

## The comparative study of natural and synthetic superdisintegrants in the formulation of fast dissolving tablets of amoxicillin trihydrates

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### Abstract

In the present study, the effects of a natural superdisintegrants, *Plantago ovata* and starch of *Solanum tuberosum* with synthetic superdisintegrants like sodium starch glycolate (SSG) and croscarmellose sodium were compared in the formulations of fast dissolving tablets (FDT). FDTs of Amoxicillin Trihydrate (model drug) were prepared by direct compression method using microcrystalline cellulose as it lends itself as direct compressible vehicle. So formulated tablets were evaluated for different test parameters viz., weight variation, hardness, disintegration time, drug content, friability, dissolution test etc. Swelling index was also investigated with an aim to compare all the factors like swelling property, *in-vitro* disintegration and dispersion time along with its *in-vitro* release rates for all the superdisintegrants. Hence, the present study revealed that this natural superdisintegrant (*Plantago ovata* mucilage) shows better disintegrating property than the most widely used synthetic superdisintegrants like SSG and Ac-Di-Sol in the formulations of FDTs.

**Keywords:** fast dissolving drug delivery, plantago ovata mucilage, swelling index, sodium starch glycolate, croscarmellose sodium

### 1. Introduction

Fast dissolving drug delivery is rapidly gaining acceptance as an important new drug delivery technology [1, 2]. These dosage forms dissolve or disintegrate in oral cavity within a minute even without the need of water or chewing. Usually, superdisintegrants are added to a drug formulation to facilitate the break-up or disintegration of tablet or capsule content into smaller particles that can dissolve more rapidly than in the absence of disintegrants [3, 4]. Many substances like microcrystalline cellulose (MCC), cross povidone [5], croscarmellose sodium (Ac-di-sol) [6], sodium starch glycolate (SSG) [7] have been used in the formulations of fast dissolving tablets (FDTs). Similarly, various natural substances viz. gum karaya, modified starch and agar have been used in the formulations of FDTs. Mucilage of natural origin is preferred over semi-synthetic and synthetic substances because they are comparatively economic, abundantly available, non-irritating and non-toxic in nature. Mucilage of *Plantago ovata* has various characteristics like binding, disintegrating and sustaining properties [8]. Hence, in the present study, mucilage of *Plantago ovata* was used to

develop FDTs of the selected model drug viz. Amoxicillin Trihydrate. The disintegration and swelling properties of FDT were compared with tablets formulated using other widely used superdisintegrants like SSG and Ac-Di-Sol. Amoxicillin Trihydrate, a beta-lactum antibiotic, was selected as the model drug as it was widely used as a first line treatment of mild to moderate infection of ENT (ear, nose and throat), respiratory tract, skin and genito-urinary tract. Amoxicillin is 80% absorbed by oral route with good efficacy, safety and limited adverse effect. The objective of the study was to choose the best superdisintegrant by comparative evaluation which gives a FDT of least disintegration time and reproducible drug release profiles.

### Materials and Methods

Amoxicillin Trihydrate was procured from commercial market. MCC, Aerosil-200, CCS were purchased from S.D. Fine Chemicals Ltd., Mumbai, Ispaghula husk, Sodium saccharin, SSG and magnesium stearate were obtained from chemical store, Department of pharmaceutical sciences, Kurukshetra University, Kurukshetra.

**Table 1:** Formulation of fast dissolving tablets of Amoxicillin Trihydrate

Ingredient(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13	F14	F15	F16
Drug	250	250	250	250	250	250	250	250	250	250	250	250	250	250	250	250
CCS	15	30	45	60	-	-	-	-	-	-	-	-	-	-	-	-
SSG	-	-	-	-	15	30	45	60	-	-	-	-	-	-	-	-
Ispaghula husk	-	-	-	-	-	-	-	-	15	30	45	60	-	-	-	-
Potato starch	-	-	-	-	-	-	-	-	-	-	-	-	15	30	45	60
MCC	317	302	287	272	317	302	287	272	317	302	287	272	317	302	287	272
Mg.stearate	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12	12
Aerosil-200	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3

Sod.Saccharin	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
Total Weight	600	600	600	600	600	600	600	600	600	600	600	600	600	600	600	600

