Available online on 15.03.2016 at http://jddtonline.info
Journal of Drug Delivery and Therapeutics
An International Peer Reviewed Journal
Open access to Pharmaceutical and Medical research

RESEARCH ARTICLE

FORMULATION AND EVALUATION OF TASTE MASK ORALLY DISPERSIBLE PARACETAMOL TABLET

***Gorle Ashish Prakash, Rajput Ritesh Bhagavansing**

Department of Pharmaceutics, R C Patel Institute of Pharmaceutical Education and Research Shirpur, Dhule, M.H.- 425405, India

Received 21 Jan 2016; Review Completed 13 Feb 2016; Accepted 04 March 2016, Available online 15 march 2016

ABSTRACT:

Mostly the drugs are administered by oral route. Orally dispersible tablets are achieving importance when compared to novel oral drug delivery system. Orodispersible tablets are suitable for all age patients by masking the taste of drug. The objective of the present study was to optimize, formulate and evaluate orally dispersible tablet (ODT) of Paracetamol which disintegrates within few seconds in presence of saliva fluid by the use of super disintegrants. Paracetamol is widely used over-the counter analgesic (pain reliever) and antipyretic (fever reducer). It is a very bitter drug so the patients unable to take orally; hence their bitter taste were masked. ODTs Formulations were prepared by Direct Compression and wet granulation method by the use of superdisintegrants and taste masking (F7;F8) is done by Eudragit EPO. The developed formulations were evaluated in terms of weight variation, drug content, friability, thickness, hardness, disintegration and *in vitro* dissolution test. Stability study of optimized formulation was also carried out as per ICH guidelines. The effects of disintegrants as well as binders in different concentration on the release profile of paracetamol ODTs were studied. The studied parameters were found to be satisfactory for all formulations. Disintegration time for the formulations was found to be less than 40 seconds. Disintegration time for all ODTs decreased with increase in disintegrant concentration. ODTs prepared using Avicel possessed least disintegration time (11s), offered better dissolution profile than that of all the ODTs formulations. Accelerated studies proved that the optimized formulation was stable even after three months.

Keywords: Orodispersible tablets, Paracetamol, Prosolv ODT; Eudragit EPO, physical characterization. in-vitro dissolution,

INTRODUCTION

Oral dispersible tablets (ODTs) are patient friendly dosage form that rapidly disintegrate or dispersed in mouth without the need of water[1]. The requirements for delivering drugs to patients efficiently with minimum side effects have provoked pharmaceutical industries to be involved in development of new drug delivery systems. The oral route of drug administration is the most and convenient way for patient regarding use of medications. Novel oral drug delivery systems that dissolve or disperse quickly in a few seconds after placement in the mouth without water can solve the problem of swallowing tablets[2]. An orally disintegrating tablet or orodispersible tablet (ODT) is a drug dosage form available for a limited range of over-the-counter (OTC) and prescription medications. ODTs differ from traditional tablets in that they are designed to be dissolved on the tongue rather than swallowed whole. Among all the routes of drug administration, the oral route of administration of drug is the most preferred route because of lot of advantages including ease of ingestion, avoidance of pain, versatility and patient compliance. But the common drawback of tablets and capsules dosage forms for paediatric and geriatric patients is difficulty in swallowing. Most of the general population, especially the elderly patients and children suffer from dysphasia which results in high occurrence of noncompliance and ineffective treatment. Swallowing problems also are very common in young individuals because of their poorly developed muscular and nervous systems[3]. Other groups who may experience problems in swallowing conventional oral dosage forms are the patients with tremors of extremities, mentally ill, developmentally disabled, non co-operative patients and patients with reduced liquid intake plans or patients suffering from nausea. The swallowing problems are also common in some cases such as patients with motion sickness, sudden episodes of allergic attack or coughing and due to lack of water. [4]

**** Corresponding Author:***
Dr Ashish Prakash Gorle
Department of Pharmaceutics
R.C. Patel Institute of Pharmaceutical Education & Research, Karwandnaka, Shirpur, Dhule, Maharashtra, 425405, India.
Mobile no. +91-9422863852
Email: ashishgorle@rediffmail.com

