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Effect of microwave drying in improving granule characteristics in tablets

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Abstract
In the present study, paracetamol is used as model drug and the granules were formed by using microwave technique and fluid bed drying technique. The granules prepared by microwave technique and fluid bed drying technique are evaluated for parameters such as amount of fines, drying time, bulk density,compressibility,angle of repose etc.The study indicated that the granules retained their structure in comparison with the conventional drying process. The prepared granules were compressed into tablets and evaluated for hardness, friability, disintegration, and dissolution etc.

Keywords: Paracetamol tablets, Microwave drying, fluid bed drying

1. Introduction

Major limitations of classical pharmaceutics experiments are longer time, higher cost, longer reaction time and environmental pollution due to the use of large of quantities of solvents/reagents. Since the heating process is very short in microwave procedure, which saves fuel/electricity, chemicals helps to reduce environment pollution.

Synthesis of drugs, intermediates, chemicals, activation of chromatographic adsorbents, determination of drug loss on drying ,drying of glasswares,sterilization of glass wares and auxiliaries, drying of granules for the preparation of tablets, enzyme inactivation of food products, hydrolysis of proteins and peptides,saponification of oils etc are a few examples of use of microwave in laboratories.[1]

The wavelengths of microwaves are in a range of about 1 to 10 mm.In microwave spectroscopy, the source is monochromatic, at a well defined single wavelength which can be rapidly varied. The resolving power is 10^5 times that of the best infrared grating spectrometer.[2]

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The advantages of microwave drying technique are microwaves systems are morecompact, requiring a smaller equipment space or footprint. Microwaves generate higher power densities, enabling increased production speeds and decreased production costs.[3] The aim of the present study was to standardize the drying process for pharmaceutical granulations by microwave technique and compare the present release of drug obtained by microwave technique with other drying technique.

2. Formulation of granules

Granules were prepared using paracetamol was used as model drug, starch as binder as well as disintegrate, talc as glidant magnesium stearate was used as lubricant.

2.1. **Procedure for Preparation of Granules by Fluidized Bed Drying (FBD):**

Wet granulation technique was used for the preparation of granules.[4]The required quantities of drug and other excipients were weighed and passed through British standard sieve no: 60 to get uniform particle size. The powders are then mixed to get uniform blend. The granulating medium was added to the powder blend and mix well until a smooth dough was obtained. The wet granules were passed through sieve no.16 and dried at 60°c for 1 hour in a fluid bed dryer for a batch. The dried granules were passed through sieve no: 16/22 and the granules which passed through sieve no: 16 but retained on sieve no: 22 were selected. The granules obtained through sieve no.22 were considered as fines.

2.2. **Microwave Granulation Procedure:**

The required quantities of drug and other excipients were weighed and passed through standard sieve no: 60, to get uniform particle size. The powders were then mixed to get a uniform blend. The granulating medium was added to the powder blend and mixed well until smooth dough was obtained. The wet granules were passed through sieve no: 16 and dried at 840 watts in microwave for different time intervals. After every 15 seconds, the granules were observed for dryness and if not dried, the drying process was continued until the granules were completely dried. After complete drying, the dried granules were passed through sieve no: 16/22 and the granules which pass through sieve no: 22 were selected .The granules obtained through sieve no: 22 were considered as fines.

3. Evaluation of granules

The granules using both fluid bed and microwave procedure were evaluated for percentage of fines [5], bulk density[6], compressibility[6] and flow properties using angle of repose[6]and moisture content determinations.

3.1. **Percentage of fines**

The granules were passed through standard sieve no: 16/22.The material retained on sieve no:22 were collected separately and weighed. From this, the percentage of fines was calculated.

3.2. **Moisture content determinations**

Moisture content (loss on drying) of granules before and after drying was determined

3.3. **Bulk density**

A given quantity of sample was transferred to a measuring cylinder and was tapped mechanically, using a tapping device till a constant volume was obtained, which referred as bulk volume. The bulk volume was calculated by
Bulk volume =mass of sample/bulk volume

3.4. **Compressibility**

The compressibility index of the granules was determined by using loose and tapped bulk densities of granules, according to the equation below;
Carrsconsolidationindex= [(Tapped bulkdensity-loosebulk density) x100]/Tapped bulk density

3.5. **Flow properties**

A funnel was fixed at a particular height 'h' cm on a burette stand and graph paper was placed below the funnel table.The sample whose angle of repose is to be determined was poured into the funnel by closing the bottom of the funnel.The bottom was opened and sample was allowed to fall onto the paper.The height of the formed pile was measured and the circumference of the pile was drawn with the pencil on the graph sheet.The radius of the pile was noted as 'r' cm and the angle of repose was calculated as follows:
$\tan\theta = h/r$ or $\theta = \tan^{-1}(h/r)$ where h=height of the pile,r=radius of pile and θ=angle of repose

4. Preparation of tablets

The granules were mixed with glidant and lubricant and compressed using a 16-station rotary tablet machine with 10mm standard concave punches. The batch size was 200 tablets. Two batches of tablets were prepared, corresponding to fluid bed drying granulation procedure and other batch corresponding to microwave drying at 840 watt. The prepared tablets were evaluated for weight variation, hardness, friability, drug content, and disintegration time and *invitro* dissolution profile.

