Research Article

Formulation and Evaluation of Oro-Dispersible Tablets of Paracetamol

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ARTICLE INFO

Date of submission: 01-02-2021

Date of Revision: 18-02-2021

Date of acceptance: 25-02-2021

Key Words:

Paracetamol, disintegration, superdisintegrants, wetting, orodispersible tablet.

ABSTRACT

This present investigation aimed at formulation of Oro-Dispersible tablets (ODTs) of Paracetamol with different superdisintegrants like PVP, SSG and CMC using 4 %, 8 %, and 12 % concentration of tablet weight. Different formulations (F1 to F9) were prepared by direct compression method using rotary-die-compression machine keeping the hardness 3.5kg/cm^2. Formulations containing crospovidone (cross linked PVP) at 8% concentration showed good results compared to tablets containing other superdisintegrants. Which means crospovidone is better than cross linked sodium CMC and SSG in this formulation of oro-dispersible tablets paracetamol. The Fourier transform infrared spectroscopy (FTIR) study showed no interaction between paracetamol and the used superdisintegrants, as there is no significant change in peak values for the characteristic functional groups in the drug paracetamol.

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INTRODUCTION

Tablets are intended to be taken by orally. Because of the simplicity of self-administration, compactness, and manufacturing, tablets are the most widely used dosage type. However, it can be challenging for paediatric and geriatric patients to swallow it. To overcome this problem, research teams have been focusing their efforts in recent years on developing tablets that dissolve or disintegrate easily in the mouth are defined as fast dissolving and dispersible tablets.Tablet disintegration is assumed to be the rate-limiting stage in faster drug release.[1- 4]

A dispersible tablet is a tablet that disintegrates in water or other liquid. These dispersible tablets disintegrate quickly in water or disperse immediately in the mouth. Dispersible tablets are uncoated tablets that are dissolved in water before being administered, resulting in a uniform dispersion. Bitter drugs are more acceptable to different groups of people when the tablets dispersed with a good taste and flavour.When put in water, the tablets must be able to form an adequate dispersion that is uniform and stable.The main advantage is that the absorption and onset of clinical effects are faster.[5-7].They are usually made for geriatric or paediatric patients, as well as those who have trouble swallowing tablets. They are made up of excipients and components that are fully water soluble. Dispersible tablets dissolve quickly in water to form a stable suspension, making them ideal for paediatric patients.In comparison to a standard compressed tablet, this formulation has a quicker onset of action. During the manufacturing process, the properties of the water dispersible tablet, such as porosity, hardness, disintegration time, and increase in viscosity after dispersion, must be investigated because they decide the product's consistency performance.[8, 9]

Paracetamol is an antipyretic and analgesic drug that is commonly administered to people of all ages. There are many types of paracetamol products on the market, including tablets, capsules, dispersible tablets, suspensions, syrups, and FDTs.Paracetamol is a medication used as antipyretic to reducepain and fever.It is typically used for mild to moderate pain.Hence it was selected as a model drug for the preparation of oral dispersible tablets.[10]

METERIAL AND METHODS:

Paracetamol (API) as well as other excipients like crospovidone i.e., poly vinyl pyrollidone (PVP), Ac-di-sol i.e., cross linked carboxy methyl cellulose sodium (CMC sodium), primogel i.e., sodium starch glycolate (SSG), microcrystalline cellulose (MCC), talc and

PEG 4000 were taken for our research work and double distilled water was used throughout the experiment.[12]

Equipment/ Instruments:

UV-visible spectrophotometer (Shimadzu Corporation), Hot air oven, Electronic balance (Shimadzu Corporation), Tablet compression machine, Tablet hardness tester (Monsanto), Roche friabilator, linear calliper, Tablet dissolution tester USP (PLC), Tablet disintegrator (Excel enterprises), Sieve (Rolex), Glass wares (Borosilicate, India), Bulk density apparatus (Excel enterprises), were employed during the course of present research work.

