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Preparation and evaluation of orally disintegrating taste masking tablet of paracetamol with Kollicoat Smart Seal 30 D

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ABSTRACT

The purpose of this research was to find out the taste masking effect of Kollicoat Smart Seal 30 D with different super disintegrants in formulation and evaluation of Paracetamol oral disintegrating tablet. Nine such formulations of oral disintegrating tablets were prepared by wet granulation technique using superdisintegrants as main ingredients, along with other excipients in various concentrations. Coating of the granules was achieved by 33.33% w/v of Kollicoat Smart Seal 30D Suspension prior compression. Compatibility study of the drug and excipients were carried out by FTIR study. The prepared tablets were evaluated for post compression parameters like thickness, weight variation, content uniformity, hardness, friability, and disintegration time, dissolution study and stability study. The taste of the formulations was analyzed by the responses of healthy volunteers. The formulations varied in disintegration time and taste masking property. Out of these formulations F6 and F7 showed good disintegration and taste masking property than others. So F6 and F7 were subjected to three months stability study and it was observed that F6 and F7 retained its property of an oral disintegrating tablet. Thus a taste masked oral disintegrating Paracetamol tablet which disintegrates within 30 sec in the mouth can be prepared with Kollicoat smart Seal 30 D.

Keywords: Paracetamol, ODT, Superdisintegrants, Taste Masking, Kollicoat Smart Seal 30 D

INTRODUCTION

Oral route is one of the most popular routes of drug delivery due to its ease of administration, patient compliance, least sterility constraints and flexible design of dosage forms. Tablets used in the oral cavity are aimed to release active pharmaceutical ingredient in oral cavity or to provide local action in this region. The tablets under this category avoids first-pass metabolism, decomposition in gastric environment, nauseatic sensations and gives rapid onset of action [1]. Orally Disintegrating Tablet (ODT) is a solid unit dosage form containing drugs that disintegrates rapidly and dissolves in the mouth without taking water within 60seconds or less. ODTs are also called as Oro-disperse, mouth dissolving, rapidly disintegrating, fast melt, quick dissolve and freeze dried wafers [2]. The USP however defines an orodispersible tablets are tablets intended to be placed in the mouth where it disperses rapidly before swallowing [3]. Administration of ODT has gained popularity to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as paediatric, geriatric & psychiatric patients [4]. Good mouth feel property helps to change the perception of medication as bitter pill particularly in paediatric patients [5]. The risk of choking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety. The challenges in the formulation of orally disintegrating tablets are optimizing the mechanical strength which influences the disintegration time and masking the bitter taste [6]. Disintegration time can be improved by adding super disintegrants intra and extra granularly. Taste masking can be achieved by using combination of right flavour,

right sweeteners or with incorporation of taste masking polymers. Hydroxy propyl methyl cellulose, Ethyl cellulose, Methacrylate, Kollicoat, Polyvinyl pyrrolidone polymers can be used to mask the taste.

The present study is aimed to prepare a commonly available drug Paracetamol, in oro - dispersible tablet form in a cost effective manner. Wet granulation technology has been used here to make tablets and is achieved by using different superdisintegrants, binders and other excipients with the application of new generation coating suspension. Taste masking is attempted by using a new polymer dispersion of Kollicoat Smart Seal 30D as a coating agent. The granules coating is done by pan coating as well as air suspension technique. The novelty of this study is instead of coating the active product ingredient (API), the prepared granules of the API were coated [7] prior compression.

MATERIALS AND METHODS

Materials

Pure drug, Paracetamol was purchased from Sri Krishna Pharmaceuticals Pvt. Ltd (Hyderabad, India). Ethyl Cellulose was from Colorcon Asia Pvt. Ltd. (India) and Kollicoat Smart Seal 30 D, Crospovidone and Sodium Starch Glycolate was from BASF Signet Chemicals Pvt. Ltd. (Germany). Croscarmellose was from Loba Chemicals (Mumbai, India). Mannitol used as diluents and sweetener, Pure Sucrose as sweetener was from Signet Chemicals Pvt. Ltd.(Germany). Acesulfame and all other ingredients were of analytical grade.

