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Effect of Various Disintegrants Blends on the Mechanical Properties of Paracetamol Tablet

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Abstract: *Paracetamol tablets were prepared using blends of various disintegrants (MCC, Starch and NaCMC). Physico technical properties such as friability, hardness and disintegration profiles were assessed.From the result, Batch 7[2.5% MCC and 2.5% NaCMC] has the least Friability Value (0.4600± 0.00577). Its Friability was significantly (p< 0.05) less than the other batches. Batch 3 (5 % MCC) had the highest Friability Value (0.6900± 0.0058) which was significantly (P<0.05) higher than other batches. All the batches produced tablets with friability within the official limits.Batches 1(control),2 (5% Starch),3(5 % MCC), 4(5% NaCMC) and 5(2.5% starch, 2.5% MCC) had similar hardness profile (P> 0.05) . Their hardness was significantly (P<0.05) less than those of batches 6(2.5% Starch,2.5% NaCMC),7(2.5% MCC, 2.5% NaCMC) and 8 (1.67% starch,1.67% NaCMC and 1.67% MCC). However, all the batches displayed hardness values that fall within the compendial limits.All the batches showed significantly (P<0.05) disintegration profile. Batch 2 had a better disintegration profile (13.14 ± 0.012)*
Keywords: *physicotechnical properties, disintegrants, paracetamol*

I. Introduction

Despite increasing interest in controlled-release drug delivery systems, the most common tablets are those intended to be swallowed whole and to disintegrate and release their medicaments rapidly in the gastrointestinal tract (GIT). The proper choice of disintegrant or superdisintegrant and its consistency of performance are of critical importance to the formulation development of such tablets. Drug release from a solid dosage form can be enhanced by addition of suitable disintegrants (Agdish,1992;Alekha et al.,2000; Andries et al.,2003). In more recent years, increasing attention has been paid to formulating fast dissolving and/or disintegrating tablets that are swallowed, but also orally disintegrating tablets that are intended to dissolve and/or disintegrate rapidly in the mouth (Bi et al.,1996; Sallam et al.,1998). Disintegrants are substances or mixture of substances added the drug formulation that facilitate the breakup or disintegration of tablet or capsule content into smaller particles that dissolve more rapidly than in the absence of disintegrants (Anthony et al.,1997; Banker,1990) . The disintegrants have the major function to oppose the efficiency of the tablet binder and the physical forces that act under compression to form the tablet. The stronger the binder, the more effective must be the disintegrating agents in order for the tablet to release its medication (Basak et al,2004; Bi,1995;Bi et al.,1996; Bi et al.,1999;Blank et al.,1990; Botzalakis et al, 1988;Budavani et al.,1996) . Ideally, it should cause the tablet to disrupt, not only into the granules from which it was compressed, but also into powder particles from which the granulation was prepared.

The objective of this research was to assess the effect of disintegrant blends on the physico technical properties of Paracetamol tablets. There is dearth of information on formulations involving disintegrants blends.

II. Material And Methods

Materials: Paracetamol powder (SKG), lactose, MCC, magnesium stearate Starch and Sodium carboxymethyl cellulose were all BDH chemicals. Others used were of laboratory grade.

Methods: Wet granulation method was used to prepare tablets. Different disintegrants and the lint formulation were kept as the controlled formulation i.e. without disintegrant. And each formulation was compressed into tablets. The required quantities of Paracetamol, ,PVP, Mg-stearate and Lactose were weighed accurately. Paracetamol, and lactose were mixed in a mortar and pestle using laboratory conditions. Accurately weighed quantity of binder (PVP) was then dispersed in IPA (Isopropyl alcohol) and stirred well. The binder solution was then slowly incorporated into the above mixed powder to obtain a damp mass. The damp mass was passed through a granulating sieve 2.0 to obtain the granules. Then the granules were dried in a hot air oven at 40 0C temperature, less than the temperature of all the ingredients used. The dried granules were passed through sieve

No 1 in order to obtain the uniformed sized granules. All the granules were lubricated with magnesium stearate and compressed using single punch in a multistation compression machine (Cadmag), which is equipped with 8mm concave edge punches. The composition of the formulation is shown in table 1.

Table 1. composition of paracetamol batches

batches	Drug (Mg)	PVP	Starch	MCC	NaCMC	Mg Stearate	Lactoseqs	
PCM0	500	0.025	-	-	-	0.005	600	
PCM1	500	0.025	2.5	-	-	0.005	600	
PCM2	500	0.025	-	2.5	-	0.005	600	
PCM3	500	0.025	-	-	2.5	0.005	600	
PCM4	500	0.025	1.25	1.25	-	0.005	600	
PCM5	500	0.025	1.25	-	1.25	0.005	600	
PCM6	500	0.025	-	1.25	1.25	0.005	600	
PCM7	500	0.025	0.83	0.83	0.83	0.005	600	

Tablet compression

Direct compression method was used. Before each compression, the die (12.5 mm in diameter) and flat faced punches were lubricated with a 1 % w/v dispersion of magnesium stearate in chloroform. Compression was achieved at a pressure setting of 10.5 N in a single punch tableting machine (THP Shangai, Tianxiang and Chentai Pharmaceutical Machinery Co.Ltd. China) fitted with flat-faced punches and compressed to a target weight of 550 ± 10 mg. Each drug compacts were stored in airtight specimen bottles and allowed to equilibrate for 24 hours before further evaluations.

Evaluation of tablet properties

Tablet dimensions

The thickness and diameter of compacts produced from powder granules were determined using vernier caliper. The mean and standard deviation of five randomly selected tablets from each batch was calculated.

