DRUG DEVELOPMENT AND INDUSTRIAL PHARMACY, 14(5), 609-616 (1988)

THE PERFORMANCE OF A SMALL Y CONE MIXER

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ABSTRACT

A small Y cone mixer is described which is suitable for the preparation of small batches of ordered mixtures of powders. Its performance has been compared with that of a conventional cube mixer.

INTRODUCTION

Mixing of powders is employed in the pharmaceutical industry for granulation, capsule production and for the direct compression of tablets. It is an essential step in ensuring uniformity of the dose of a drug.[1]

The mixing of free-flowing particles of comparable size and density usually produces random mixtures.[2]

The efficiency of the equipment used is very important and there are extensive reviews in the literature of the various types of commercially available mixers and their performance [4,5,6,7,8]. However, except for the Turbula mixer [9], there do not appear to be any other types that can be employed for preparing uniform mixtures when the amounts of the ingredients are small.

This paper describes a Y cone mixer which has been constructed for the preparation of mixtures containing up to 250 gm of a coarse excipient (~ 600 μm diameter) and up to 2.5 gm of a model fine drug, namely calcium carbonate (~ 3 μm diameter). The performance of each mixer was measured in terms of the time taken to achieve the acceptable standard deviation in the mixtures, and the standard deviation after mixing for 60 min. A study was made of the effects on their performance of the total amount of powder used, the particle size of the excipient and the angle of tilt of the mixer from the horizontal.

METHODS

The mixer was essentially a Y cone driven by an electric motor (Erweka Gmbh, FRG) and consisted of a metal cylinder with a wedge-shaped knife which was attached to the cover of the cylinder (Fig. 1a, b). Calcium carbonate (Sturcal F from Sturge Lifford Chemicals) with a mean particle diameter of 3 μm determined by air permeability was used as a model fine drug. Lactose monohydrate (EPD 10 from Forum Chemicals) was chosen as the

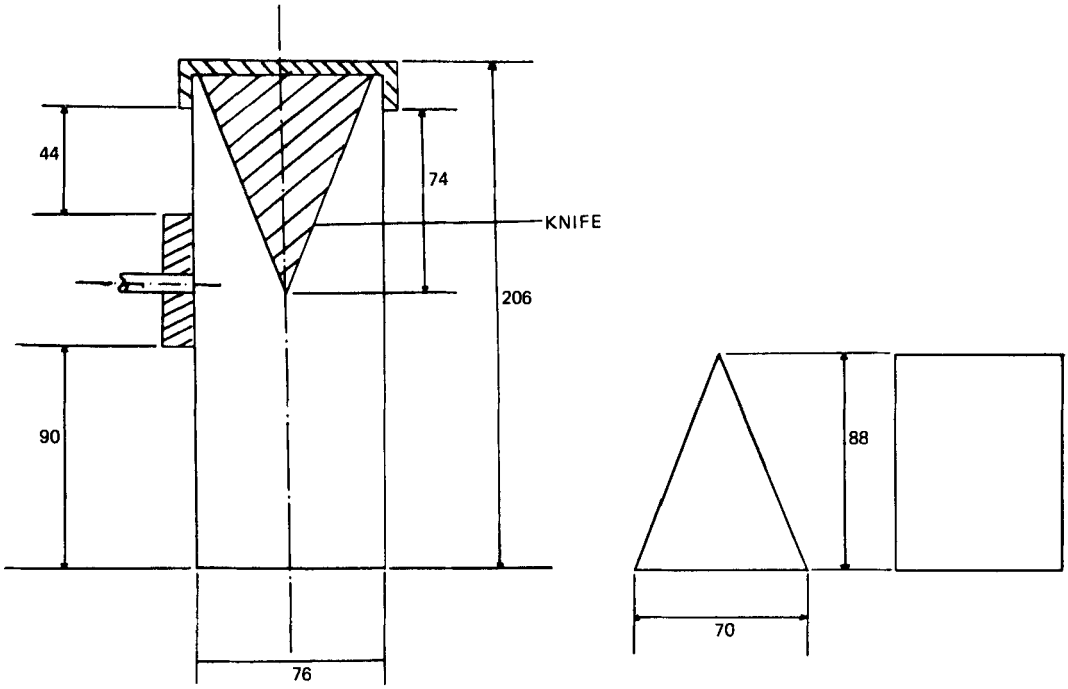

Fig. 1a Section view of the Y mixer. Scale 1 : 2 (All dimensions in mm).