### Preparation of Fast Dissolving Tablets

250.0 mg of Amoxicillin Trihydrate was accurately weighed and thoroughly mixed with one of the superdisintegrants *viz.* SSG, CCS, Ispaghula husk and Potato starch used in various concentrations to prepare sixteen (F1–F16) formulations. Microcrystalline cellulose was incorporated as diluent in each formulation to the above mixture, so that each formulation has a constant weight of 600 mg. 3 mg of sodium saccharin as sweetening agent, 12 mg of magnesium stearate and 3mg of aerosil-200 as lubricant was incorporated in each of the sixteen formulations (F1–F16) so that the final weight of each formulation could become 600 mg. Table 1 shows the composition of each tablet formulation developed for current investigations the resultant blend was directly compressed by using 13 mm flat punches and dies in a Mini Rotary 8-Station Tablet Punching Machine (Fluid Pack Machinery, Ahmadabad) A minimum of 50 tablets were prepared for each batch.

### Evaluation of Fast Dissolving Tablets

Quality Control tests for FDTs of all formulations were performed, and the average values were calculated. Weight variation was determined by weighing 20 tablets individually; the average weight and percent variation of each tablet was calculated. Hardness was determined by taking six tablets from each formulation, using a digital tablet hardness tester (Electrolab Ltd., India), and the average of applied pressure (kg/cm<sup>2</sup>) for crushing the tablet was determined. Friability was determined by first weighing 10 tablets after dusting and placing them in a friability tester (Electrolab Ltd.), which was rotated for 4 min at 25 rpm. After dusting, the total remaining mass of tablets was recorded and the percent friability was calculated. Disintegration test was performed using disintegration test apparatus (Electrolab Ltd.) using distilled water as medium.

### Prefomulation Studies

#### Fourier transform infra-red (FTIR) studies of Pure Drug and excipients

Various samples were subjected to FTIR spectroscopy in a Fourier-transform infrared spectrophotometer as KBr pellet. The FTIR spectra of pure amoxicillin trihydrate, SSG, croscarmellose sodium, ispaghula husk, potato starch and microcrystalline cellulose were recorded in KBr pellet using an FTIR spectrophotometer.

#### Preliminary studies of superdisintegrants

During preliminary studies of various superdisintegrants *viz.* CCS & SSG (synthetic), and ispaghula husk & potato starch (natural) were characterized on the basis of their swelling index value and chosen for formulating oral fast dissolving tablets of amoxicillin trihydrate in different ratios.

#### Determination of Swelling Index

Swelling index which represent the volume in mL occupied by the swelling of 1 gm plant material, under specified conditions. Swelling index value of all the superdisintegrants *viz.* CCS, SSG, potato starch and ispaghula husk were determined. For this an accurately weighed 1 gm of the disintegrant under study was transferred into 25 mL glass

Stopper measuring cylinder. To this 25 mL of water was added and the mixture was shaken thoroughly after every 10 min for 1 hour. Then it was allowed to stand for 3 hrs at room temperature, and the volume in mL occupied by the superdisintegrants was measured <sup>[9]</sup>.

### Micromeritic Studies

Blends of all the formulations (F1-F16) were studied in terms of following parameters. The powder blend was evaluated for flow properties as follows:

#### Angle of Repose

Flow properties of the blend were evaluated by determining the angle of repose and the compressibility index. Static angle of repose was measured according to the fixed funnel and free standing core method of Banker and Anderson. A funnel with the end of the stem cut perpendicular to the axis of symmetry is secured with its top at a given height of 1 cm denoted by h, above a graph paper placed on a flat horizontal surface <sup>[10]</sup>. The powder was carefully poured through the funnel until the apex of the conical pile so formed just reached the tip of the funnel. Thus, with r being the radius of the base of the blend conical pile and the angle of repose ( $\theta$ ) was calculated by using the eqn.1.

$$\tan \theta = h/r \quad \dots (1)$$

#### Bulk density and Tapped density

Both loose bulk density (LBD) and tapped bulk density (TBD) were determined by using tap density tester. A suitable amount of granules from each formulation, previously lightly shaken to break any agglomerates formed, was introduced into a 100mL measuring cylinder. After observing its initial volume, the cylinder was allowed to tap on to a hard surface from a height of 2.5 cm at 2 seconds intervals. The tapping was continued until no further change in volume was noted. LBD and TBD were calculated using the following formula.

