

## FORMULATION, DEVELOPMENT AND EVALUATION OF AMOXICILLIN FAST DISSOLVING TABLETS

Mahmoud Mahyoob Alburyhi<sup>1\*</sup>, Abdalwali Ahmed Saif<sup>1</sup>, Maged Alwan Noman<sup>1</sup>, Abdulmalik Abudunia<sup>2</sup>, Shada Hassan Yassin<sup>3</sup> and Jalal H. Abdullah<sup>3</sup>

<sup>1</sup>Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

<sup>2</sup>Assistant Professor Dr. of Pharmaceutical Biotechnology, Department of Pharmacology, Faculty of Medicine and Health Sciences, Sana'a University, Sana'a, Yemen.

<sup>3</sup>Professor Dr. of Medicinal Chemistry and Drug Design, Department of Medicinal Chemistry, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.



\*Corresponding Author: Prof. Dr. Mahmoud Mahyoob Alburyhi

Professor Dr. of Pharmaceutics and Industrial Pharmacy, Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Sana'a University, Sana'a, Yemen.

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### ABSTRACT

The development of formulation and evaluation of Amoxicillin Trihydrate Fast Dissolving Tablets to improve the bioavailability of Amoxicillin Trihydrate. Amoxicillin Trihydrate is classified as a biopharmaceutics classification system (BCS) Class-I, Class-II and Class-IV Drug according to the dose. Amoxicillin is a hydrophilic drug, increase the solubility and permeability improve the bioavailability and onset of action of Amoxicillin Trihydrate has been done. The drug-excipient compatibility studies were conducted to characterize the drug Amoxicillin Trihydrate present in Fast Dissolving Tablets Delivery System FDTs. The objective of this study was to formulate Amoxicillin Fast Dissolving Tablets to ensure the release of the drug at the sites of its absorption, also to develop a patient-friendly Fast Dissolving Tablets of Amoxicillin to increase the patient's adherence and compliance to the therapy. Amoxicillin was prepared as a Fast-Dissolving Tablets in 500mg dose. Six formulae containing Amoxicillin Trihydrate and various excipients as mannitol, and MCC as diluents, and sodium starch glycolate, croscarmellose sodium, and crospovidone as superdisintegrants in different ratios. Then, each formula was evaluated for precompression parameters, then prepared by direct compression method. Finally, the compressed tablets of each formulation were evaluated for the post compression parameters. All the formulations showed satisfactory tablet properties. Among the 12 formulations the drug release of formulation F12 was found to be 94.78% at 2 minutes. Formulation F12 was the best formulation as it showed a drug release percentage was 94.78% at 2 minutes, due to rapid disintegration and fine dispersion of particles formed after disintegration within 30 seconds.

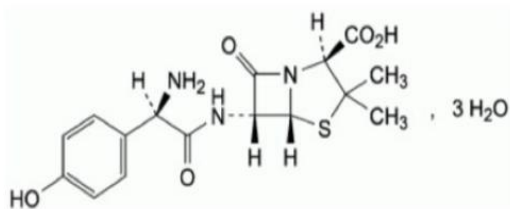
**KEYWORDS:** Amoxicillin Trihydrate, Fast dissolving tablets, Superdisintegrants, Antibiotics.

### INTRODUCTION

#### Drug Delivery System FDTs<sup>[1-170]</sup>

Oral administration is the most popular route due to ease of ingestion, pain avoidance, versatility to accommodate various types of drug candidates, and, most importantly, patient compliance. Also, solid oral delivery systems do not require sterile conditions and are, therefore, less expensive to manufacture. Several novel technologies for oral delivery have recently become available to address the physicochemical and pharmacokinetic characteristics of drugs, while improving patient compliance. Electrostatic drug deposition and coating. The most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in

swallowing, leading to patient in compliance particularly in case of pediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water. So, oral dispersible tablet can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention. Fast Dissolving Tablets are not only indicated for people who have swallowing difficulties, but also are ideal for active people.