ODTs are beneficial for patients because of a) ease of administration to patients who refuse to swallow a tablet, such as paediatric and geriatric patients and, psychiatric patients, b) convenience in administration of drug and accurate dosing as compared to liquid formulations c) water is not required for swallowing the dosage from, which is convenient feature for patients who are travelling and do not have immediate access to water. d) good mouth feels properly of ODTs helps to change the basic view of medication as "bitter pill", particularly for paediatric patients e) fast dissolution of medicament and absorption which will leads to rapid, onset of action f) some drugs are absorbed from the month pharynx and oesophagus as the saliva passes down into the stomach, in such cases bioavailability of drugs is increased g) It provides advantages of liquid formulations in the form of solid dosage form h) pre-gastric absorption can result in improved bioavailability and as a result of reduced dosage, improved clinical performance through a reduction of unwanted effects[5].

The centre for drug evaluation and research states an orally dissolving tablet to be "*A dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon tongue* [2]" This system is recognized with other synonyms like fast dissolving tablets; melt in mouth tablets, porous tablets, rapidly disintegrating tablets, quick dissolving, and rapimelt tablets. Despite various nomenclatures the function and concept of all these Drug Delivery System (DDS) is similar[6].

To overcome the problems associated with conventional tablets/capsules ODTs were developed. Paracetamol is a widely used over-the-counter analgesic (pain reliever) and antipyretic (fever reducer). It is a very bitter drug. The main objective of the present work is to formulate dispersible or oro-dispersible tablets of Paracetamol wherein its bitter taste is masked. Such taste masked formulations have been found to improve the quality of treatment in pediatrics patients. The oro-dispersible tablets have the advantage that they can be swallowed without water. They increase the patient compliance as well as provide quicker onset of action[7]. In these cases, the bioavailability of drugs from these formulations might be greater compared to the conventional oral dosage forms. This creates porous structure and results in rapid disintegration [8]. Basic approaches to develop dispersible tablet include maximizing the porous structure of the tablet matrix, incorporating the appropriate disintegrating agent and using highly water soluble excipients in the formulation, dispersible tablet can be achieved by various direct compression and wet granulation technique. Superdisintegrants are generally used at a low level in the solid dosage form, typically 1 – 10 % by weight relative to the total weight of the dosage unit. Various synthetic disintegrants like microcrystalline cellulose, crosspovidone, crosscarmellose sodium, sodium starch glycolate have been used in the formulation of fast dissolving tablets[9].PROSOLV ODT is a choice due to high functionality excipient for orally disintegrating tablet formulation Smooth and creamy mouthfeel, Excellent flowability, Superior compaction profile when compared to other matrices, Excellent blending characteristics for improved content uniformity, High patient compliance [10]. Crosspovidone CL, the cross-linked PVP, is not only one of the three "super-disintegrants". Moreover, Crosspovidone CL accel-erates the dissolution and the bioavailability due to its power to form complexes with many insoluble actives.Taste masking by polymer coating has been widely used techniques for taste masking of drug [11]. Thus, by considering aforesaid mentioned advantages; authors decided to develop taste masked oro-dispersible tablets of Paracetamol.

MATERIALS AND METHODS

Materials

Paracetamol was obtained as a gift sample from Biocon, Bangalore. Micro crystalline cellulose/Avicel PH 102(diluent) was obtained from PMC polymers. Crosspovidone (super disintegrant), and magnesium stearate (glidant) were obtained from Signet chemicals Pvt. Ltd. India. Eudragit EPO was obtained from Evonik, Mumbai, Sodium carbonate (Rankem), Acesulfame potassium (sweetener) was obtained from Nutrinova. Orange flavour was obtained from Kerry bioscience. All other chemicals used were of analytical grade.

Methods:

Drug-excipient compatibility study were done by using Differential scanning calorimetry (DSC): DSC-60 Shimadzu, Japan was used to check the physical, chemical and biological characteristics of drug substance alone and its combination with various formulation excipients used in the final product. The samples were placed in a sealed aluminium pans and heated under nitrogen flow (30 ml/min) at a scanning rate of 5^0C/min from25^0C to 325^0C .