$$\text{LBD} = \text{weight of the powder} / \text{volume of the packing} \dots (2)$$

$$\text{TBD} = \text{weight of the powder} / \text{tapped volume of the packing} \quad \dots (3)$$

#### Compressibility Index <sup>[11]</sup>

Compressibility index of the powder was determined by Carr's compressibility index as given by following eqn. (4)

$$\text{Carr's index (\%)} = [(TBD - LBD) \times 100] / TBD \quad \dots (4)$$

#### Hausner's ratio

It is the ratio of tapped to bulk density was calculated by using the eqn.<sup>3</sup>

$$\text{Hausner's ratio} = TBD / LBD \quad \dots (5)$$

### Evaluation Parameters of Fast Dissolving Tablets

The prepared tablets were evaluated for quality control tests like hardness, thickness, friability and drug content uniformity, weight variation, *In vitro* dissolution studies and analyses of dissolution profiles was performed.

## Physical Parameters and content uniformity

### Tablet hardness

Hardness of a 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 condition of storage transformation and handling before usage depends on its hardness. The hardness of prepared tablets was determined for 10 tablets from each batch by using Pfizer tablet hardness tester.

### Friability

Friability test was done with the help of Roche's friabilator. Ten tablets were weighed and were subjected to combined effect of attrition and shock by utilizing a plastic chamber that revolves at 25 rpm for 4 minutes. The tablets were reweighed after removal of the fine particles using mesh size of 60. The percentage friability was calculated by using the formula:

$$\% \text{ friability} = (\text{Loss in weight} / \text{Initial weight}) \times 100$$

### Uniformity of weight

I.P. procedure for uniformity of weight was followed, twenty tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight<sup>[12]</sup>.

### Thickness

Six tablets were examined for their thickness using Vernier calipers and the mean thickness value was calculated.

### Uniformity of Content

Twenty tablets selected randomly from each batch were weighed and powdered in mortar using pestle. The powdered tablet equivalent to 250mg drug in one tablet was taken and transferred in to a 50 mL volumetric flask and to this 25 mL of citro phosphate buffer pH 7.2 was added, sonicated for 10 minutes, shaken thoroughly for 15 minutes and then made the volume with citro phosphate buffer pH 7.2. Filtered and further dilutions were made. The absorbance of these solutions was measured at 231 nm against solvent blank. The concentration of amoxicillin trihydrate in solution was estimated from the standard curve of amoxicillin trihydrate at 273 nm.

## In-Vitro Disintegration and Dissolution studies

### In-vitro Disintegration time

Six tablets of each formulation were used to determine disintegration time. Phosphate buffer pH 6.8 was used as a disintegration medium and temperature was maintained at 37±0.5°C

### In-vitro dissolution studies

Dissolution studies were conducted to determine the release pattern of the product. Dissolution test for amoxicillin trihydrate was carried out as per USP method for dissolution test for amoxicillin tablets and capsules using apparatus-II. Dissolution medium used was 900 ml of phosphate buffer 6.8 pH. The temperature was maintained at 37.5°C and the speed of paddle was set at 50 rpm. An aliquot of 10 mL of sample was withdrawn and filtered promptly through a filter paper. The Absorbance of the resulting solution was measured at the maximum of 273 nm. Concentration of amoxicillin trihydrate was calculated from the calibration curve of amoxicillin trihydrate in phosphate buffer 6.8 pH.

### In- vitro dispersion time

*In vitro* dispersion time is the time required for complete dispersion of tablet when it is dropped in a beaker containing 50 mL of phosphate buffer pH 6.8. *In vitro* dispersion time was measured by dropping a tablet in a beaker containing 50 mL of phosphate buffer pH 6.8. Three tablets from each formulation were randomly selected and *in vitro* dispersion time was performed.