**Amoxicillin Trihydrate<sup>[121]</sup>****Fig. 1: Chemical Structure of Amoxicillin Trihydrate.**

**Chemical Name of Amoxicillin Trihydrate:** (2S,5R,6R)-6-[[[(2R)-2-Amino-2-(4-hydroxyphenyl)acetyl]-amino]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate. As shown in Figure 1.

Amoxicillin is a penicillin-class, effective broad-spectrum antibiotic, which is commonly prescribed to children for treatment of pneumonia and other illnesses, including other bacterial infections of the ears, sinuses, throat, urinary tract, skin, abdomen, and blood.

**Therapeutic Indications:** WHO recommend oral amoxicillin as the first-line treatment for childhood fast-breathing and chest-indrawing pneumonia. Oral amoxicillin is also indicated for the treatment of the following infections in adults and children: Acute bacterial sinusitis, Acute otitis media, Acute streptococcal tonsillitis and pharyngitis, Acute exacerbations of chronic bronchitis, Community-acquired pneumonia, Acute cystitis, Asymptomatic bacteriuria in pregnancy, Acute pyelonephritis, Typhoid and paratyphoid fever, Dental abscess with spreading cellulitis, Prosthetic joint infections, Helicobacter pylori eradication, and Lyme disease. Oral amoxicillin is also indicated for the prophylaxis of endocarditis.

**Fast Dissolving Tablets FDTs<sup>[50-215]</sup>**

Fast Dissolving Tablets (FDTs) are solid dosage forms containing drugs that disintegrate in the oral cavity within less than 1 minute leaving an easy-to-swallow residue. The European Pharmacopeia adopted the term Fast Dissolving Tablets for a tablet that disperses or disintegrates within <3 minutes in the mouth before swallowing. FDTs is a good choice of drug delivery for pediatric and geriatric patients because it troubleshoots the problem of dysphagia.

In the pharmaceutical industry oral route is considered as the safest and convenient route. Fast Dissolving Tablets (FDTs) are solid dosage forms containing drugs that disintegrate in the oral cavity within less than 1 minute leaving an easy to swallow residue. These dosage form contains superdisintegrants which imparts quick disintegration with presence of saliva and can be swallowed easily. FDTs are the very good choice for the pediatric and geriatric patients. To improve the bioavailability of many drugs, Fast Dissolving drug delivery systems are used extensively. Advanced

technologies used for manufacturing Fast Dissolving Tablets are by direct compression method, freeze drying method, sublimation method, mass extrusion and cotton candy process. Taste is the important factor because these tablets disintegrate directly in the mouth. FDTs are evaluated by following parameters like hardness test, friability test, disintegration test and dissolution test.

Oral delivery is currently the gold standard in the pharmaceutical industry where it is regarded as the safest, most convenient and most economical method of drug delivery having the highest patient compliance. Formulation of a convenient dosage form for oral administration, by considering swallowing difficulty especially in case of geriatric and pediatric patient leads to poor patient compliance. To troubleshoot such problems a new dosage form known as orally disintegrating tablet (FDTs), has been developed which rapidly disintegrate & dissolve in saliva and then easily swallowed without need of water which is a major benefit over conventional dosage form. In addition, patients suffering from dysphasia, motion sickness, repeated emesis and mental disorders prefer such preparation because they cannot swallow large quantity of water. Further, drugs exhibiting satisfactory absorption from the oral mucosa or intended for immediate pharmacological action can be advantageously formulated in such type of dosage form. The popularity and usefulness of the formulation resulted in development of several FDT technologies for preparation.

Pharmaceutical Industry Scientists confirm that providing the drug in a fast drug delivery system helps achieve the effective goal of the drug more accurately and reduces the use of large doses. In addition to the patient acceptance of this drug in fast delivery systems, and thus innovating the formulation of medications in this drug delivery systems is considered one of the most important in developing the pharmaceutical industries.

