amitriptyline:

Parameters / **Formulation**	**Drug Content** (mg per Tablet)	**% Drug Content**
ST_1	95.12±0.015	95.12
ST_2	97.44±0.009	97.44
ST_3	96.21±0.015	96.21
ST_4	97.03±0.010	97.43
ST_5	97.12±0.025	97.12
ST_6	97.51±0.021	97.51
ST_7	96.23±0.018	96.23
ST_8	98.12±0.015	98.12
ST_9	96.35±0.012	96.35



INTERNATIONAL JOURNAL OF PURE AND APPLIED SCIENCE & TECHNOLOGY
IJPAST
ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

Figure.2: DSC Thermogram of Amitriptyline

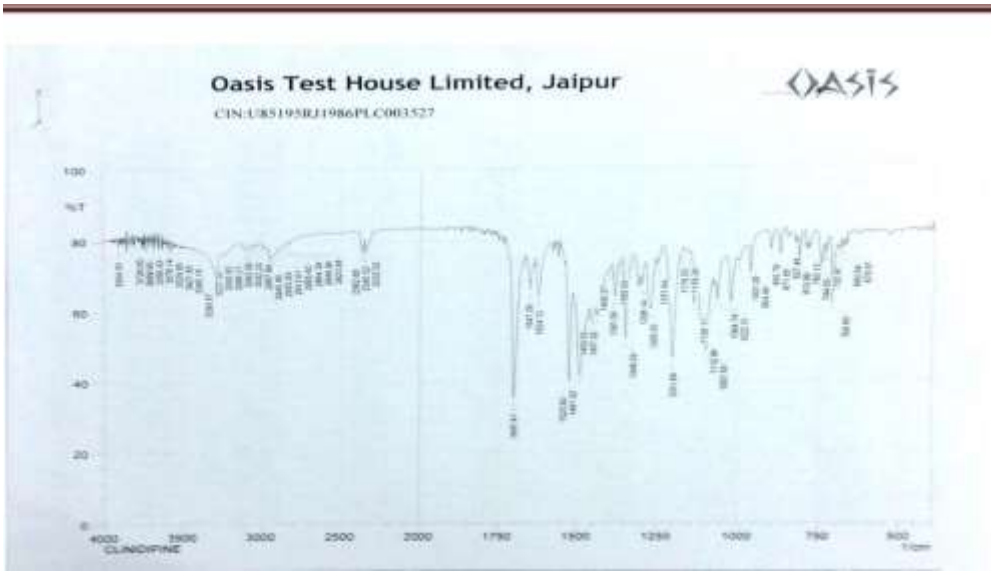


Figure.3: IR Spectra of Amitriptyline

RESULTS AND DISCUSSION:

Bulk Density and Tapped Density of the Blend were found in standard range as per IP guidelines. Carr's index of the prepared blend fall in the range of 13.90 to 24.61% and this is also supported by Hausner's factor values which were in the range of 1.16 to 1.32. Hence the prepared blends posses good flow property and can be used for manufacturing of the tablet. The values of angle of repose were found in the range of 20.22 to 24.61. The average weight of the Fast Dissolving tablet was 96.02 to 102.02 mg. Hardness of prepared tablet was between 3.02 to 3.45 kg/cm^2. The percent friability of formulations was found to be 0.55 to 0.65 and thus hardness and friability of all formulation are found within the standard acceptable limit.

The disintegration time is very important

ISSN 2229-6107
www.ijpast.in
Vol 12,Issuse 2. June 2022

and it is desired to be less than 1 minute. The quick disintegration may assist quick swallowing and drug absorption in buccal cavity, thus greater bioavailability of the drug. Disintegration time of prepared Fast Dissolving tablet was found in the range of 34 to 45 seconds. Swelling time is the indicator for the ease of disintegration of the tablet in the buccal cavity. It was observed that swelling time of tablet was in the range of 18 to 22 seconds. It was found that the nature of superdisintegrants present affected the swelling of the tablets. In Vitro dissolution study: In vitro dissolution study was performed by using Methanolic Sorenson's buffer pH 6.8 as dissolution medium using dissolution test apparatus LAB INDIA DS 8000 at a paddle speed of 50 rpm. At the end of 6 minutes the cumulative percentage drug release from various fast dissolving tablets was found in range 95.12% to 98.12%. This clearly indicates that when Superdisintegrants are used in combination than they provides better release than alone.

CONCLUSION:

It can be concluded from the whole study that Fast Dissolving tablets of Amitriptyline drug. Natural superdisintegrant can be used as pharmaceutical excipients for oral drug delivery. So natural superdisintegrant like Isapghula Husk exhibited faster drug dissolution which leads to improve bioavailability, effective therapy (Therapeutic ratio), improve patient compliance, and satisfies all the standards as Fast Dissolving tablet. It was concluded formulation ST8 maximum percentage drug release was found 98.12, with Natural superdisintegrant 4%.

From the study, it was concluded that Isapghula Husk superdisintegrant showed better disintegrating property over the synthetic super disintegrate like, SSG(Sodium starch glycolate) CP (Crospovidone).

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