Preparation of taste masking film coating suspension for paracetamol granules:

The lipophilic antioxidant Butylated Hydroxy Toluene (BHT) was dissolved in the plasticizer Tri Ethyl Citrate (TEC) as mentioned in Table 1. Elevated temperature of approximately 50⁰C can speed up the process. The talc was dispersed in water with a high shear mixer for 15min. Kollicoat Smart Seal 30 D and subsequently the mixture of BHT and Plasticizer, Colorant and Sucrose solution directly added to the talc suspension and Stirred for 2hours and then pass through 200 µm sieve.

Table 1: Film Coating Suspension Formula

S.NO	Ingredients	Content (%)
1	Kollicoat Smart Seal 30 D	33.33
2	Tri Ethyl Citrate	13
3	Butylated Hydroxy Toluene	2.5
4	Talc	8
5	Pure Sucrose	12
6	Tartrazine Colorant	0.4
7	Water	q. s

Table 2. Composition of Oral Disintegrating Tablet Containing Paracetamol

Ingredients (mg/tab)	Formulations							
	F-1	F-2	F-3	F-4	F-5	F-6	F-7	F-8
Paracetamol	250	250	250	250	250	250	250	250
Ethylcellulose10Premium	75	75	75	75	75	75	75	75
Mannitol	29	29	29	29	29	29	29	29
Avicel PH 101	50	50	50	50	50	50	50	50
Crospovidone	25	25	25	--	25	30	--	--
Croscarmellose	--	--	--	25	--	--	30	--
Sodium starch glycolate	--	--	--	--	--	--	--	30
Tween 80	5	5	5	5	5	5	5	5
Glyceryl Monostearate	25	25	25	25	25	25	25	25
Pure Sucrose	25	25	20	20	22.5	22.5	22.5	22.5
Acesulfame	--	10	7.5	7.5	5	5	5	5
Peppermint flavour	5	5	2.5	2.5	2.5	2.5	2.5	2.5
Menthol	1	1	1	1	1	1	1	1
Aerosil-200	5	5	1	1	1	1	1	1
Magnesium stearate	5	5	1	1	1	1	1	1
Ethanol	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Total weight	500	500	500	500	500	500	500	500

Preparation of Taste Masked Granules

Granules of Paracetamol were prepared by wet granulation method. Binder solution was prepared by dissolving Ethyl Cellulose10 Premium in Ethanol with continuous stirring on hot plate at 50⁰ C, Glyceryl Monostearate and Tween 80 were added to enhance the solubility. Paracetamol, Ethyl cellulose 10 premium, Avicel ph 101, Mannitol as mentioned in Table 2 were sifted through 30 mesh sieves and were dry mixed by loading into the high shear mixer granulator and mixed for 10min at slow speed. Granules were prepared by adding binder solution to the loaded material and were dried in Rapid dryer at 50⁰ C till the Loss on drying of 1.5-2.0% is achieved. Dried

granules were passed through 25 and 30 mesh sieves. The dried granules of formulation F1, F2, F3 and F4 were loaded in pan coater and F5, F6, F7 and F8 were loaded into the Glatt Powder Coater and Granulator containing top spray container. The granules were film coated with the coating suspension as given in Table 1 to get the build of 3.0%. During coating the optimized process parameters for R& D coater and Glatt Powder Coater and Granulator are listed in the Table no 3 and Table no 4 respectively. Each coated granules from both the coating machines separately passed through 35 mesh sieve and transferred to octagonal blender. Superdisintegrant, Avicel PH 101, Mannitol, Sweetener, Flavor, Menthol, Colloidal Silicon dioxide were sifted through 40 mesh sieve and added in blender. Magnesium stearate was sifted through 60 mesh sieve and added and mixed for 3 minutes. Paracetamol tablets with immediate release granules were compressed in B-Tooling compression machine (10 stations, Rimek, India) using 12 mm round punches, with the specifications.