In the present study, it was proposed to formulate Fast Dissolving Tablets FDTs of Amoxicillin Trihydrate by using direct compression technique method, with the aim of reaching high serum concentration of the drug in a short time period. In this study, effort has been made to formulations the Fast Dissolving Tablets using superdisintegrants like sodium starch glycolate, croscarmellose sodium and crospovidone.

**MATERIALS AND METHODS**

As shown in Table 1.

**Table 1: List of Materials Used.**

NO	Materials
1	Amoxicillin Trihydrate
2	Sodium Starch Glycolate
3	Microcrystalline Cellulose
4	Crospovidone
5	Croscarmellose Sodium
6	Magnesium Stearate
7	Talc
8	Aerosil
9	Sodium Saccharin
10	Mannitol
11	Dibasic Sodium Phosphate
12	Monobasic Potassium Phosphate (KH <sub>2</sub> PO <sub>4</sub> )
13	Calcium Carbonate
14	Orange Flavor
Most materials were a gift sample from (Shaphaco Pharmaceutical Industry Company-Yemen). While other materials were a gift sample from (Biopharm Pharmaceutical Industry Company-Yemen and Shiba Pharmaceutical Industry Company-Yemen).	

The equipment's used as shown in Table 2.

**Table 2: The Equipment's Used.**

No	Equipment's
1	UV/VIS Spectrophotometer
2	Friability Tester (CPD-300D)
3	Hardness Tester (YPD-200C)
4	Disintegration Tester (ERWEKA)
5	Digital Dissolution Tester (JASCO DT- 810)
6	Moisture Tester
7	Density Tester
8	pH Meter
9	Ultra-sonic
10	Accelerate Stability Study Chamber
11	Electronic Balance
12	Single Punch Tablet Machine

### Formulation and Evaluation of Amoxicillin Fast Dissolving Tablets<sup>[50-215]</sup>

#### Formulation of Amoxicillin Fast Dissolving Tablets

The Fast Dissolving Tablets that contained a selected solid dispersion were prepared by direct compression method using a single punch tablet machine to produce round tablets with a biconvex surface, tablets were 500mg in weight. 100 tablets were prepared for each formula batch. The formulations were developed by

using superdisintegrants. The superdisintegrants (crospovidone, sodium starch glycolate, and croscarmellose sodium) were used in varied concentrations to develop the formulations. All the ingredients of the 12 formulations are shown in Table 3. Each ingredient was passed through a sieve no.18 except mg stearate passed through sieve no.35, the ingredients were co-grounded in a glass pestle motor, then mixed geometrically. The prepared blends were evaluated for mass-volume relationship (bulk density, tapped density, hausner ratio, and compressibility index) and flow properties (Angle of Repose). The prepared blends were compressed using a tablet compression machine.

**Mixing and Compression Processes:** Mixing was performed geometrically, in which all excipients were accurately weighed then all of them with the exception of talc, aerosil, magnesium stearate and orange flavor, were blended with specified quantity of Amoxicillin for 15minutes, while the other excipients were blended for 5 minutes and added to the former excipients. Then each blend was subjected to powder properties examination and that will be shown in the evaluation of precompression parameters section. Finally, each mixture of each formula has been compressed directly into tablets using tablet compression machine to prepare tablets weighing 500mg.

