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Research Article

Formulation and Evaluation of Paracetamol Tablets using Coconut Oil as a Binder

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Abstract

Tablets are the medicament with suitable excipients. It comprises a mixture of active substances and excipients, usually pressed or compacted from a powder into a solid dose. The aim of this study was to formulate paracetamol tablets using Coconut oil as a binder in different concentrations (1%, 2%, 3%) and evaluate them with basic parameters. The granules manufactured using the binder had good flow property and compressibility. There are various examples of binders that can be used for tablet formulation. Here the efforts were made to formulate the paracetamol tablets by using coconut oil to check whether the tablet can be formulated and the other evaluation parameters for tablets, thereafter. Using coconut oil as a binder in the end gave satisfactory result as we could formulate a tablet with effective concentration of coconut oil with 1%. The formulated tablets thereafter were evaluated for the characterization for granules to check such as flow property, bulk density, tap density etc. as well as the tablets were also evaluated for disintegration and dissolution as well.

Keywords: Paracetamol, Binder, Dry granulation, Excipients, Direct compression, Disintegration, Dissolution

INTRODUCTION

Tablets are the solid oral dosage forms formulated with their greatest dose precision, low cost, easy transportation and patient compliance and that's why more than 70% of drug dosage forms are formulated in tablets. Binder plays an important role in formulation of tablet dosage form. It may be added either dry or in solution form to the tablets prepared by wet granulation^{1,2}. It help the powder to turn into granules which possesses good flow properties and compact ability and enhances cohesiveness. Quality of tablet depends on type, quantity and the way the binder is added. Therefore, choice of binder is extremely important in determining final tablet performance.

Tablets are solid masses made by the compaction of suitably prepared medicament (granules) by means of tablet machine³. The clinical effectiveness exerted by tablet formulation depends on two factor such as, labeled amount and its availability to the body. The main objective of oral tablet is to deliver the drug to human body at certain amount through gastro intestinal system for producing therapeutic effect.

Excipients are the substance formulated alongside the active ingredient of medication, included for the purpose of long

term stabilization, bulking up solid formulation that contain potent active ingredients in small amount such as lubricants, binders, disintegrants etc. Excipients can have multiple doses in a single dosage form or even in various roles in different formulation types⁴. Various different examples of binders used in tablets are cellulose, gelatin, polyvinyl pyrrolidone, starch, sucrose, mannitol, polyethylene glycol and liquid glucose, etc. Coconut oil is a white solid highly saturated fat with a characteristic odor. It is extracted by either cold pressing or solvent extraction of the coconut flesh. Chemically it is very high in saturated fats, typically up to 85%. When the solid is further treated by fractionating it gives clear oil. This commercial product is referred to as fractionated coconut oil. It contains more fatty acids of a shorter chain length, like octanic (8 carbon atoms) and decanoic (10 carbon atoms) than the solid⁵.

Coconut oil belongs to class of fixed oil and it's a commercially available edible oil. Extracted from the kernel of matured coconuts harvested from the coconut palm. It has various applications in food, medicine and industry. Coconut oil also contains lipid-oily and fatty substances with high percentage of saturated hydrocarbons. It is therefore applied in carefully

regulated amount that it will improve the lubrications efficiency in lubricants used in tableting.

MATERIALS AND METHODS

Materials

Paracetamol (Acetaminophen) was taken as API (Active Pharmaceutical Ingredient). Coconut Oil was used as a binder; lubricant used was Magnesium Stearate, and starch. Talc and Starch (dry) were used as disintegrants and glidant. A solution of 0.1 N HCl was used for disintegration and dissolution purpose. The chemicals were purchased from Central Drug House, New Delhi. All the chemicals and reagents were of analytical grade. The paracetamol stock solution and standard solutions were prepared as mentioned in Indian Pharmacopoeia.

Preparation of tablets

Paracetamol tablets contain 500 mg of paracetamol were prepared using three different concentration of coconut oil

(binder). A 500 mg of Paracetamol (API) was weighed accurately along with 2 gm of starch, 3.6 gm of talc and 0.6 gm of magnesium stearate. All the ingredients were transferred to mortar pestle and were mixed until properly blended. The composition of paracetamol tablets is given in Table 1. Then, 2 ml (1%) coconut oil was added to the blended mixture of powder and again mixture was being triturated for about 5 minutes. The powder was then passed through sieve no. 25 to prepare small granules. The granules were then dried at 60 °C for about 1hour in hot air oven and screened through No 24 mesh. Similarly, 4 ml (2%) and 6 ml (3%) of coconut oil was used as binder and same procedure was carried out for the other two batches. The resulting mixture was compressed using tablet Compression Machine. About 20 Tablets were prepared for each formulation i.e., for each concentration of coconut oil (1%, 2%, 3%). The compressed tablets of each batch were stored in proper containers at room temperature. Such method of tablet production has previously been described by several authors who provided reproducible experimental results in terms of *in vitro* release.