Table 3. Parameters for R & D Coater

Optimized Parameters	Batches			
	F1	F2	F3	F4
Spray rate (ml/min)	12	12	12	12
Pan speed (rpm)	11	11	11	11
Atomization air pressure (Bar)	0.6-0.8	0.6-0.8	0.6-0.8	0.6-0.8
Air inlet temperature ($^{\circ}$ C)	50	50	50	50

Table 4. Glatt Powder Coater and Granulator

Optimized Parameters	Batches			
	F5	F6	F7	F8
Inlet temperature ($^{\circ}$ C)	50-60	50-60	50-60	50-60
Product temperature ($^{\circ}$ C)	40-50	40-50	40-50	40-50
Outlet temperature ($^{\circ}$ C)	40	40	40	40
Spray Nozzle Position (mm)	1.2	1.2	1.2	1.2
Spray rate (g/min)	35	35	35	35
Spray Pump Speed (rpm)	12	12	12	12
Atomization Pressure (Bar)	1.1	1.1	1.1	1.1
Drying temperature ($^{\circ}$ C)	55	55	55	55

FORMULATION AND EVALUATION

Compatibility Study of Drug and Excipients

The compatibility studies are carried out to study the possible interactions between Paracetamol and inactive ingredients, and kept for stability at 25 $^{\circ}$ C/60% RH and 40 $^{\circ}$ C/75% RH for one month. Samples were taken out after two weeks and four weeks and were subjected to physical and chemical testing by FT-IR Spectrophotometer 8300, Shimadzu-Corporation, Japan.

Evaluation of Granules

Bulk Density

It is the ratio of total mass of powder to the bulk volume of powder and measured by Tap Density Apparatus, Electro Lab ETD -1020, India [8].

Tapped density

It is the ratio of total mass of powder to the tapped volume of powder (Tap Density Apparatus, Electro Lab ETD -1020, India [8]).

Compressibility Index

The flow ability of powder can be evaluated by comparing the Bulk density (D_b) and Tapped density (D_t) of powder and the rate at which it packed down [8]. Compressibility index is calculated by

$$\text{Compressibility index (\%)} = (D_t - D_b) \times 100 / D_t \quad (1)$$

Hausner's Ratio

It is the ratio of Tapped density to the Bulk density [8]. It is given by

$$\text{Hausner's ratio} = D_t / D_b \quad (2)$$

Tablet Evaluation

Uniformity of thickness and diameter

The tablet thickness was measured using digital vernier calipers (Mitutoyo Absolute). Six tablets were randomly picked from each formulation from which the mean and standard deviation values were calculated.

Weight Variation test

Twenty tablets were weighed individually and all together. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight.

Hardness test

Hardness (diametric crushing strength) is a force required to break a tablet across the diameter. The hardness of a tablet is an indication of its strength. The tablet should be stable to mechanical stress during handling and transportation. The degree of hardness varies with the different manufactures and with the different types of tablets [9]. The hardness was tested by using Hardness tester (Erweka, India).

Friability test

Friability is the loss of weight of tablet in the container or package, due to removal of fine particles from the surface. This in process quality control test is performed to ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and shipment. Electro Lab, ET-2(India) friabilator was used to measure the friability of the tablets. 20 tablets were weighed initially and rotated at a rate of 25 rpm. After 100 rotations (4 minutes), the tablets were taken out from the friabilator and intact tablets were again weighed collectively [10]. The percent friability was determined.

$$\text{Friability} = (W_{\text{initial}} - W_{\text{final}}) \times 100 / W_{\text{initial}} \quad (3)$$

Where,

W_{initial} = weight of the tablets before test.

W_{final} = weight of the tablets after test.

Wetting Time

The method was applied to measure tablet wetting time. A piece of tissue paper folded twice was placed in a small petri dish containing 6 ml of water, a tablet was placed on the paper, and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined [11].