**Table 3: Composition of Amoxicillin Formulations FDTs.**

Ingredients	Quantity Per Tablet (mg)												Percentage
	Formulation Code												
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	
Amoxicillin Trihydrate	250	250	250	250	250	250	250	250	250	250	250	250	50%
Croscarmellose Sodium	10	25	50	---	---	---	---	---	---	25	---	25	2-10%
Sodium Starch Glycolate	---	---	---	10	25	50	---	---	---	25	25	---	2-10%
Crospovidone	---	---	---	---	---	---	10	25	50	---	25	25	2-10%

MCC	154	139	114	154	139	114	154	139	114	114	114	114	18-25%
Mannitol	30	30	30	30	30	30	30	30	30	30	30	30	6%
Calcium Carbonate	25	25	25	25	25	25	25	25	25	25	25	25	5%
Saccharin Sodium	3	3	3	3	3	3	3	3	3	3	3	3	0.6%
Orange Flavor	20	20	20	20	20	20	20	20	20	20	20	20	4%
Talc	5	5	5	5	5	5	5	5	5	5	5	5	1%
Magnesium Stearate	5	5	5	5	5	5	5	5	5	5	5	5	1%
Aerosil	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	7.5	1.5%

### Pre-Compression Evaluation of The Powder

#### Micrometric Properties

##### Angle of Repose ( $\theta$ )

Angle of repose is defined as the maximum angle possible between the surface of a pile of the powder and horizontal plane. The frictional force in a loose powder or granules can be measured by angle of repose as shown in Table 4.

$$\tan \theta = h / r$$

$\theta = \tan^{-1} (h/r)$  Where,  $\theta$  is the angle of repose,  $h$  is the height of pile,  $r$  is the radius of the base of pile.

**Table 4: Relationship Between Angle of Repose and Flow Properties.**

Flow Property	Angle of Repose
Excellent	<25
Good	25-30
Passable	40-30
Very Poor	>40

#### Bulk Density

Bulk density is defined as the mass of a powder divided by the bulk volume. The bulk density of a powder depends primarily on particle size distribution, particle shape, and the tendency of the particles to adhere to one another.

$$\text{LBD} = \frac{\text{Weight of the powder (m)}}{\text{Volume of the packing (vo)}}$$

#### Tapped Density

The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume ( $V_t$ ) occupied in the cylinder and the weight ( $M$ ) of the blend was measured. The tapped density ( $\rho_t$ ) was calculated using the following formula:

$$\rho_t = M / V_t$$

#### Compressibility Index

The compressibility index of the granules was determined by Carr's compressibility index as shown in Table 5.

(%) Carr's Index can be calculated by using the following formula:

$$\text{Carr's Index (\%)} = \text{TBD} - \text{LBD} / \text{TBD} \times 100$$

#### Hausner Ratio

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

$$\text{Hausner ratio} = \rho_t / \rho_d$$

Where  $\rho_t$  is tapped density and  $\rho_d$  is bulk density. Lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).

**Table 5: Grading of the Powders for Their Flow Properties According to Carr's Index.**

Compressibility Index	Flow Properties
5-15	Excellent
12-16	Good
18-21	Fair to Passable
23-35	Poor
33-38	Very Poor
>40	Very Very Poor

#### Post Compression Parameters

##### Diameter Test

Diameter test is one of tests which used for determination of the tablets size, it is done by taking ten tablets randomly. Diameter may have obtained by using suitable micrometer.

##### Thickness Test

The thickness of the tablets was determined by using vernier calipers. Randomly 10 tablets selected were used for determination of thickness that expressed in Mean SD and unit is mm.

##### Hardness Test

Hardness of tablet is defined as the force applied across the diameter of the tablet in the order to break the tablet. The resistance of the tablet to chipping, abrasion or breakage under the condition of storage transformation and handling before usage depends on its hardness. The hardness of FDTs is generally kept lower than conventional tablets as increased hardness delays the disintegration of the tab. Hardness of tablets (randomly) from whole tablet batch was determined by Monsanto hardness tester. Hardness measured in  $\text{kg/cm}^2$ .

##### Weight Variation Test

The weight variation test is carried out in order to ensure uniformity in the weight of tablets in a batch. The total weight of 20 tablets randomly from whole batch was determined and the average was calculated. The individual weights of the tablets were also determined

accurately and allowed deviation rang was calculated from average weight. The tablets pass the USP test if no more than 2 tablets deviate from (average weight  $\pm$  allowed deviation) and if no tablet differs by more than 2 times the allowed deviation as shown in Table 6.