Fig. 1b Front and side views of the wedge-shaped knife. Scale 1 : 2 (All dimensions in mm).

excipient. The 500-710 μm size fraction obtained by sieving was shape sorted on a Jeffrey Gallion shape sorting table[10] and essentially spherical particles were collected from pots 1, 2 and 3.

To compare the performance of the new Y mixer with the cube mixer, both were initially orientated horizontally. The former was filled with 200 gm of the 500-710 μm lactose and 2 gm of

calcium carbonate, the latter with 1000 gm of the lactose plus 10 gm of calcium carbonate. Both were rotated at 45 rev min^{-1}. Ten 250 mg samples were removed from each mixer at time intervals of 1, 2, 5, 10, 15, 30 and 60 minutes, using a sampling thief. The concentration of the calcium carbonate in each sample was determined by atomic absorption spectroscopy (Instrumentation Laboratory model 151). A total of four experiments was performed in each apparatus by (i) changing the angle of tilt from the horizontal to 40°, (ii) changing the particle size of the lactose from 500-710 μm to 125-250 μm, (iii) reducing the charge in each machine to half of that stated above.

RESULTS AND DISCUSSION

Fig. 2 shows typical graphs of the standard deviation σ of the amounts of calcium carbonate in the sample plotted against mixing time. The acceptable standard deviation σ_A with a 95% confidence limit within $\pm$ 10% of the mean $\bar{x}$ was calculated using equation (1) and is included in the figure.

$$1.96\,\sigma_A = 0.10\,\bar{x} \qquad (1)$$

Similar types of graphs were obtained using the other experimental conditions and the results are summarised in Table 1 in terms of the times required to achieve σ_A (if in fact it is achieved) and the value of σ after one hour.

On the basis of these two criteria, it is seen that the acceptable standard deviation σ_A is achieved in the Y cone

