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Formulation And Evaluation Of Of Fast Disintegrating Tablets Without Disintegrating Agent

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Abstract:

The novel formulation of Fast Disintegrating Tablet (FDT) without using a disintegrating agent was prepared and evaluated. The purpose of this investigation was to develop a fast-disintegrating tablet by using (API) as a model drug. The formulation prepared by sublimation technique by using camphor as a sublimating agent. Disintegration is obtained by the porous structure of the tablet which is obtained by sublimation of camphor. This research mainly includes the drug delivery system which is cost effective and easy for manufacturing. Porosity plays a major role in this system. As porosity will increase the disintegration time will decrease means tablets will disintegrate fast and drug release will also be good. The most widely used and appropriate route of administration for FDT is the oral route because of versatility, simplicity of intake, and most importantly patient compliance. FDT are modern system of drug delivery because it has leas disintegration time in comparison with normal tablets and gives disintegration of within a few seconds to minutes. The study carried out on five different combination (i.e. F1 to F5), and the F4 formulation shows better test results which disintegrates in 30 sec which is within the limit. The prepared FDT were characterized for hardness, weight variation, friability, disintegration time, content uniformity.

Keywords: Rapid disintegrating tablets, patient compliance, sublimation, spray drying, freeze drying.

BACKGROUND

Because of its simplicity of absorption, capacity to reduce discomfort, versatility (to handle a range of drug candidates), and above all patient compliance, oral administration is the most widely utilized drug administration route. The development of oral drug delivery systems is less costly because sterile conditions are not necessary. Recently, a variety of cutting-edge oral delivery technologies have emerged to enhance the pharmacokinetic and physicochemical characteristics of drugs while simultaneously boosting patient compliance .[1][2] Regardless of their physical form, pharmaceutical medications meant

for oral administration need to have their dosage form's characteristics optimized to varied degrees within the limitations of GI physiology.[3]

Therefore, the successful establishment of the oral pharmaceutical dosage form in a systemic approach requires a basic understanding of several disciplines, such as gastrointestinal physiology, pharmacokinetics, pharmacodynamics, and formulation design. The many different disciplines that go into designing and optimizing a delivery system get more complex as it gets more sophisticated. In any event, a basic comprehension of the previously listed components.[4] [5]

INTRODUCTION

Research has concentrated on creating rapid disintegrating tablets (RDTs), which are solid oral formulations that dissolve quickly in the oral cavity in less than a minute, combining the advantages of tablets and liquids. This makes administering medications easier for patients who are physically disabled, uncooperative, mentally ill, paediatric, or elderly. For fast-release formulations, the pharmaceutical industry mostly uses oral wafers or films, orodispersible tablets, and rapid disintegrating tablets because of these benefits.[9][10] When compared to ordinary tablets, oral rapid dissolving tablets (RDTs) have a higher acceptance rate and a safer profile.[11] It quickly breaks down and releases its active ingredient as it comes into contact with saliva, making it possible to consume it without the need for more fluids.[12]

According to the US Food and Drug Administration (US FDA), RDTs should have a rapid disintegration time (less than 30 seconds) and a tablet weight of at least 500 mg.[8] These are the two most critical characteristics of this oral dosage form, and they have posed some difficulties for the formulator.[12]

Oral dispersible pills, rapid disintegrating tablets, mouth dissolving tablets, quick dissolving tablets, porous tablets, and rapid melts are other names for these tablets. However, these dosage forms are recognized by the US Pharmacopeia (USP) as ODTs (orally disintegrating tablets).[15] RDT is a solid dose form with a pleasant flavour that dissolves or disintegrates in the oral cavity without the need for water in less than a minute. Additional names for FDT include mouth-melting, fast-melting, orally dissolving, and fast-dissolving tablet.[16]

Rapid dissolving tablets can be made in a variety of ways, however the final products may differ in terms of their mechanical qualities, stability, bioavailability, swallowability, dispersion and disintegration in saliva, and taste masking. Rapid disintegrating tablets can be prepared using a variety of widely recognized techniques, including compaction, molding, freeze-drying, melt granulation, spray-drying, effervescent technology, cotton candy, and phase transition.[28]

In this approach of research work we mainly focus on making formulations without disintegrating agent. Here we took aspirin as a model drug. In this formulation we took various excipients like lactose, talc, magnesium stearate along with the camphor (which act as a sublimating agent).

MATERIAL AND METHOD

Preformulation study involves organoleptic evaluation, solubility determination, melting point determination. It also includes identification studies of API by using FTIR, UV spectroscopy. It also deals with drug excipient compatibility studies.