**Table 6: Limits According to U.S.P.**

Average Weight of Tablet	%Deviation
80mg or less	$\pm 10$
More than 80 mg but less than 250 mg	$\pm 7.5$
250 mg or more	$\pm 5$

### Friability Test

Friability test is the loss of weight of tablet in the container due to removal of fine particles from the surface during transportation or handling. Friabilator was employed for finding the friability of the tablets. For tablets with an average weight of 0.65 g or less take a sample of whole tablets corresponding to about 6.5 g and for tablets with an average weight of more than 0.65 g take a sample of 6 whole tablets. Friabilator is rotated at 25rpm for 4 minutes for 100rounds. The tablets were dedusted and weighed again. The percentage of weight loss was calculated using the formula:

$$\%f = \frac{W_0 - W_1}{W_0} \times 100$$

%f = Percentage friability

W<sub>0</sub> = Initial weight (before test)

W<sub>1</sub> = Final weight (after test)

% Friability of tablets less than 1% are considered acceptable.

### Disintegration Time Test

Disintegration time test is the process of breakdown of a tablet into smaller particles is called as disintegration. The USP device to rest disintegration was six glass tubes that are "3 long, open at the top, and held against 10" screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is

poisoned in 900ml beaker of distilled water at  $37 \pm 2^\circ\text{C}$ , such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of the beaker.

### In-Vitro Dissolution Studies

Dissolution Parameters: Apparatus: Dissolution tester (JASCO DT-810). Medium: 900 ml Phosphate buffer at (pH 6.8). RPM: 75. Temperature:  $37^\circ\text{C} \pm 0.5^\circ\text{C}$ . Sampling interval: 2,5,10, and 15 minutes. Sample withdrawn: 5 ml. Wavelength: 272.6 nm. Instrument: UV spectroscopy. Preparation of phosphate buffer at (PH 6.8): 0.896 g of NaOH and 6.804 g of KH<sub>2</sub>PO<sub>4</sub> dissolve in sufficient quantity of water, the volume was completed to 1000ml with distilled water and mix well by sonication.

Procedure: *In-vitro* dissolution studies of Amoxicillin Fast Dissolving Tablets perform using dissolution Tester (JASCO DT-810). The volume of dissolution medium phosphate buffer at (pH 6.8) using 900 ml and the temperature maintain at  $37^\circ\text{C} \pm 0.5^\circ\text{C}$ . The speed of the basket set at 75 rpm. One tablet place in each jar of dissolution apparatus. 5 ml of sample from each jar withdrawn at every 2,5,10, and 15 minutes then filter withdrawn samples. the same volume of phosphate buffer replaces to each dissolution jar, so that volume of dissolution medium maintains to 900 ml. The amount of Amoxicillin released from FDTs determine spectrophotometrically at 272.6nm nm using phosphate buffer as blank.

## RESULTS AND DISCUSSION

### Preformulation Tests of Powder

#### Micrometric Properties of Amoxicillin

The powder of Amoxicillin was evaluated for the following parameters such as angle of repose, bulk density, tapped density, compressibility index and Hausner ratio. The results are given in Tables 7 and 8.

**Table 7: Micrometric Properties of Amoxicillin.**

Formulation Code	App Wt	App Vol	Tapp Wt	Tapp Vol	App D	Tapp D	Voids	Porosity %	Bulkiness
F1	11.79	25	11.78	18.8	0.472	0.627	0.248	24.8	2.119
F2	4.83	19	4.82	12.6	0.254	0.383	0.337	33.7	3.937
F3	7.99	25	7.97	18.2	0.319	0.438	0.272	27.2	3.135
F4	5.54	13	5.53	9	0.426	0.614	0.307	30.7	2.347
F5	5.61	21.2	5.60	14.8	0.265	0.378	0.302	30.2	3.773
F6	13.29	25	13.26	19.6	0.532	0.677	0.216	21.6	1.879
F7	11.11	25	11.04	17.6	0.444	0.627	0.296	29.6	2.252
F8	11.81	25	11.79	18.2	0.472	0.648	0.272	27.2	2.119
F9	9.24	25	9.23	20.1	0.369	0.459	0.196	19.6	2.710
F10	9.73	25	9.72	19.8	0.389	0.491	0.208	20.8	2.571
F11	12.14	25	12.11	18.2	0.486	0.665	0.272	27.2	2.057
F12	8.47	25	8.46	19.4	0.338	0.436	0.224	22.4	2.959