### Wetting time and water absorption ratio

Wetting time and water absorption ratio for each formulation (F1-F16) were determined. For determination of Wetting time and water absorption ratio a piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID = 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each formulation were carried out and the standard deviation was also determined. For measuring water absorption ratio the weight of the tablet before keeping in the petridish is noted (Wb), the wetted tablet from the petridish is taken and reweighed (Wa). The water absorption ratio, R was determined according to the following equation<sup>[3]</sup>

$$R = 100 (Wa - Wb) / Wb \dots (10)$$

### Comparison with Marketed Formulation

Comparative dissolution study of amoxicillin trihydrate tablets containing different disintegrants with marketed formulation was carried out. *In-vitro* dissolution studies of the marketed tablets (Moxilium250, Biochem.) of amoxicillin trihydrate were carried out under similar conditions as that were used for studying dissolution profiles of formulations F1-F16.

## Results and Discussion

The current study was undertaken to compare the oral fast dissolving tablets of amoxicillin trihydrate by using natural and synthetic superdisintegrant swelling index of disintegrants *viz.* SSG, CCS, ispaghula husk and potato starch in various solvents like water, 0.1NHCl and Phosphate buffer (pH 6.8).

**Swelling index:** The mean swelling index values for tablets containing CCS were found to be 77.05±0.21, 73.41± 1.00 and 71.35±1.32 in water, 0.1NHCl and Phosphate buffer (pH 6.8) respectively. These values for same vehicles in same order were 58.58±0.75, 55.65±0.60 and 54.44±0.79 in case when SSG was incorporated in tablets. Tablets made using Ispaghula Husk showed these values to be 87.13±0.37, 84.25±0.58 and 83.18 ±0.55 in these vehicles. The potato starch showed lowest values *i.e.* 9.10±0.33, 4.76±0.18 and 4.76±0.18

From the results we could arrive at an opinion that ispaghula husk has the highest swelling index value in all the solvents *viz.* water (87.13), 0.1 N HCL (84.25) and phosphate buffer pH 6.8 (83.18) and hence it could had strong opinion in its favor to act as potential superdisintegrant for the development of fast dissolving tablets of Amoxicillin trihydrate.

**Angle of repose:** The angle of repose of pre-compressed blends of amoxicillin Trihydrate was in the range 26.75° to 30.02°, indicating that the studied blends could have excellent flow properties because for a formulation to have good flow properties,  $\theta$  should be  $\leq 30^\circ$ .

**Loose bulk density (LBD) and tapped bulk density (TBD):** The LBD and TBD for all the formulations ranged from 0.429 to 0.444 and 0.492 to 0.511 respectively, thus supporting data was obtained.

**Compressibility Index (%):** It ranged from 10.56 to 15.38 for all the formulations. These results obtained were in agreement with the desired value of compressibility index (5-15), which are obvious for a formulation to possess so as to declare it having good compressibility index. Therefore, all the formulations studied (F1-F16) exhibited good compressibility index.

**The Hausner's ratio:** The Hausner's ratios of pre-compressed blends of amoxicillin trihydrate were in the range of 1.120 to 1.183, indicating that the studied blends have good flow properties because for a formulation to have good flow properties the Hausner's ratio value should be  $\leq 1.25$ . All the tablet formulations (F1-F16) were evaluated in terms of various parameters *viz.* Hardness, % friability, weight variation, Uniformity of drug Content, thickness, disintegration time, *In vitro* dispersion time, wetting time and water absorption ratio. *In vitro* dissolution studies and analysis of dissolution data, includes the values (Mean  $\pm$  S.D) of all the parameters of F1-F16 tablet formulations prepared.

**Tablet weight:** The mean Tablet weight was in the range of 597.6 to 603.6 mg.

**Friability:** The mean values for Friability were found to be between 0.19% to 0.31%.

**Hardness:** The average Hardness values for all batches of tablet formulations were found to be in the range of 4.23 to 4.58 Kg/cm<sup>2</sup> lending itself for acceptance criteria.

**Thickness of tablets:** The average values for Thickness of tablets were found to be between 4.785 to 4.858 mm.

**Uniformity of drug content:** The mean values of Uniformity of drug content were found to lie in the range of 96.60% to 99.36%.

Thus, all the physical parameters of the manually compressed tablets were quite within control limits.