Table 1: Composition of paracetamol tablets

Ingredients	Batch (A1)	Batch (A2)	Batch (A3)
Paracetamol	500 mg	500 mg	500 mg
Corn Starch	2 gm	2 gm	2 gm
Coconut Oil	2 ml	4 ml	6 ml
Magnesium Stearate	0.6 gm	0.6 gm	0.6 gm
Talc	3.6 gm	3.6 gm	3.6 gm

Evaluation of prepared granules of paracetamol⁶⁻⁸

1. Bulk Density:

Apparent bulk density was determined by pouring the blend into graduated cylinder. The bulk volume (V_b) and the weight of powder (M) were determined. The bulk density was calculated using the formula: $P_b = M/V_b$

2. Tapped Density:

The measuring cylinder containing known mass of blend was tapped 100 times using density apparatus. The minimum value (V_t) occupied in the cylinder and the weight (M) of the blend was measured. The tapped density was calculated using the formula: $P_t = M/V_t$

3. Compressibility Index:

The simplest way for measurement of flow of powder is its compressibility, an indication of ease with which a material can be induced to flow is given by Compressibility (Carr's) index (I) which is calculated as follows: $I = P_t - P_b/P_t \times 100$

4. Hausner's Ratio:

Hausner's ratio is an indirect ease of powder flow. It is calculated by the following formula: $H_r = P_t/P_b$

5. Angle of Repose:

Angle of Repose was determined using funnel method. The blend was poured through a funnel that can be raised vertically until a specified cone height (h) was obtained. Radius of the heap (r) was measured and angle of repose (θ) was calculated using the formula: $\theta = \tan^{-1} (h/r)$

Evaluation of prepared paracetamol tablets

1. Disintegration The USP device to test disintegration uses 6 glass tubes that are 3 inches long, open at the top, and held against a 10 mesh screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is positioned in a 1000 ml beaker of 0.1 N HCl at 37 ° C. Such as the tablet remains 2.5 cm below the surface of the liquid on their upward movement. A standard motor driven device used to move the basket assembly containing the tablets up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles¹⁵.
2. Dissolution: For this test apparatus used was USP Type 1 (Basket), paddle no 6. Gastric fluid as dissolution medium: The tablets formed were immersed into 900 ml of dissolution medium, simulated gastric fluid (0.1N HCl). The temperature of dissolution medium was maintained at 37 °C. The basket was rotated at the speed of 150 rpm. After an interval of every 15 min 2 ml of the medium was pipette out and replaced with fresh medium (0.1 N HCl). This was continued all along for 2 hrs. The withdrawn out samples were then diluted to 10 ml with fresh dissolution medium and were then filtered¹⁶.

RESULTS AND DISCUSSION

Paracetamol granules and tablets were prepared by dry granulation and were further characterized. Results obtained after further characterization of granules of paracetamol tablets are mentioned in Table 2. The bulk density of A1-A3 batches prepared by varying concentration of coconut oil as a binder was found to be 0.35, 0.32, 0.44 gm/ml respectively and tapped density was found to be 0.44, 0.43, 0.56 gm/ml

respectively. The flow property of all the batches (A1-A3) was found to be good with angle of repose 33.95°, 39.68°, 35.43° respectively. The Carr's index (Compressibility index) of batches A1-A3 was observed as 20.4%, 25.75%, 21.4% respectively and Hausner's ratio was found to be 1.25, 1.34, and 1.27 respectively. The disintegration time of all batches

was satisfactory as uncoated USP tablets have disintegration time standard as low as 5 min. Results of dissolution study suggest that % drug release of all the batches after 60 mins was in range from 61.4 to 76.25 % (Table 3).