After a brief literature research and with the help of preformulation study we finalize the some excipients for our formulation. We use camphor (sublimating agent), magnesium stearate (lubricant), lactose (diluent, binder), talc (glidant). Formulation procedure is majorly divided into parts. First part focuses on making the tablet while the other part focuses on the sublimation process. It was described in the following figures. Various batches were formulated and evaluated by using various parameters.

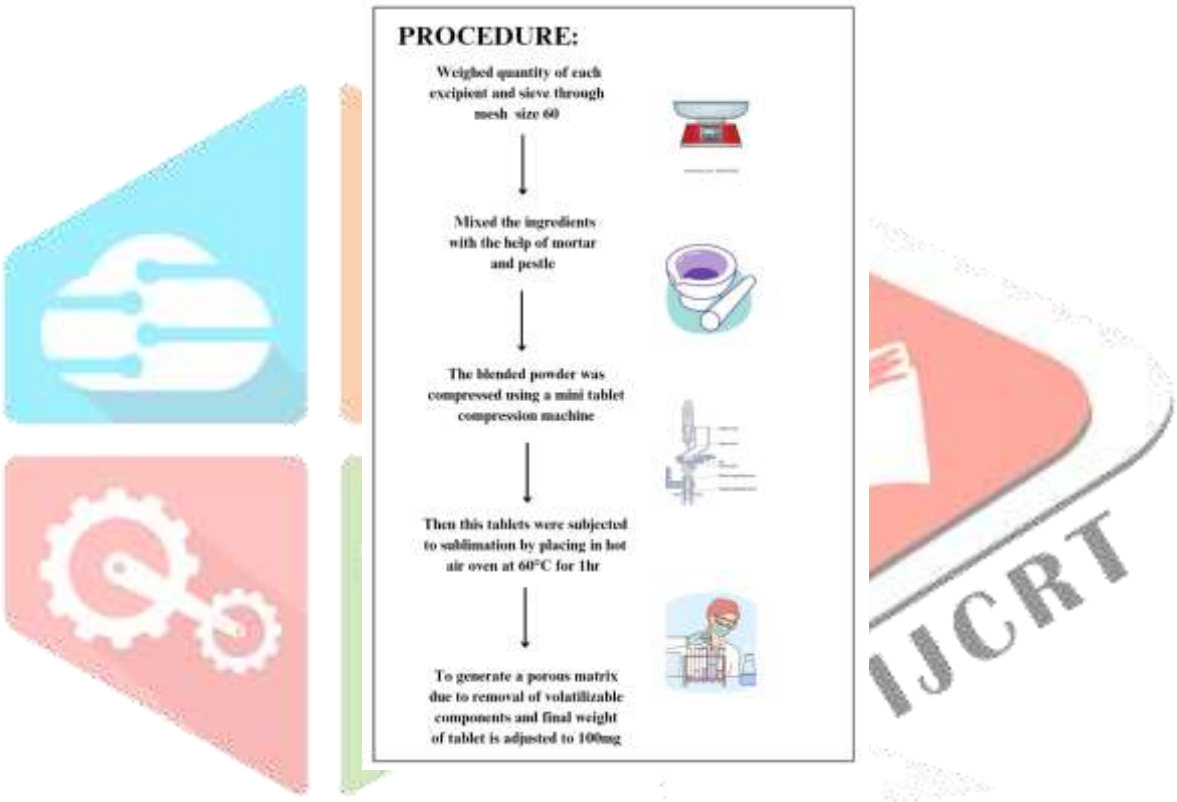

Figure 1: PROCEDURE FOR MAKING RAPID DISINTEGRATING TABLET

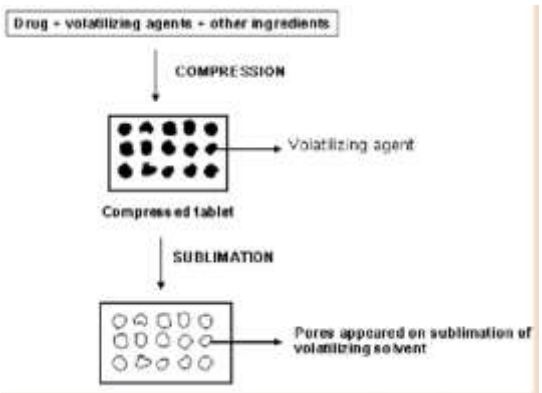

Figure 2: SUBLIMATION PROCESS

Table 1 : FORMULATION TABLE

Ingredients (in mg)	F1	F2	F3	F4	F5
Aspirin	50	50	50	50	50
Camphor	5	10	15	20	25
Lactose	40	35	30	25	20
Magnesium Stearate (2%)	19	19	19	19	19
Talc (2%)	19	19	19	19	19
Total	133	133	133	133	133