#### The disintegration time and *in vitro* dispersion time

The disintegration time and *in vitro* dispersion time values obtained from various formulations F1-F16. Disintegration

time was found to be in range of 13.26 to 61.00 sec., *In vitro* dispersion time was found to be in range of 16.00 to 70.33 sec. In case of formulation F1-F4 i.e. having SSG as superdisintegrant, disintegration time as well as *in vitro* dispersion time decrease with increasing concentration of SSG (F1-F3) with the exception of F4 where, in disintegration time was suddenly enhanced. The usual concentration employed in a formulation was between 2% and 8% with the optimum concentration about 4%. This indicated that SSG as superdisintegrant should not to be used in higher concentration to formulate amoxicillin trihydrate fast dissolving tablets. In case of formulation F5-F8 in which CCS was used in concentration of 5-10%, no significant differences were achieved in disintegration time as well as *in vitro* dispersion time. It also indicated that CCS could be used in lower concentration. Likewise in case of formulation F11 & F12 in which ispaghula husk was used in concentration of 7.5 and 10% and similarly in formulation F15 & F16 in which potato starch was also used in concentration of 7.5% and 10% showed almost similar results which indicated us that ispaghula husk and potato starch can be incorporated as superdisintegrants up to a concentration of 7.5 %.

The Wetting time was found to be in the range of 21.00 to 153.00 sec.

**Water absorption ratio** was found to be in the range of 79.33 to 199.53% sec. In case of formulation F1-F4 i.e. having SSG as superdisintegrant, wetting time value decreased and water absorption ratio value increased with increased concentration of SSG (F1-F3) with the exception of F4 where, in wetting time was suddenly enhanced and in water absorption ratio value suddenly reduced. This indicated that SSG as superdisintegrant should not to be used in higher concentrations to formulate amoxicillin trihydrate fast dissolving tablets. In case of formulation F7-F8 made from CCS no significant difference in wetting time and water absorption ratio has been observed when CCS was used from 7.5-10%. Likewise with natural disintegrant i.e. ispaghula husk and potato starch showed almost similar results indicating that ispaghula husk and potato starch as superdisintegrants could be used individually up to concentration of 7.5%.

**Table 2:** Disintegration time and *in vitro* dispersion time

Formulation code	Avg. disintegration Time (sec), ( $\pm$ SD) n=6	Avg. <i>In vitro</i> dispersion time (sec), ( $\pm$ SD) N=3
F1	61.00 $\pm$ 1.55	70.33 $\pm$ 4.02
F2	53.75 $\pm$ 2.15	62.33 $\pm$ 2.05
F3	50.66 $\pm$ 1.88	57.00 $\pm$ 0.81
F4	57.40 $\pm$ 1.89	61.00 $\pm$ 1.63
F5	19.41 $\pm$ 1.15	22.00 $\pm$ 0.816
F6	16.75 $\pm$ 1.27	20.66 $\pm$ 0.47
F7	14.43 $\pm$ 0.62	18.33 $\pm$ 1.24
F8	13.26 $\pm$ 0.57	16.00 $\pm$ 0.81
F9	23.48 $\pm$ 2.85	30.00 $\pm$ 0.81
F10	20.13 $\pm$ 1.44	22.66 $\pm$ 2.05
F11	19.48 $\pm$ 1.54	22.66 $\pm$ 1.24
F12	16.88 $\pm$ 2.09	17.33 $\pm$ 1.24
F13	22.51 $\pm$ 2.09	22.66 $\pm$ 1.69
F14	19.16 $\pm$ 1.37	20.66 $\pm$ 1.24
F15	15.83 $\pm$ 0.47	18.66 $\pm$ 1.24
F16	15.33 $\pm$ 0.94	17.33 $\pm$ 1.24