Water absorption ratio

A piece of tissue paper folded twice was placed in a small Petri dish containing 6 ml of water. A tablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using following formula [12].

$$R = 100 [W_a - W_b] / W_b \quad (4)$$

Where,

W_a = weight of tablet after absorption,

W_b = weight of tablet before absorption.

Three tablets from each formulation were performed and standard deviation was also determined.

Drug content uniformity

Randomly 30 tablets were selected. 10 of these assayed individually. Tablets were weighed and crushed in a mortar then weighed powder contain equivalent to 100 mg of drug transferred in 100 ml phosphate buffer pH 6.8 solution. After preparing a suitable dilution, the Absorbance was measured by UV spectrophotometrically method ((UV-1601), (UV-2550) Shimadzu-Corporation, Japan) at 243 nm [13-14]. The drug content was calculated by the following formula.

$$\text{Drug content} = (\text{Absorption} \times \text{Dilution Factor}) / \text{Slope} \quad (5)$$

Dispersion time

Tablets were added in 10 ml of phosphate buffer pH 5.8 at 37 ± 0.5 °C. Time required for complete dispersion of the tablet was measured [15].

Disintegration

The disintegration time of tablet was measured in water (37°C) USP disintegration test apparatus. Three trials for each were performed [13].

***In vitro* dissolution studies**

Dissolution rate was studied by using USP type-II apparatus (TDT-08L, Electro lab, India, at 50 rpm) using 900ml of phosphate buffer pH (5.8) as dissolution medium. Temperature of the dissolution medium was maintained at 37 ± 0.5 °C, aliquot of dissolution medium was withdrawn at every 2 min interval and filtered. The absorbance of filtered solution was measured by UV spectrophotometrically method at 243 nm and concentration of the drug was determined from standard calibration curve [16].

Taste evaluation

Taste evaluation of ODT of Paracetamol was performed by volunteers in the age group of 19 to 22 years. The study protocol was explained and written consent was obtained from volunteers. The tablets containing 250 mg of Paracetamol was held in the mouth for 30 seconds by each volunteer. Bitterness levels were recorded instantly and then after 30 sec [17]. The bitterness level was recorded against pure drug using a numerical scale. A numerical scale was used with the following values: 5= good, 4 = tasteless, 3 = acrid, 2 = slightly bitterness, 1=bitter.

Statistical analysis

The difference in the release data for the different formulation was done by one way analysis of variance of means (ANOVA) at 5 % significance level using Microsoft 2007 excel package. *In vitro* disintegration time was taken as the parameter for ANOVA analysis.

Stability studies

The selected formulations in two batches were stored in three Ambered bottles and at 40°C/75% RH for three months and evaluated for their physical appearance, drug content and *in vitro* dispersion time at specified intervals of time. Two batches were taken to check the reproducibility characters of the formulation. The samples were withdrawn periodically from stability chamber after each month and studied for physical characteristics like appearance, average weight, hardness, thickness, content uniformity, disintegration, dissolution. The data so obtained was compared with the initial data of the tablets [18].

RESULTS AND DISCUSSION

Compatibility study

Figure 1 illustrates the FTIR spectra of prepared coated granules of Paracetamol with Kollicoat Smart seal 30D. The characteristic hydroxyl band between $3400\text{-}3200\text{cm}^{-1}$ of the Paracetamol molecule is observed in the spectra of Paracetamol coated granules. Peaks observed at $3500\text{-}3100\text{cm}^{-1}$ are attributed to that of NH stretching. In the spectra the peak between $1655\text{-}1620\text{cm}^{-1}$ is due to the amide stretching. The peak in the range of $1570\text{-}1515\text{cm}^{-1}$ is indicative of amide II band. The vibrations of C-N-H group and Para distributed aromatic ring were observed at 1250 and $850 - 750 \text{cm}^{-1}$ range respectively. This study proved that there was no interaction between drug and excipients.