Methods:

Preparations of ODT of Paracetamol:

Formulation of Dispersible tablet containing a complex of Paracetamol withdifferent polymers like PVP, SSG and CMC were prepared in 4%, 8%, and 12% respectively, which value is given in the table no.1. Then tablets were compressed in automatic direct compression machine of Shimadzu by keeping the hardness 3.5kg/cm^2 and volume 600mg for 20 tablet of each formulation.[13-15]

TABLE 1: Formulation of Paracetamol Oro Dispersible Tablets

INGRIDIENTS	F1	F2	F3	F4	F5	F6	F7	F8	F9
Paracetamol	500	500	500	500	500	500	500	500	500
SSG	32	48	72	---	---	---	---	---	---
Ac-di-sol	---	---	---	32	48	72	---	---	---
Crospovidone	---	---	---	---	---	---	32	48	72
MCC	52	36	12	52	36	12	52	36	12
PEG 4000	8	8	8	8	8	8	8	8	8
Talc	8	8	8	8	8	8	8	8	8

PVP=Polyvinyl pyrollidone, SSG= Sodium starch glycolate, CMC=Carboxymethylcellulose, MCC=Microcrystalline cellulose.

Evaluation of ODT of paracetamol:

Dissolution test of optimized Trial batch:

Using a USP dissolution apparatus, the tablets were evaluated for in vitro drug release. The following criteria were used. Form II USP Dissolution Apparatus for dispersible tablets (Paddle). Distilled water is used as the medium. 900 mL of dissolution medium Paddle rotating speed is 50 rpm, and the temperature is 37.0 ± 0.5 °C. 5ml sample removed at 5, 10, 15, 30, 45, and 60 minute intervals and diluted even 10 times further. The absorbance was measured at 242 nm using UV (Shimadzu-1800).

From where we found that, the % of drug release F1, F2, F3, F4, F5, F6, F7, F8, F9 is 74.50, 76.24, 83.37, 75.15, 72.51, 79.68, 83.57, 82.89, 85.31 respectively in 60 min.

Wetting test of tablets:

A Petridis was taken where all formulation was kept. Then 2, 3 drop of color was added to the petridish containing moisture tissue paper and observation was done by observing the color of the tablets.[16] The results are given bellow table 2.

TABLE: 2

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Time in sec.	54	47	42	55	59	57	53	48	43

Dispersibility test: For Dispersibility test 2 tablets of each formulation was taken in a beaker with water and a continuous stirrer was done with a glass rod and Dispersibility time was observed which is given bellow table no.3.[17]

TABLE: 3

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Time in sec.	2.28	1.5	1.4	2.5	2.37	2.12	1.44	1.56	1.19

Linear plot for paracetamol:

Linear plot for paracetamol was obtained for the estimation or quantitative estimation of drug.

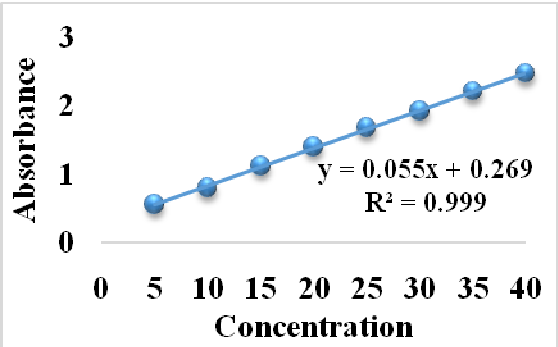

Figure 1: Linear plot for paracetamol

Drug content study:

After the dissolution test, drug content test was performed for each formulation. In which first we take 3 tablet of each formulation and triturate in mortar & pestle from where 60mg of powder was taken for each formulation and stock solution Was prepared in 50ml of volumetric flask from which 10,20,30 ppm was taken for absorbance study in uv-spectrometer.[18]

Then % of drug content was found by applying formula

% of drug content = test absorbance/standard absorbance x 100

The average value for each formulation was found which are given bellow table 4

TABLE: 4

Formulation	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug content (%)	96.01	95.91	97.02	96.46	97.32	98.65	99.69	98.8	99.46