Uniformity of weight

The weight of ten randomly selected tablets from each batch of both , were determined individually and collectively. The mean weight and standard deviation were computed.

Crushing strength (hardness test)

The Monsanto hardness tester was used to determine the force required to crush ten randomly selected tablets from paracetamol tablet batches.

Friability

Five tablets selected randomly from tablet batches were dusted and weighed using analytical balance. These were introduced into a friabilator (Roche) and set to rotate at 25±1 r. p. m for 4 minutes after which the tablets were dedusted ,re-weighed and the percentage friability .

Statistical data analysis

This was done by carrying out ANOVA with Duncan post hoc test using SPSS V 17 software

III. Results And Discussion

Table 2 mechanical properties of paracetamol batches

batches	Hardness(Kg/F)	Friability	Disintegration time
PCM0	5.66±0.26	0.6±0.02	35.18±0.26
PCM1	6.08±0.32	0.63±0.00	13.14±0.26
PCM2	6.06±0.27	0.69±0.00	58.2±0.26
PCM3	6.13 0.22	0.64±0.01	29.36±0.26
PCM4	5.96±0.14	0.63±0.00	44.566±0.26
PCM5	7.30±0.15	0.63±0.01	36.32±0.26
PCM6	7.46±0.13	0.46±0.00	40.51±0.26
PCM7	7.42±0.12	0.57±0.01	37.34±0.26

The mechanical properties of paracetamol tablets are shown in table 2.

From the result, Batch PCM 7 [2.5% MCC and 2.5% NaCMC] has the least Friability Value (0.4600± 0.00577). Its Friability was significantly ($p< 0.05$) less than the other batches. Batch 3 (5% MCC) had the highest Friability Value (0.6900± 0.0058) which was significantly ($P<0.05$) higher than other batches. All the batches produced tablets with friability within the official limits.

Batches 1 (control), 2 (5% Starch), 3(5 % MCC), 4(5% NaCMC) and 5(2.5% starch, 2.5% MCC) had similar hardness profile (P> 0.05) . Their hardness was significantly (P<0.05) less than those of batches 6 (2.5% Starch,2.5% NaCMC), PCM 7 (2.5% MCC, 2.5% NaCMC) and 8 (1.67% starch,1.67% NaCMC and 1.67% MCC). However, all the batches displayed hardness values that fall within the compendial limits.
All the batches showed significantly (P<0.05) different disintegration profile. Batch 2 had a better disintegration profile (13.14 ± 0.012)

IV. Conclusion

Paracetamol tablets were prepared using blends of various disintegrants (microcrystalline cellulose, starch and sodium carboxymethylcellulose). Friability test, hardness and disintegration profiles were used as bases to assess the performance of the formulations.

From the results (table 2), Batch 2 (5 % starch) had a better disintegration profile (13.14 ± 0.012). It is also observed that the disintegrants blend produced tablets with poor disintegrants profiles.

This project reveals that starch is an ideal disintegrant in wet granulation.
The other disintegrants (MCC, NaCMC) and their blends may be considered in direct compression.

References

[1]. Agdish Singh., 1992. „Current Status of Tablet Disintegrants:A Review". Drug. Dev. nInd. Pharn., **(1998)**18(3):375-383.
[2]. Alekha K., Charles Gayser., Hector Fausett.,2000. „Evaluation of Quick Disintegrating Calcium Carbonate Tablets". AAPSPharm.Sci.Tech., 1(3):20.
[3]. Andries F Marais., Mingna Song., Melgardt M., de Villers., 2003. „Effect of compression force, humidity and disintegrant concentration on the disintegration and dissolution of directly compressed furosemide tablets using croscarmellose sodium as disintegrant". Tropical.J .Pharm Res., 2(1):125-135.
[4]. Antony P J., Sanghavi NM., 1997. „A New Binder for Pharmaceutical Dosage Forms".Drug. Dev. Ind. Pharm., 23(4):413-415.
[5]. Banker SG., 1990. Modern pharmaceutics, second edi, Marcel Dekker, newyork,372 - 379.
[6]. Basak SC., Rao YS., Manavalan R., Rao PR., 2004. „Development and Invitro evaluation of an oral Floating matrix tablet formulation of ciprofloxacin". Ind.Pharm. Sci., 66:313-316.
[7]. Bi al yen., 1995. „Rapidly Disintegrable multiparticular Tablets".Chem.Pharma.Bull., 18(9): 1308-1310.
[8]. Bi Y., Sunada H., Yonezawa Y., 1996. „Preparation and evaluation of a compressed tablet rapidly disintegrating in the oral cavity". Chem. Pharm. Bull., 44:2121-2127.
[9]. Bi YX., Sunada H., Yonezawa Y., Danjo K., 1999. „Evaluation of rapidlydisintegrating tablets prepared by a direct compression method". Drug. Dev. Ind. Pharm., 25:571-581.
[10]. Blank et al.,1990. „Fast Dissolving dosage form"., US Patent 4,946,684 .
[11]. Botzalakis JE., Dngsburger L L.,1988. „Disintegrating Agents in Hard Gelatin Capsules. Part II: Swelling Efficiency". Drug.Dev.Ind.Pharm.,14(9):1235-1248.
[12]. Budavani S O., Neil N J., Smith A., 1996. „The Merck Index, An Encyclopedia of Chemicals, Drugs and Biologicals, 29th Ed. Published by Merck Research Laboratories, Division of Merck & Co. Inc 181
[13]. Sallam., Ibrahim H., R Abu Dahab., M. Shubair., Enam Khalil., 1998. Drug.Dev and Industrial Pharmacy, Vol. 24, 6: 501–507.