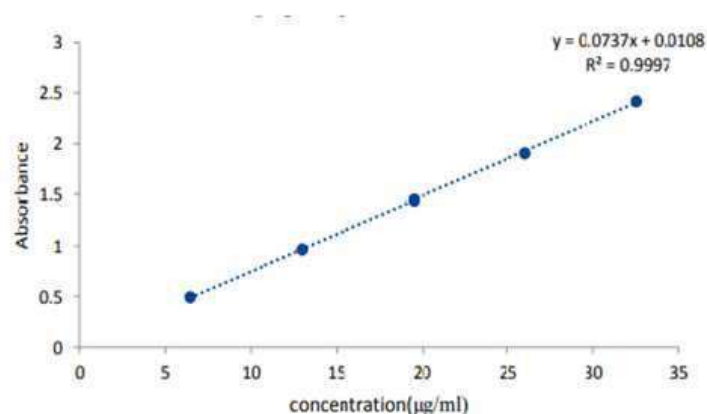


Figure 1: Standard curve of paracetamol

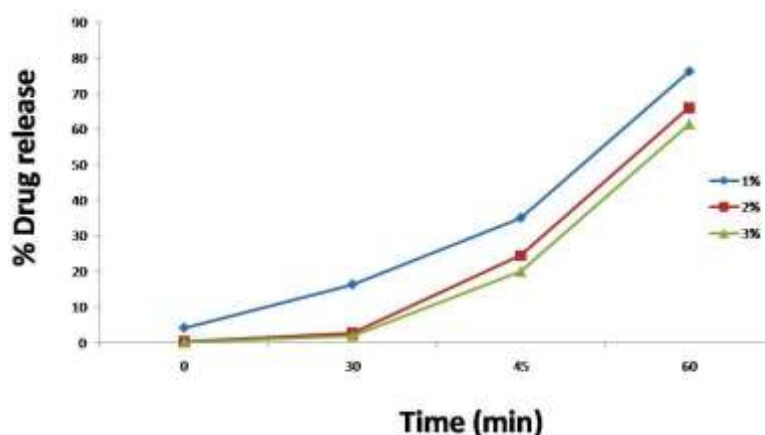


Figure 2: Dissolution profile of paracetamol tablets (Batches A1, A2, A3)

Table 2: Pre-compression properties of granules

Batches	Bulk Density	Tapped Density	Carr's Index	Hausner's Ratio	Angle of Repose	Disintegration
A1	0.35 g/ml	0.44 g/ml	20.4 %	1.25	30.83°	2 min 12 sec
A2	0.32 g/ml	0.43 g/ml	25.75 %	1.34	31.37°	2 min 53 sec
A3	0.44 g/ml	0.56 g/ml	21.4 %	1.27	31.80°	3 min 10 sec

Table 3: Content of drug release

Time (min)	% Drug release (1%) A1	% Drug release (2%) A2	% Drug release (3%) A3
0	4.10	0.21	0.1
30	16.28	2.62	1.39
45	35.04	24.4	20.02
60	76.25	66.05	61.4

Parameters studied for the granules of paracetamol using coconut oil were angle of repose, Carr's index, hausner's ratio, bulk density, tapped density and bulkiness. Lesser bulkiness showed ease of compaction into tablet dosage form over conventional dosage forms containing binders such as starch. As per the results of physical characterization batch from A1 to A3, do not show much difference in micromeritic studies and granule flow property (Figure 3). The values ranged

within that of the Pharmacopoeial limits. The disintegration time of all the uncoated tablets was found to be satisfactory. The release profile of the tablets containing coconut oil as a binder showed that among the formulated tablets batch A1 controlled the release up-to maximum extent, of the total drug incorporated during the time duration of drug release. Thus, coconut oil stands as a good binder and also has good binding capacity.

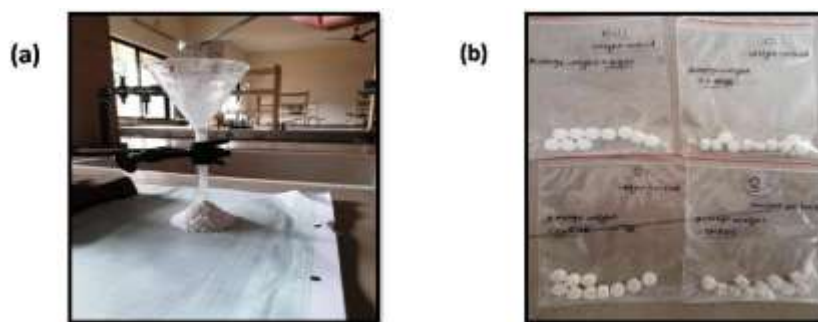


Figure 3: (a): Measuring angle of repose, (b): Prepared tablets

CONCLUSION

As the objective of this study was to attempt a formulation of the paracetamol tablets by using coconut oil as a binder. The formulation attempts were made by doing variations in the concentration of coconut oil as a binder and A1 composition was near to the satisfactory result for the compression purpose. Further it was sent for compression and again with A1 formulation the compression was found to be better compared to others and the tablets those were formulated were stable, consistent and without any defects. It is concluded from the research work that varying the concentration of coconut oil as a binder, prepared by dry granulation of paracetamol tablets there was difference seen in every concentration of tablet. From the study it also was identified that bulk density, tapped density, Carr's Index, Hausner's ratio and angle of repose was found to be satisfactory. We found that using coconut oil used as a binder we could formulate the tablets produced were showed satisfactory result.

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