The Angle of repose of Amoxicillin formulations range was found to be 18.2-23.32%, which indicated Passable –may hang up flow property. The bulk density range was

found to be 0.254-0.532 (g/ml), the tapped density range was found to be 0.378- 0.665(g/ml). The compressibility index range was found to be 19.61-33.68% which



indicates very, very poor flowability. The hausner ratio range was found to be 1.24 -1.51.

### Evaluation of Precompression Parameter

#### Micromeritic Properties

**Table 8: Evaluation of Precompression Parameters of Powder Blend.**

Formulation Code	Angle of Repose (°)	Compressibility Index (%)	Hausner Ratio	Evaluation of Angle of Repose	Powder Taste
F1	18.2	24.72	1.33	Passable	No Bitterness
F2	20	33.68	1.51	Passable	No Bitterness
F3	18.67	27.17	1.37	Passable	No Bitterness
F4	18.93	30.62	1.44	Passable	No Bitterness
F5	20.15	29.98	1.43	Passable	No Bitterness
F6	21	21.42	1.27	Passable	No Bitterness
F7	23.32	29.19	1.41	Passable	No Bitterness
F8	18.52	27.16	1.37	Passable	No Bitterness
F9	19.44	19.61	1.24	Good	No Bitterness
F10	19.39	20.77	1.26	Good	No Bitterness
F11	16.07	26.92	1.37	Passable	No Bitterness
F12	21.8	22.48	1.29	Passable	No Bitterness

The results in terms of micromeritics properties revealed that the flow property of formulations F9, F10 were good and other formulations were passable as shown in Table 8.

### Evaluation of Amoxicillin Fast Dissolving Tablets FDTs

#### Post Compression Parameters of Amoxicillin Fast Dissolving Tablets FDTs

The prepared tablets were evaluated for various post compression parameters. The results are presented in Tables 9 and 10.

**Table 9: Post Compression Thickness Results of Amoxicillin Fast Dissolving Tablets FDTs.**

NO	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Mean(X)	3.16	3.21	3.16	3.23	3.19	3.10	3.20	3.32	3.46	3.09	3.22	3.26
SD=X*5%	0.158	0.161	0.158	0.162	0.160	0.155	0.16	0.166	0.173	0.154	0.161	0.163
Lower Range	3.002	3.053	3.002	3.068	3.03	3.945	3.04	3.153	3.283	3.932	3.056	3.099
Higher Range	3.318	3.375	3.318	3.392	3.35	3.255	3.36	3.485	3.629	3.24	3.378	3.425

The diameter of the tablets was measured and found to be in the range of 13.03mm to 13.26mm. All formulations possessed a uniform Diameter. The hardness of the tablets was measured and the values were found in the range of 4.5 to 6.3Kg. The prepared tablets possessed good mechanical strength with sufficient hardness. The thickness of the tablets was measured and were found in the range of 3.09mm to 3.32mm, all the

formulations possessed uniform Thickness. The percentage of friability values of the prepared Amoxicillin Fast Dissolving Tablets showed less than 1%. All formulations of Amoxicillin Fast Dissolving Tablets passed the weight variation test since the values are within the acceptable variation limit of the tablet as shown in Table 10.