Direct Compression Method (Batch F1 to F4): Weigh and sift the dry complex, passed through 30 #sieves. Paracetamol, Diluents (Mannitol, Avicel PH 102) and superdisintegrant (Crospovidone CL), through 40# sieve and Colloidal Silicon Dioxide, Sweeten, Flavors, Lubricant through 60# sieve. Mix all the ingredient in poly begs for 5 min. Lubricated blend were compressed into tablets using 12mm FFBE (Flat Face Bevel Edge) punch set using a eight station tablet press[12].

Wet Granulation Method (Batch F5 to F6): Weigh and sift Paracetamol, Diluents (Mannitol, MCC) and superdisintegrant (Croscarmellose Sodium, Crospovidone CL) through 40# sieve. Then, Paracetamol and diluents were mixed in octagonal blender for 5 minutes. Then, Dissolve the binder (PVP K30) into pure water (approximately 25%). Now slowly add above binder solution into the mix powder in Rapid Mixer Granulator. Now allow to dry the obtained granules into a tray dryer for around 2 hr at 60˚C. Pass the drying granules through 20# sieve. Weigh and sift Colloidal Silicon Dioxide, Sweetener,

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Flavors, and Lubricant through 60# sieve. Mix all ingredients in poly beg for 5 minutes. Lubricated granules were compressed into tablets using 12mm FFBE (Flat Face Bevel Edge) punch set using an eight station tablet press.

Coating (Batch F7 to F8): Coating of the dry granules with Eudragit EPO were done in GPCG (Glatt Powder Coater Granulator)**.** Weigh and sift Colloidal Silicon Dioxide, Sweetener, Flavors, and Lubricant through 60# sieve. Mix all ingredients in poly beg for 5 minutes. Lubricated granules were compressed into tablets using 12mm FFBE (Flat Face Bevel Edge) punch set using an eight station tablet press.

Table 1: Composition of ODTs batches From F1 to F8

Sr	Ingradient	F1	F2	F3	F4	F5	F6	F7	F8
1	Paracetamol	250	250	250	250	250	250	-	-
2	Eudragit EPO Coated Paracetamol granules	-	-	-	-	-	-	400	400
3	Prosolv ODT	227.5	127.5	-	25	-	25	-	35
4	Avicel PH 102	-	100	100	100	100	100	25	25
5	PVP K30	-	-	25	25	25	25	-	-
6	Crospovidon CL	-	-	25	-	25	-	35	-
7	Mannitol	-	-	55	55	55	55	-	-
8	Colloidal Silicon Dioxide	-	-	5	5	5	5	5	5
9	Aspartame	10	10	25	25	25	25	15	15
10	Orange	10	10	10	10	10	10	15	15
11	Magnesium Stearate	2.5	2.5	5	5	5	5	5	5
12	Purified water	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.	Q.S.
	Net Wt.	500	500	500	500	500	500	500	500

Physico-chemical characterization:

The prepared oro-dispersible tablets were characterized for their physicochemical properties, the methods are discussed along with disintegration time and drug dissolution characteristics as discussed below;

Weight variation: 20 tablets were randomly selected from the prepared batches and their average weight was calculated using a digital balance. Individual weight of each tablet was also determined and compared with the average weight [13].

Hardness/Crushing Strength: Erweka hardness tester was used to determine the tablet hardness for all the formulated batches. The limit is toward the lower range in order to help early disintegration in mouth. It is the tensile strength of tablets expressed in kg/cm^2. It is the pressure required to break the tablet in to two halves by compression [14].

Friability: Friability is related to the ability of tablet to withstand both shocks and abrasion without crumbling during manufacturing, packing, transportation and consumer handling. Friability can be evaluated by means of friability test apparatus (The Roche friabilator). In all aspect, the range is within limit of 0.1%-0.9% are generally considered acceptable [14].