RESULT AND DISCUSSION

Aspirin is a white, crystalline, odorless, amorphous powder. It has a melting point of 136°C (277 °F) 136°C (277 °F). While talking about solubility, it is slightly soluble in water and more soluble in ethanol. UV and IR spectrum of aspirin are given in figure 4 and 5 respectively. Also for compatibility study excipients and drugs are mixed together and take IT spectra of them. It doesn't show any interference in the aspirin spectras. Figure 6. Heans, it shows excipients are compatible with the drug. The identity of the drug was confirmed by comparing the IR Spectrum of Aspirin. The reported peaks of pure aspirin remained unaltered in the spectrum obtained for the received drug sample. This confirms that the drug obtained was not degraded and can be used for formulation. We perform the evaluation tests for all the batches of tablets. Their results are given in table 2. We also perform an assay of final formulation to make sure that when it is suspected to heat while sublimation process drug activity is intact.

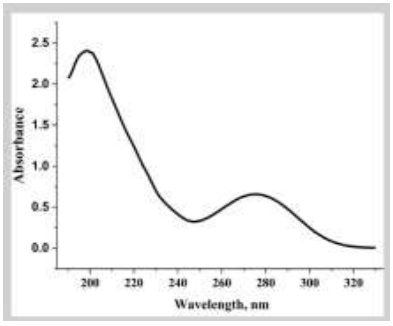

Figure 3: UV SPECTRUM OF ASPIRIN

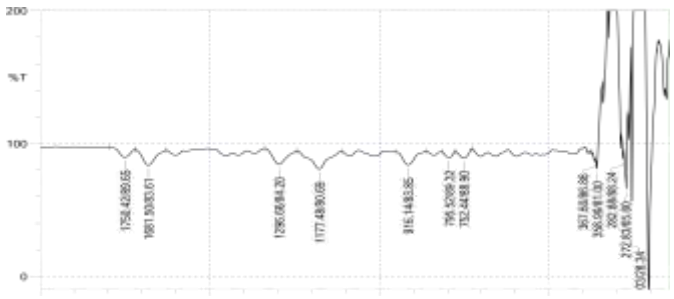

Figure 4: IR SPECTRUM OF ASPIRIN

Table 2: RESULTS OF EVALUATION TESTS

Formulation/ Parameters	F1	F2	F3	F4	F5
Angle of repose	25.50	24.76	26.58	28.61	26.42
Bulk density	0.24	0.22	0.25	0.37	0.24
Tap density	0.78	0.86	0.92	0.68	0.89
Carr's index	69.23	74.41	72.83	45.58	73.03
Hausner's ratio	3.25	3.90	3.68	1.83	3.70
Hardness	3.4	2.5	2.6	3.0	3.2
Friability	0.75	0.72	0.48	0.4	0.58
Weight variation	0.11	0.11	0.11	0.11	0.10
Wetting time (sec)	18.6	21.5	16.7	15.2	20.8
Disintegration time	7 min 4 sec	5 min 12 sec	3min 20sec	2 min 18 sec	8 min 15 sec

Figure 6: F4 FORMULATION (RDT)

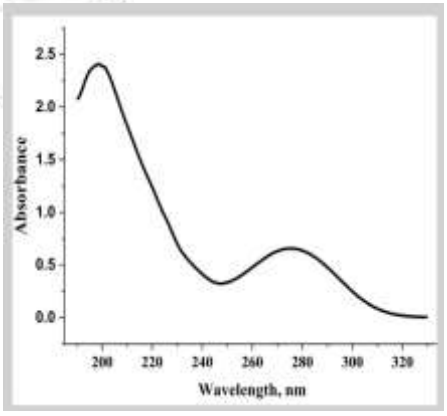

Figure 7: UV SPECTRUM OF RDT

CONCLUSION

Here we successfully developed a novel formulation Rapid Disintegrating Tablet with the model drug aspirin that also without disintegrating or super disintegrating agent. which shows instant actions. Among prepared five combinations F4 batch complies with all the parameters. F4 batch is optimised and can lead further.Because pharmaceutical manufacturer's value improved bioavailability, a quicker start of action, convenience, and consistency, RDTs provide a number of advantages over traditional oral dosage forms. Some RDT manufacturers may have challenges in masking the flavour and improving mechanical efficiency, as well as the potential to lower prices when consumers look for alternatives to create new product kinds. By employing taste-masking chemicals, it is possible to include bitter medications in RDTs. RDT research is still under progress. RDT acceptability has grown as a result of patient demand and the availability of many technology choices.

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