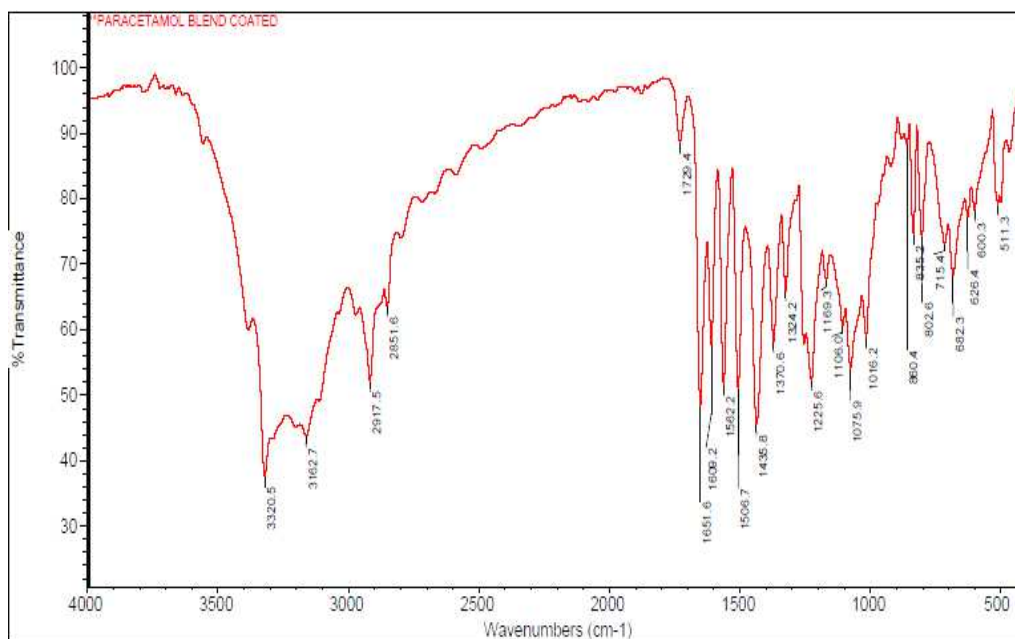


Figure 1 FTIR of Paracetamol coated granules.

Evaluation of Granules**Flow property**

The flow properties of the granules were evaluated by Bulk density, Tapped density, Carr's Index and Hausner Ratio. Bulk density was found to be in the range of 0.48 ± 0.01 to 0.53 ± 0.01 g/ml. Tapped density was in the range of 0.56 ± 0.01 and 0.63 ± 0.01 g/ml. Carr's index was between 12.28 ± 0.02 and $16.45 \pm 0.02\%$. Hausner ration was within the range of 1.14 ± 0.01 and 1.19 ± 0.01 as indicated in Table 5. The preformulation study conducted on granules evaluation for flow property showed Hausner's ratio below 1.19 and Carr's Index below 16.45. So all the formulations showed good blend properties for compression and hence tablets were prepared by wet granulation technology.

Table 5 Pre compression parameters of the coated granules

Formulations	Bulk Density (g/ml)	Tapped Density (g/ml)	Carr's Index (%)	Hausner Ratio
F1	0.52 ± 0.01	0.63 ± 0.01	15.34 ± 0.02	1.19 ± 0.01
F2	0.53 ± 0.01	0.62 ± 0.01	14.51 ± 0.02	1.16 ± 0.01
F3	0.50 ± 0.01	0.57 ± 0.01	12.28 ± 0.02	1.14 ± 0.01
F4	0.48 ± 0.01	0.58 ± 0.01	16.45 ± 0.02	1.17 ± 0.01
F5	0.50 ± 0.01	0.58 ± 0.01	13.23 ± 0.03	1.16 ± 0.01
F6	0.48 ± 0.01	0.56 ± 0.01	14.25 ± 0.03	1.18 ± 0.01
F7	0.53 ± 0.01	0.64 ± 0.01	16.38 ± 0.05	1.15 ± 0.01
F8	0.48 ± 0.01	0.56 ± 0.01	14.05 ± 0.03	1.16 ± 0.01

All values are mean \pm Standard deviation (SD) and no of replicates (n) =3.