**Table 3:** Wetting time and water absorption ratio

Formulation code	Avg. wetting time (sec), ( $\pm$ SD)	Avg. Water absorption, ( $\pm$ SD)
	n=3	n=3
F1	153.00 $\pm$ 2.16	120.83 $\pm$ 0.62
F2	130.66 $\pm$ 2.49	131.80 $\pm$ 0.21
F3	102.00 $\pm$ 2.49	144.6 $\pm$ 0.71
F4	135.00 $\pm$ 0.81	130.26 $\pm$ 0.75
F5	67.66 $\pm$ 2.05	153.7 $\pm$ 0.35
F6	40.00 $\pm$ 2.45	166.86 $\pm$ 0.98
F7	28.00 $\pm$ 0.81	186.20 $\pm$ 0.57
F8	21.00 $\pm$ 1.63	199.53 $\pm$ 1.04
F9	118.00 $\pm$ 2.16	134.73 $\pm$ 0.70
F10	92.00 $\pm$ 2.16	155.66 $\pm$ 0.49
F11	83.66 $\pm$ 3.09	166.16 $\pm$ 0.65
F12	71.00 $\pm$ 3.74	170.26 $\pm$ 0.83
F13	109.00 $\pm$ 0.29	79.33 $\pm$ 0.30
F14	97.00 $\pm$ 2.16	84.26 $\pm$ 0.57
F15	81.00 $\pm$ 2.16	90.43 $\pm$ 0.77
F16	71.33 $\pm$ 2.05	95.03 $\pm$ 0.75

### In-Vitro Dissolution studies

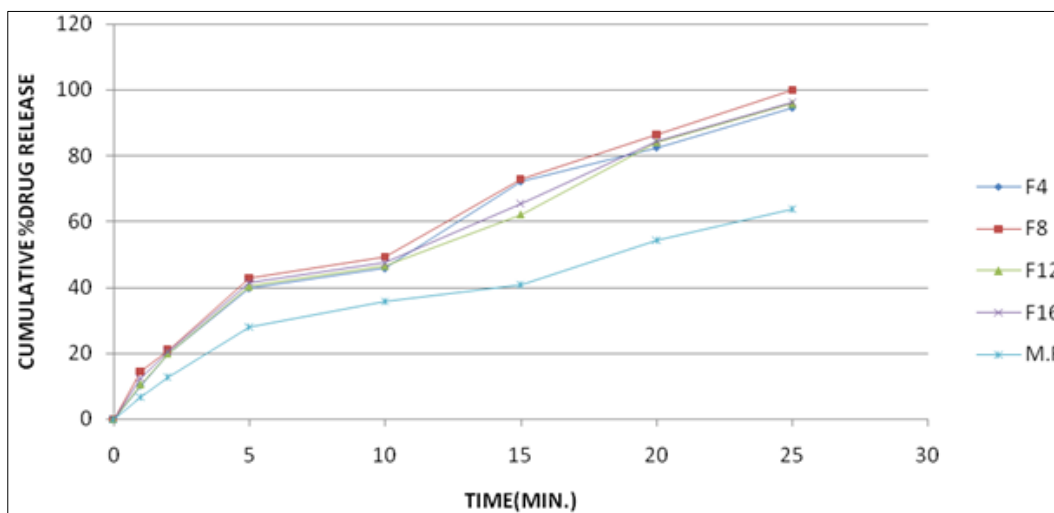
*In vitro* dissolution data of all tablet formulations were analyzed using PCP Disso v3 software. Mean values of cumulative drug release is shown in Table 4 and corresponding plot for dissolution profile of all selected tablet formulations is depicted in Fig.1. The comparative effect of four different superdisintegrants on the release profile of amoxicillin from formulations showed that formulation containing synthetic superdisintegrants i.e. croscarmellose sodium and natural superdisintegrants potato starch and ispaghula husk showed the comparative percent release profiles. While on the other hand SSG (synthetic) showed the least percent release profile of amoxicillin trihydrate from formulations at the comparative concentration used in the formulation of amoxicillin trihydrate. On comparison of drug release values as well as their profiles it can be concluded that drug release rate increase with increase in concentration of the superdisintegrant irrespective of the nature of superdisintegrants used. However, on comparison of set of formulations prepared using SSG, CCS and ispaghula husk, potato starch it is evident that release profiles of drug is comparatively better in case of formulation prepared using CCS and potato starch than that of ispaghula husk and SSG. Cumulative percent (%) drug release values of all the formulations (F1-F16) developed using SSG, CCS and ispaghula husk and potato starch as superdisintegrants is shown in Table 4. Fig. 1 depicts the corresponding plots and overall profile between cumulative % drug releases *versus* time for all performance based selected formulations. In order to predict the actual position of our fast dissolving tablet of amoxicillin trihydrate developed using varied superdisintegrants, a conventional tablet formulation of amoxicillin trihydrate was selected. *In-vitro* dissolution studies of the marketed tablets (Moxilium250, Biochem.) of amoxicillin trihydrate were carried out under similar conditions as that were used for studying dissolution profiles