Thickness: Vernier calliper was used to determine the thickness of the prepared tablets. 20 tablets were randomly selected from each trial batch and were measured by placing the tablet between the anvils and knob was rotated until the two edges of anvil touch the tablet and the reading was noted [15].

Drug content: 20 tablets were randomly selected from the prepared batch and triturated to get fine powder. 100mg of the powder was taken and dissolved in 100 mL of phosphate buffer. Absorbance was noted spectrophotometrically at 243nm. Accordingly drug content was calculated [16].

***In vitro* Disintegration test:** The *in-vitro* disintegration time was determined by disintegration test apparatus. The time for disintegration of orodispersible tablets is generally <1 min and actual disintegration time that patient can experience ranges from 5 to 30 s. It is expected that disintegration test for orodispersible tablets should mimic disintegration in mouth within salivary contents. The various ODT formulations prepared by direct compression as well as wet granulation method are subjected to disintegration studies using 900ml water (as a disintegrating medium) and the time taken for disintegration is noted. To comply the test all tablets should disintegrate within 3 minutes [17].

***In vitro* Dissolution test:** Dissolution studies were conducted to determine the release pattern of the drug from the product. Dissolution test for paracetamol was carried out as per USP method for dissolution test for tablets and capsules using apparatus II (paddle type). 900ml of Phosphate buffer pH 5.8 was used as dissolution medium, and the paddle was rotated at 50 rpm for 1 hr at a temperature of 37 ±5 ^{0}C. Sampling was done at regular intervals and was replaced by pH 5.8 phosphate buffer after each sampling interval. These Samples were filtered and diluted. Absorbance of the resulting solution was measured at 243.0 nm

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Percent drug release was calculated. The samples are then analysed spectrophotometrically at 243 nm [15, 18] .

Stability studies: Stability is defined as the ability of a particular drug or dosage form in a specific container to remain within its physical, chemical, therapeutic, and toxicological specifications. Drug decomposition or degradation occurs during storage, because of chemical alteration of the active ingredients or due to product instability, lowering the concentration of the drug in the dosage form. The stability study indicates that the formulation is quite stable at different conditions of storage. Accelerated stability studies carried out at 40°C ± 2°C/75% RH ± 5% RH for 3 months. The optimized formulation F5 was stored in aluminum capped clear glass vials and was subjected to a storage condition for 3 months in humidity chamber. The samples were withdrawn at time intervals of 0, 1, 2, 3 months and evaluated for hardness, friability, disintegration time, drug content and *in-vitro* dissolution study [15].

RESULT & DISCUSSION

The pure drug and the optimized Formulation were subjected to the compatibility studies, using Differential Scanning Calorimetry (DSC) which is shown below in **figure.** The thermograms of mixtures showed no appreciable change in the melting endotherms of the optimized formulation as compared to pure drug (169.7^{0}C) indicating absence of any interaction. API was confirmed by DSC by keeping the heating rate of 1ºC/min. The thermogram of API exhibited sharp endothermic peak with onset temp 165.65 ºC and peak temp 169.62ºC as shown in figure.