Tablet Evaluation**Uniformity of thickness and diameter**

The Thickness of tablet ranged from 5.66 – 5.68 mm, all the batches of tablets showed less deviation in thickness as mentioned in Table 6a.

Weight Variation test

The Average percentage deviation in weight of 20 tablets of each batch was less than $\pm 3\%$ (Table 6a). The tablets passed the USP limits.

Hardness and Friability test

The Hardness varied from 39 ± 3.31 to 43 ± 4.06 N. Percentage Friability of all batches ranged from and 0.33 – 0.81 % (within the limit $<1\%$) which indicates the non hindrance in disintegration and transportability respectively (Table 6a). The Hardness and Percent Friability indicated good mechanical strength of the tablets [19-20].

Table 6a Evaluation of Physical Characteristics of the compressed tablets

Formulations	Thickness (mm)	Hardness (N)	Friability (% w/w)	Weight variation(mg)	Drug Content (%)
F1	5.66 ± 0.01	40 ± 3.89	0.44	500 ± 2.30	98.89
F2	5.68 ± 0.01	40 ± 3.0	0.32	499.8 ± 2.74	99.65
F3	5.67 ± 0.01	39 ± 3.31	0.55	499.6 ± 1.90	99.87
F4	5.67 ± 0.01	43 ± 3.07	0.61	501.1 ± 2.42	98
F5	5.67 ± 0.01	43 ± 4.06	0.74	500 ± 2.25	95
F6	5.67 ± 0.01	41 ± 3.31	0.65	499.5 ± 1.54	99.45
F7	5.68 ± 0.01	42 ± 3.16	0.81	500.4 ± 2.26	99.86
F8	5.67 ± 0.01	40 ± 2.4	0.71	501.3 ± 2.56	98.56

All values are mean \pm Standard deviation (SD) and no of replicates (n)=3.

Wetting Time and Water absorption ratio

% Water absorption ratio was found to be within 60.22 ± 0.37 and 66.04 ± 0.13 . Wetting time ranged from a minimum of 36.3 ± 0.94 s for F7 and maximum of 75.6 ± 1.37 s for F2 as shown in Table 6b. The granules coated in R & D coater showed comparatively higher wetting time than granules coated in Glatt Powder coater and granulator.

Drug content uniformity

Drug content of ODT of Paracetamol was found to be between 95 and 99.65% as shown in Table 6b. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labelled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labelled content.

Dispersion time

The dispersion time was found to be a minimum of 14.2 ± 0.68 s and maximum of 47.1 ± 1.07 s. As wetting time and dispersion time are two related parameters, dispersion time of F6 and F7 was less than other formulations owing to its wetting time as shown in Table 6b[21-22].

Disintegration and *In vitro* dissolution studies

Formulations F6 and F7 showed good disintegration and drug release at 10 mins. The lowest disintegration time was 25 ± 0.68 s for F6 and 29 ± 0.74 s for F7 respectively and maximum % drug release at 10 mins was obtained from F6 as shown in Table 6b. When the super disintegrants concentration increased in the formula a significant increase in disintegration time and drug release was observed in formulation F6 and F7. The increase in concentration of Crospovidone and Croscarmellose in F6 and F7 respectively promoted rapid swelling and thereby disintegration of the tablet into apparently minute particles [23-24]. Except for formulation F8 with high concentration of sodium starch glycolate failed to disintegrate at < 30 s which may be attributed to the presence of hydrophobic excipients, such as lubricants that hindered the water uptake by the superdisintegrant.

Table 6b Evaluation of Physical Characteristics of the compressed tablets

Formulation	Water absorption ratio (%)	Wetting time(s)	Dispersion time (s)	Disintegrating time(s)	% Drug release At 10min	Taste masking
F1	60.41±0.37	47±1.34	44.8±1.07	110±2.21	78	2
F2	63.39±0.26	75.6±1.37	47.1±1.07	60±0.75	71	3
F3	65.26±0.44	47±1.15	20±0.82	28±0.89	89	3
F4	66.04±0.13	56.8±1.06	31.7±1.49	46±0.95	80	4
F5	60.71±0.35	57.3±1.06	46.7±1.11	119±0.96	65	5
F6	60.49±0.37	37.3±1.11	14.2±0.68	25±0.68	95	5
F7	60.22±0.37	36.3±0.94	17±0.82	29±0.74	92	5
F8	60.69±0.37	46.1±1.06	43.3±1.49	169±1.10	87	5

All values are mean ±Standard deviation (SD) and no of replicates (n)=3.