of formulations F1-F16. Table: 4 shows the cumulative % drug release  $\pm$  SD (n=3) of Moxilium tablets, and fig.1 portrays the comparative profile of all selected formulations. On comparing the *in vitro* dissolution profiles of marketed formulation and formulations under investigation till first 25 minutes of drug release, it is concluded that only 63.68 $\pm$ 0.14% drug release was possible in case of marketed formulation of amoxicillin trihydrate whereas a cumulative drug release of 99.78 $\pm$ 0.09% was seen in case of formulation F8 developed using CCS as super disintegrant and 96.20 $\pm$ 0.11% of formulation F16 prepared using potato starch as super disintegrant.

**Table 4:** Comparison of Cumulative % drug release till 25 minutes of marketed formulation (Moxilium) and various formulations (F4, F8, F12 & F16) developed in the current study.

Formulation	Cumulative % drug release								
	Time (min)→	0	1	2	5	10	15	20	25
F1	0	7.2	15.38	31.21	38.21	65.27	78.58	91.14	
F2	0	8.46	16.11	36.09	43.69	67.2	79.1	92.2	
F3	0	9	17.2	37.73	45.16	68.16	80.96	92.28	
F4	0	10.26	19.91	39.75	45.77	72.19	82.52	94.57	
F5	0	12.06	16.15	38.65	43.75	67.63	80.61	93.54	
F6	0	13.32	16.7	40.11	45.95	69.13	81.23	94.89	
F7	0	13.86	19.59	41.05	47.44	69.92	83.1	96.06	
F8	0	14.4	21.04	42.69	49.28	72.86	86.25	99.78	
F9	0	8.46	15.93	32.13	40.4	66.94	80.09	92.12	
F10	0	9.36	15.94	37.54	45.15	67.96	79.87	92.61	
F11	0	10.08	17.39	38.46	45.72	69.08	81.9	92.51	
F12	0	10.62	19.91	40.29	46.5	62.13	84.04	95.75	
F13	0	10.26	15.95	32.51	41.68	67.16	80.49	92.35	
F14	0	10.44	16.13	39.17	45.36	68.54	80.63	94.1	
F15	0	10.98	17.76	39.37	47.01	69.3	82.48	94.35	
F16	0	12.42	20.47	41.4	47.44	65.41	84.49	96.2	
M.F.	0	6.66	12.85	27.93	35.8	40.69	54.27	63.68	

M.F. = Marketed formulation (Moxilium) of amoxicillin Trihydrate



**Fig 1:** Comparison of Cumulative % drug release till first 25 minutes of marketed formulation (Moxilium) and performance based selected formulations (F4, F8, F12 & F16) developed in the current study

### Conclusion

Fast disintegrating tablets of Amoxicillin Trihydrate can be successfully prepared by using direct compression method. Undoubtedly the availability of various technologies and the manifold advantages of FDT will surely enhance the patient compliance, rapid onset of action, fast disintegration, low side effect, good stability and its popularity in the near future. From the present study, it can be concluded that fast dissolving tablets of Amoxicillin Trihydrate can be successfully prepared employing different disintegrants viz. Natural as well as synthetic using direct compression method. In this study, the natural superdisintegrants shows better results as compared to synthetic superdisintegrants. The prepared tablets disintegrate within few seconds without need of water; thereby enhance the patient compliance and the absorption leading to its increased bioavailability. Direct compression technique would be an effective and simple alternative approach compared with the use of more expensive process and adjuvants in the formulation of oral disintegrating tablets. From the characterization of oral dispersible tablets of Amoxicillin Trihydrate it can be concluded that formulation containing Ispaghula 10% is most acceptable. Further *in vivo* studies in human volunteers are recommended with emphasis to correlate *in vitro* release data.

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