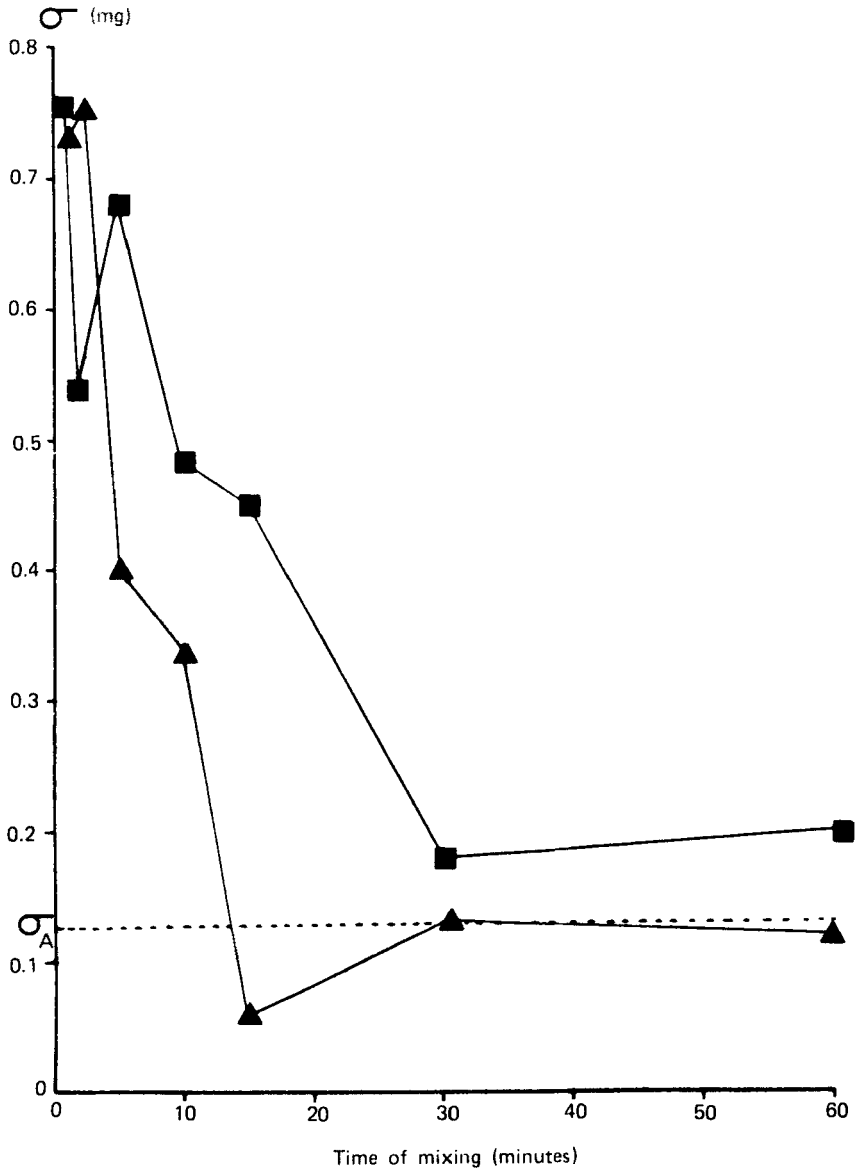

Fig. 2 Standard deviation versus mixing time using lactose (500-710) μm, a charge of 1010 gm for the cube mixer and 505 gm in the case of the Y cone mixer. Both mixers are at horizontal position.

■ Y cone mixer

▲ Cube mixer

TABLE 1

Experimental conditions	Cube mixer		Experimental conditions	Y mixer	
	Time in minutes to achieve σ_A	Value of σ(mg) after 60 mins		Time in minutes to achieve σ_A	Value of σ(mg) after 60 mins
Lactose (500-710) μm, charge 1010 gm, horizontal	*	0.20	Lactose (500-710) μm charge 202 gm, horizontal	15	0.12
Lactose (500-710) μm, charge 1010 gm, mixer tilted at angle of 40°	*	0.70	Lactose (500-710) μm charge 202 gm, mixer tilted at angle of 40°	60	0.12
Lactose (125-250) μm, charge 1010 gm, horizontal	*	0.36	Lactose (125-250) μm charge 202 gm, horizontal	60	0.13
Lactose (500-710) μm, charge 505 gm, horizontal	*	0.60	Lactose (500-710) μm charge 101 gm, horizontal	30	0.13

* Not attained.

mixer, but not in the cube mixer. This is because of its inferior tumbling action, the presence of a "dead space" (particularly when tilted) and because some of the calcium carbonate adheres to the perspex container as a result of acquiring frictional electrostatic charges.[11] The time taken to achieve σ_A in the Y cone mixer is least with 500-710 μm lactose, a charge of 202 gm and the mixer in the horizontal position.

These conditions produce the best mixtures (smallest value of σ after 60 minutes) in both types of mixer, but in all cases the final results from the Y cone mixer are better than those from the cube mixer. Moreover, they are practically unaffected by the changes made in the experimental conditions. Optimum mixing occurs when the Y cone mixer is about at least one quarter filled, and when the excipient is reasonably coarse (500-710 μm). These conditions ensure that the shearing forces generated during mixing are sufficient to break up aggregates of the fine calcium carbonate and distribute it as an ordered mixture over the surface of the lactose with little tendency subsequently to de-mix.

ACKNOWLEDGEMENTS

We thank Dr K Ridgway for the use of his shape sorting equipment and Sturge Lifford Chemicals for the gift of material.

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