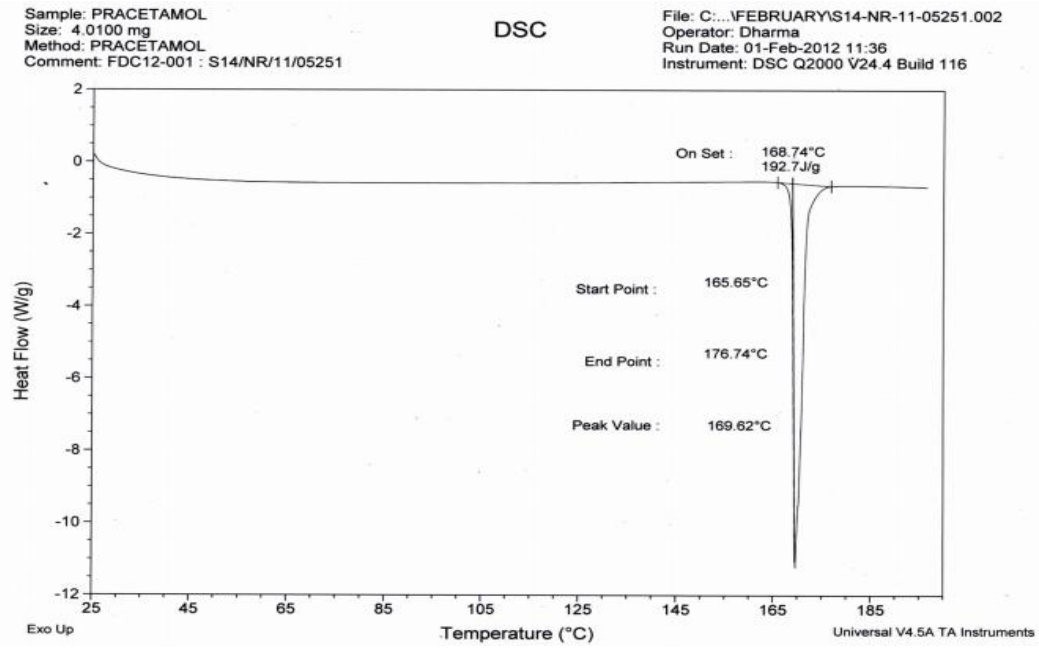

Figure 1: DSC studies of the pure drug

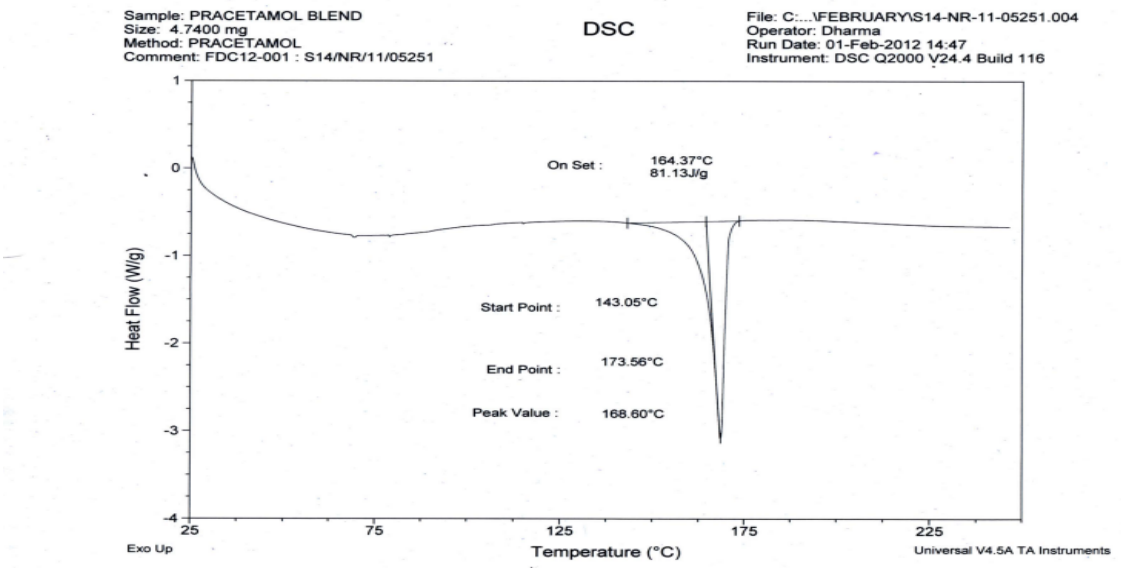

Figure 2: DSC studies of optimized formulation (F8)

The DSC thermograms of drug-polymer complex are shown in figure 2. The thermogram of drug-polymer exhibited sharp endothermic peak with onset temp 143.05 ºC and peak temp 168.60ºC.This indicates the no interaction between drug-polymer complexes.