***InVitro* drug release study:**

Drug release studies were carried out using USP (XX111) dissolution apparatus following paddle method. Freshly prepared buffer of pH 5.8 (900ml) was placed in the dissolution flask and allowed to attain a temperature of 37 ± 1^{o}C.The tablet was placed at the bottom of the dissolution flask. The paddle was rotated at 50 rpm for 30 minutes. One ml of the sample was withdrawn at different time intervals at 5, 10,15,20,25 and 30 minutes. After each withdrawal, the medium was replaced by equal amount of fresh buffer. The samples were diluted to 10 ml with dissolution medium and used for measurement of absorbance 257nm, in a UV-visible spectrophotometer.

Percentage release of drug = Absorbance of sample ×content of standard × Dilution factor/ Absorbance of standard× label claim.

5. Results & discussion

5.1. **Evaluation of Granules:**

One batch of granules corresponding to fluid bed dried wet granulation and other batch corresponding to microwave drying were prepared and evaluated for percentage of fines, bulk density, compressibility and flow properties using angle of repose. The granule drying time was found to be very less in case of microwave drying. The fluid bed drying method took 60 minutes for complete drying of granules whereas the microwave method took a maximum of 3 minutes at 840 watt. The results of evaluations of granules shown in Table 1

5.2. **Evaluation of Tablets:**

The tablets were evaluated for weight variation, hardness, friability, drug content, disintegration and *in Vitro* dissolution.. The results of evaluations of tablets shown in Table 2

5.3. **Dissolution test**

From the results, it was found that the tablets prepared by fluid bed dried granulation and those prepared by microwave granulation at an intensity of 840 watt exhibit good release profiles.
They released 98-99.5 release in 30 minutes time. From the results, it can be concluded that the batch which were dried at an intensity of 840 watt was ideal batch, and the results were comparable with that of fluid bed dried tablets.Hence, higher intensities can be used for drying of granules in regular classes. The results of *in vitro* dissolution studies of two batches of tablets were shown in Table 3 and Figure 1

Conclusion

It can be concluded that microwave drying effectively improve the characteristics of granules in tablets. It can be stated that the tablet granulation can be dried successfully using a microwave oven. By adopting microwave drying technique, tablets can be prepared in less duration of time, at least 10 times less than fluid bed drying procedure. This can save time, energy and cut down the cost of conducting practical classes.Also, use of such technique can reduce environmental pollution.

Table 1: Properties of paracetamol granules using Fluid bed and Microwave methods:

Physical properties granules	Microwave dried granules at 840w	Fluid bed dried
Amount of fines(%)	13.61	14.10
Bulk density(g/cc)	0.94±0.006	0.94±0.5
Compressibility (%)	6.15± 0.005	6.02 ± 0.003
Angle of repose(^{0})	15.99± 0.5	14.94 ±0.42
Drying time(min)	2.8± 0.52	60.2± 0.31
Loss on drying (%)	2.5-3.45	3.0-4.5

All the values are represented as mean ± s.d; n=3

Table 2: Properties of paracetamol tablets prepared using fluid bed dried and Microwave dried methods.

Evaluation parameters	Microwave dried tablets at 840 w	Fluid bed dried tablets
Average weight (mg)	660± 0.5	607±0.4
Hardness(kg/cm2)	5.3±0.02	4.56±0.04
Friability (%)	0.109	0.124
Drug content(mg)	508±0.024	506±0.046
Disintegration(sec)	55.02±0.1	44.66±0.4

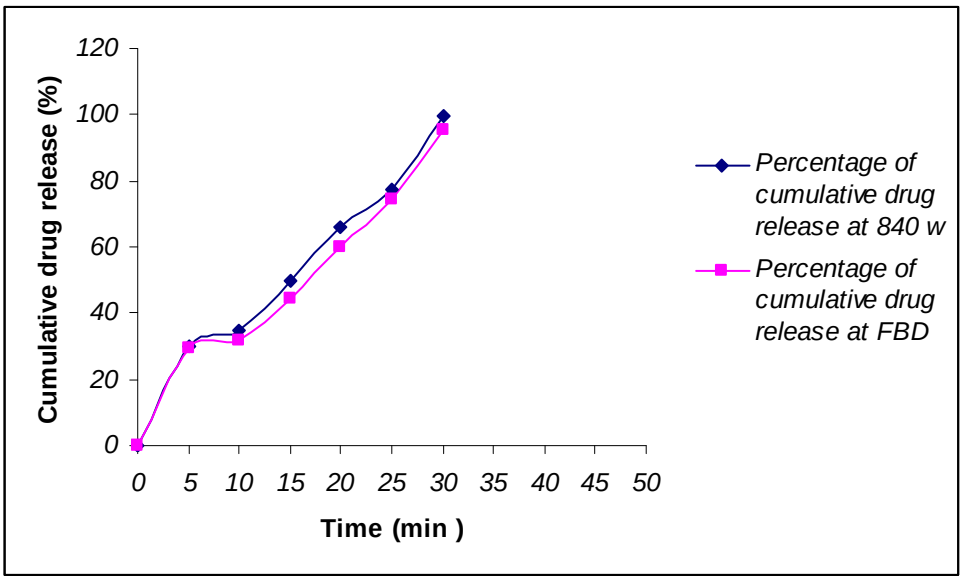
All the values are represented as mean± s.d; n=3

Table 3: Cumulative release of drug from two batches of tablets prepared by microwave and fluid bed drying methods

Time(min)	Cumulative drug release from Microwave dried tablets at 840 w (%)*	Cumulative drug release from Fluid bed dried tablets (%)*
5	30.15	29.41
10	34.81	31.85
15	49.75	44.59
20	65.93	59.70
25	77.54	74.11
30	99.87	95.54

*Average of three determinations

Figure 1 *In Vitro* dissolution profiles of two batches of tablets prepared by microwave and FBDmethods



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