Fourier-Transform Infrared Spectrophotometry

For FTIR the drug and drug with polymer mixture of 1:1 were taken. Then the pellets have been prepared using potassium bromide (KBr) for FTIR study. The pellets were subjected to FTIR instrument 'FTIR spectrometer, spectrum' for the collection of IR spectra which are illustrated in Figures 2.[11]

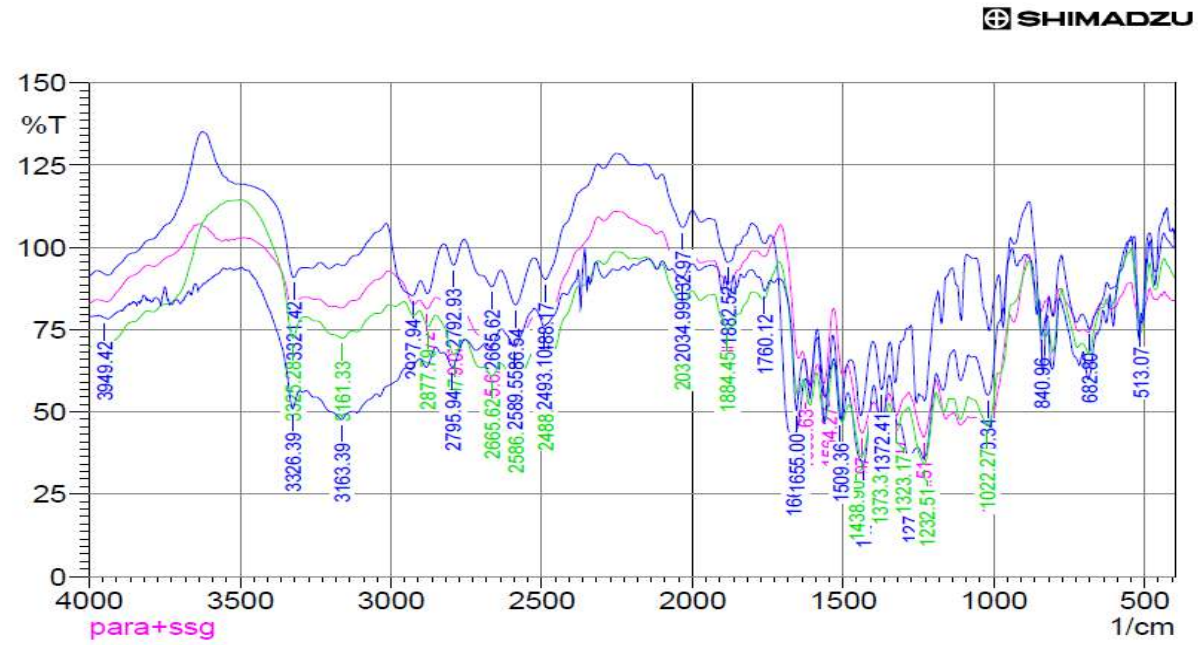

Figure 2: FTIR study of drug paracetamol, and mixture of paracetamol with polymer (A) PVP (B) SSG, (C) CMC

Results and discussion:

From the above experiment it was noticed that F7, F8, F9 shows good results of dissolution data among the other, which is F7=83.57 %, F8= 82.89 %, F9=85.31 %. Like that % of drug content of F7, F8, F9 is 99.69%, 98.80%, 99.46% respectively. Wetting test and dispersibility test was also good compares to others, and F9 formulation shows the best results in comparison to others.

Conclusions:

The F7, F8, F9 formulation shows good results compares to others because this formulation contains crospovidone. The rapid dispersion of tablets is due to wicking and bursting of tablets. That means crospovidone is better than Ac-di-sol (swelling and splitting into layers) and SSG (swelling of tablets) in case of formulation of dispersible tablets of paracetamol. Like that F8 shows the best result compares to other two, because F8 contain 8 % of crospovidone which shows nearly the same time for the dispersion of tablets as the tablets containing 12 % of crospovidone. Hence 8 % concentration of crospovidone may be considered as the optimum in the formulation of oro dispersible tablets of paracetamol.

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