Taste evaluation

The taste masking was achieved for the formulations F5, F6, F7 and F8 which are coated in Glatt Powder Coater and Granulator. The difference in tablet coating machine with a proper process controlled parameters in a fluid bed system resulted more uniform coating of the granules and thereby able to mask the taste of Paracetamol with Kollicoat smart seal 30 D suspension.

Statistical analysis

The differences in the disintegration time of the formulations were done by one way analysis of variance of means (ANOVA) at 5 % significance level using Microsoft 2007 excel package. Disintegration time was taken as the parameter for ANOVA analysis. The P-value was determined and the result is shown in the Table 7. One way ANOVA at 5% significance level and disintegration time as parameter yielded a P- value 0.000225, so it can be concluded all the formulations were found to be different (P-value < 0.001).

Table 7 ANOVA

Source of Variation	SS	df	MS	F	P-value	F crit
Between Groups	25294.36	2	12647.18	12.86452	0.000225	3.4668
Within Groups	20645.22	21	983.1055			
Total	45939.58	23				

Table 8 Stability study of formulations F6 and F7

Test	Formulations	40°C/75% RH			
		Time period in months			
		0	1	2	3
Hardness	F6	41	40.5	40	40
	F7	42.3	42.3	42.6	42.8
Friability	F6	0.654	0.65	0.65	0.647
	F7	0.805	0.81	0.8	0.802
Drug content	F6	99.45	99.23	99.2	99.2
	F7	99.86	99.75	99.6	99.6
Disintegration time	F6	25	24	24	24
	F7	29	28	28	29
Invitro Dispersion time	F6	14.2	13.6	13.2	13
	F7	17	16.8	16.7	16.7

Stability Study

Therefore among all the formulations F6 and F7 were considered as optimum formulations which showed lesser disintegration time, wetting time, dissolution time and taste masking. So these optimum formulations were taken for stability studies. Stability studies were carried out at 40°C / 75% RH for 3 months. Different parameters like hardness, friability, drug content, disintegration time and Invitro dispersion time were evaluated at a periodic interval. By observing the effect of storage and temperature on these parameters it was confirmed that the

formulated tablets F6 and F7 possess good stability and retain taste masking property as shown in Table 8. Both the formulations showed no significant variations in all the parameters and hence were concluded to be stable.

DISCUSSION

The present study was carried out to prepare taste masked Paracetamol orally disintegrating tablet. To mask the bitter taste of Paracetamol [25], coating of the tablet granules were done with Kollicoat smart Seal 30 D in two different coating machines prior compression. The coated granules were compressed by wet granulation method. To enhance the disintegration, superdisintegrant like Crospovidone, Croscarmellose and Sodium starch glycolate were used in the formulation at different concentration. Eight such formulations were prepared with varying concentration of superdisintegrant at the aim of preparing taste masked ODT of Paracetamol. Each formulation varied with their disintegration time, dispersion time and taste. It was seen that two parameters - Invitro dispersion time and taste masking were greatly affected by the concentration of the disintegrants and the coating technology used for granules coating. With the increase of superdisintegrants- Croscarmellose and Crospovidone concentration the dispersion time as well as the disintegration time improved and when the granules were coated in fluidized bed coating technique in Glatt Powder Coater and Granulator, the taste of the tablets improved due to uniform coating with Kollicoat smart seal 30 D suspension [26]. So it can be concluded that an orally disintegrating taste masked tablet of Paracetamol can be prepared with Kollicoat smart seal 30 D as novel taste masking agent.

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