Table 2: Physical Parameter of batch F1 to F8

Batch	Weight variation (mg)	Hardness Kg/cm^2	Drug Content %	Friability (%)	Thickness mm(±SD)
F1	499	3.96± 0.01	98.89	0.34	5.54±0.15
F2	499	3.99± 0.12	100.56	0.31	5.48±0.41
F3	500	3.94± 0.04	98.64	0.25	5.34±0.01
F4	499	4.05± 0.08	98.23	0.28	5.46±0.09
F5	496	3.89± 0.02	100.48	0.24	5.49±0.05
F6	496	4.09± 0.19	99.75	0.18	5.37±0.02
F7	499	3.73± 0.14	101.58	0.27	5.86±0.02
F8	502	3.88± 0.1	101.11	0.21	5.02±0.06

Total eight formulations (F1-F8) were prepared using various ingredients and two different superdisintegrants (Prosolv ODT; Crospovidon CL) was utilized with various concentrations. ODTs were prepared by direct compression method and wet granulation method and evaluated for Hardness, weight variation, friability, Thickness, content uniformity, disintegration time and dissolution.

Weight variation of formulated batches F1 to F8 was shown to be within the acceptable limits i.e., 500±5 mg. The drug content was found to be uniform for all the prepared formulations and was found to be 100.3%. The % drug content was found in the range of 98.89 - 101.58% (within the acceptable range) and the hardness was found between 3.73 - 4.09 kg/cm^2. Thickness of ODTs was found in between 2.37-2.86 mm. Friability of was found below 1% indicating good resistance against mechanical shear (Table-3). Among the different formulations,

The hardness of tablets was found to be 3.73 to 4.09 kg/cm^2. The formulations containing low concentration of disintegrants have shown maximum hardness so they shows less % friability and it was found that hardness was increased with decrease in the proportion of concentration of disintegrants. The lowest hardness was obtained in formulations containing high disintegrants concentration and shows % friability just near to the limit. All the tablet shows % friability in the range of 0.1-0.3 % which is within the limit. All the formulations pass the weight variation test as all tablets within the range limit for weight variation.

F- 7 was chosen as optimized batch containing crosscarmellose sodium as superdisintegrant, as it has produced the ODT having least disintegration time of 11 sec. The dissolution study was carried out in SSF, yielding about 70% and 90% dissolution respectively in 10 minutes. These results showed that taste masking was also effective. On the basis of above results it can be concluded that an oral disintegrating tablet of Paracetamol can be prepared using superdisingrates. Eudragit EPO also found to be efficient in taste-masking. From the disintegration test, (F7) has lower disintegration time (11 seconds). Drug release profile of all prepared immediate release tablets was shown in fig.1.Based on the dissolution data of all the prepared ODTs, the F7 and F8 batch shows 99.6 % drug release whthin 10 minutes. Formulations found to be stable for three month when tested for its *in vitro* dissolution studies (98.2% release at the end of 20 minutes), which were evident of stability of the product. The dissolution curves show that Crospovidon CL has the best performance, followed by Prosolv ODT (F8). The drug release from FDTs increased with increasing concentration of superdisintegrants and was found to be highest with formulations containing crosspovidone. In some cases customers may wish to have a slightly slower disinter-gration for specific applications; the new materials prosolv could help to produce a dissolution profile fitted to such a requirement, e. g. for generics; which further enhances taste as creamy mouth feel. Formulations found to be stable for three month when tested for its *in vitro* dissolution studies (98.2% release at the end of 30 minutes), which were evident of stability of the product.