**Table 10: Post Compression Evaluation of Amoxicillin Fast Dissolving Tablets FDTs.**

Formulation Code	Average Weight (mg) ±SD	Thickness (mm)±SD	Mean Diameter (mm)	Friability%	Mean Hardness (kg/cm <sup>2</sup> )	In-Vitro Disintegration Time (Sec)
F1	505±25.3	3.16±0.158	13.04	0.1	6.3	72
F2	508±25.4	3.21±0.161	13.18	0.4	5.8	22
F3	512±25.6	3.16±0.158	13.18	0.3	5.4	18
F4	512±25.6	3.23±0.162	13.15	0.4	5.2	53
F5	508±25.4	3.19±0.160	13.18	0.4	5.3	36
F6	512±25.6	3.10±0.155	13.16	0.6	5.3	32
F7	509±25.5	3.20±0.16	13.03	0.4	5.3	29
F8	509±25.5	3.32±0.166	13.15	0.4	5.2	30
F9	518±25.9	3.46±0.173	13.26	0.5	5.1	36
F10	503±25.2	3.09±0.154	13.25	0.3	5.1	172

<b>F11</b>	512±25.6	3.22±0.161	13.18	0.4	5.1	47
<b>F12</b>	510±25.5	3.26±0.163	13.07	0.4	4.5	30

As shown in Table 10, the disintegration time of Amoxicillin Fast Dissolving Tablets ranges between 18 to 72 seconds. From the results, it was concluded that the formulation F2, F3 and F12 showed better tableting properties compared to the other formulations.

#### **In-Vitro Dissolution Studies**

The in vitro drug release of Amoxicillin FDTs were shown in Table 11.

**Table 11: Comparative In-Vitro Drug Release Studies of Formulations of Amoxicillin Fast Dissolving Tablets FDTs.**

Time (min)	Percentage Drug Release (%)												
	Formulation code												
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	Glumox
<b>2</b>	44.64	53.19	67.65	55.18	50.30	45.79	67.98	76.21	71.11	78.36	81.11	94.78	62.09
<b>5</b>	84.44	89.20	94.74	93.72	96.21	100.53	104.89	111.15	105.60	98.84	108.61	107.42	78.93
<b>10</b>	95.91	94.01	101.50	100.03	96.84	101.28	106.28	111.33	112.27	99.62	111.01	110.15	80.75
<b>15</b>	98.96	95.56	102.16	105.67	98.42	102.14	106.43	111.98	116.96	100.55	112.51	110.15	82.00

As shown in Table 11, Amoxicillin Fast Dissolving Tablets drug release was studied in phosphate buffer pH (6.8) for up to 15 minutes. The drug release of formulations F10, F11 and F12 were found to be 178.36%, 81.11% and 94.78% at 2 minutes. While Glumox was found to be 62.09% at 2 minutes. The highest dissolution rate and the maximum drug release was observed in formulation F12, which was 94.78% at 2 minutes, due to rapid disintegration and fine dispersion of particles formed after disintegration within 30 seconds.

#### **CONCLUSION**

Amoxicillin Trihydrate Fast Dissolving Tablets to improve the bioavailability FDTs have a major benefit over the conventional tablets due to their rapid disintegration and dispersion. Amoxicillin is a direct oral antibiotic that is used in the treatment of different infections. In order to ensure the drug release rapidly before reaching the proximal small intestine, and to increase the patient's adherence and compliance to the therapy a Fast Dissolving Tablets of Amoxicillin were formulated. A total of 12 formulations of Fast Dissolving Tablets of Amoxicillin were formulated by direct compression using mannitol, and MCC as diluents, and sodium starch glycolate, croscarmellose sodium, and crospovidone as superdisintegrants then evaluated. Among the 12 formulations the drug release of formulation F12 was found to be 94.78% at 2 minutes. formulation F12 was the best formulation as it showed a drug release percentage was 94.78% at 2 minutes, due to rapid disintegration and fine dispersion of particles formed after disintegration within 30 seconds.

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