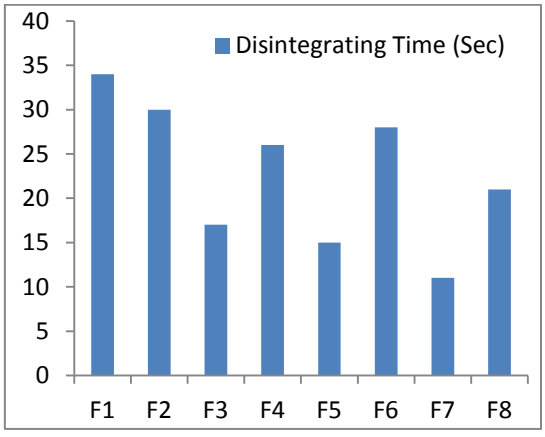

Figure 3: Disintegration of oro-dispersible Tablets Formulation

Table 4: Dissolution study of Batch F1 to F8

Time (min)	% Drug Release in 900ml P^H 5.8 phosphate buffer 50 RPM, 37°C ± 0.1°C, USP Type II (Paddle)							
	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
2	22.35	24.27	27.22	21.41	18.94	26.34	22.94	19.54
4	28.48	31.45	40.72	38.42	37.26	34.86	58.11	33.42
6	36.49	46.22	56.49	49.65	46.49	51.28	71.29	50.11
8	45.24	53.84	7015	64.23	68.64	66.48	80.78	64.54
10	61.41	72.45	84.21	79.12	79.98	81.12	95	79.65
12	76.49	84.61	96.48	86.43	98.49	88.34		88.21
14	85.37	91.28		94.28		92.49		95.68
16	93.82	97.89						

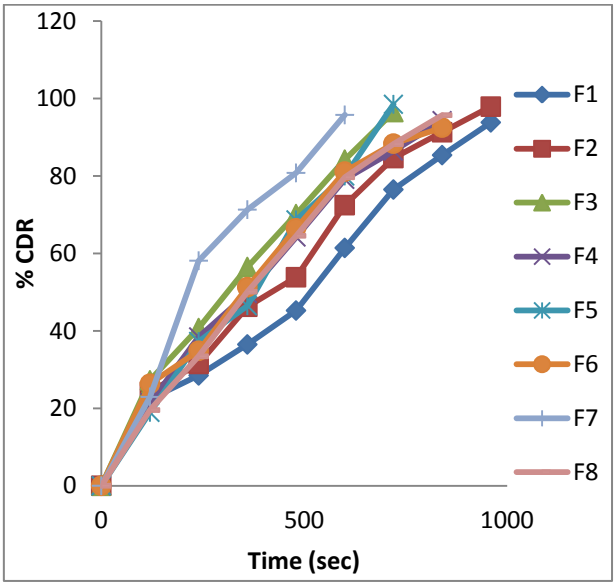

Figure 4: Dissolution profile of batch F1 to F8

CONCLUSION:

Oro-dispersible tablets have precious advantages over conventional solid dispersible dosage form. By the use of Prosolv it makes the tablets creamy mouth feels but not disintegrate with least time as compared to Crospovidon CL. This drug delivery (ODTs) is one of the great innovations of all the novel drug-delivery systems. By formulating oro-dispersible tablets it disintegrates within 30 sec hence dissolution process is improved, further solubility is enhanced. As such absorption is directly proportional to solubility of drug, and furthermore the bioavailability is also increased. So this drug delivery will improve patient compliance, convenience for administration of bitter drugs, bioavailability, and rapid onset of action. However, ordinary people are not much conscious of this delivery system. Therefore, pharmacists should inform to the patient regarding this system. It is the job of the pharmacist to advice the patients about use, advantages, storage and maintenance of product. The developed formulations ODTs should be handled carefully because they do not have sufficient mechanical strength. Patients who suffer from dryness of mouth should not be prescribed oro-dispersible tablets, since minimum volume of saliva is necessary for it to disintegrate/dissolution. Oro-dispersible formulations are very much suitable for pediatrics having no primary teeth and for geriatric patients who lost their teeth permanently.

Thus, in near future, it is expected that this delivery system ODTs will get huge importance as that of conventional delivery.

Acknowledgments: Authors would like to thank the support of RCPIPER, Shirpur, Biocon, banglore and FDC, syngene intl. Ltd

Conflict of interest: I/we do not have any conflict of interest (financial or other) other than those declared. No one who has contributed significantly to the work has been denied authorship and those who helped have been duly acknowledged.

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How to cite this article:
Gorle AP, Rajput RB, Formulation and evaluation of taste mask orally dispersible paracetamol tablet, Journal of Drug Delivery & Therapeutics. 2016; 6(2):30-36

 ISSN: 2250-1177 CODEN (USA): JDDTAO