嘉南藥理科技大學專題研究計畫成果報告

蛋殼回收物之利用-溶離增進劑之可行性評估

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The search of a new pharmaceutical disintegrant
The evaluation of egg shell membrane as dissolution enhancer

Introduction

Active ingredients in the oral solid dosage forms must be dissolved in the gastrointestinal fluid in order to be absorbed (Martin et al., 1983). A disintegrant is often added into the oral solid dosage forms to enhance the dissolution rate of the solid dosage forms (Lachman et al., 1986). Starch is commonly used in the tablet formulation as a natural disintegrant traditionally. Also, synthetic disintegrants like sodium croscarmellose, crospovidone, and sodium starch glycolate are used very often in the tablet formulation (Peck et al., 1989). The search of a more efficient disintegrant to enhance the dissolution rate and onset of the therapeutic effect is always continued.

The efficiency of a disintegrant is generally attributed to its swelling and wicking functions (Rudnic and Schwartz, 1995). In this study we try to look for a new and inexpensive material –egg shell membrane, with the function of swelling and wicking for the use as a disintegrant.

Materials and Methods

Materials

acetaminophen (Seven Stars Chem. Corp., Taiwan), lactose (HMS, Holland), starch, prejel, Kollidon (BASF, Germany), magnesium stearate (Akcros Corp., Holland), were all USP/NF grade. All reagents were all analytical grade. The egg shell membrane was prepared by separating from egg shell, followed by washing, drying and grinding to 80 mesh powder.

Tablet Preparation for disintegration test

Weigh 100 gm of lactose and 30 gm of starch. Pass them through an 80 mesh sieve and mix well. Prepare starch paste, and add it into the above mixture. Knead well and pass through a 20 mesh screen to make granules. Dry them in a oven at 50 ℃. Divide them into two parts, adding pre-sieved egg shell membrane (80 mesh) to one part and make tablets. The other part is without adding egg membrane powder.

Disintegration test:

The disintegration of tablets was studied using the USPXXV method with 900 ml purified water as the medium. Each of six tablets was put into one tube of the disintegration tester and the disintegration time was measured at 37 ℃.

Tablet Preparation for dissolution test:

Prepare tablets with the following formulation: acetaminophen 50 mg, prejel 30 mg, magnesium steare 2 mg, disintegrant 8 mg, lactose q.s to 200 mg. The tablet in the controlled group is without disintegrant.

Dissolution test:
The dissolution of tablets was studied using the USPXXV method with 900 ml purified water as the medium. A tablet of each formulation was put inside one flask of the dissolution tester. Five ml of solution was sampled at 5 minutes intervals till 30 minutes and was replaced with an equivalent amount of fresh purified water. The rotating speed was 100 rpm and the temperature of the medium was 37 ℃. The sample was filtered and assayed by UV at 235 nm.

Results and Discussions
Disintegration test:
The disintegration time is 1'23" for the tablets containing egg membrane and the disintegration time is 3'23" for the tablets without containing egg membrane. It was observed that egg membrane absorbs water significantly. It seems that the wicking function of egg membrane helps to break up the tablets.

Dissolution test:
The dissolution of the tablets containing disintegrant Kollidon is fastest. It dissolves completely within the first 5 minutes. The dissolution of tablets containing egg membrane and that of controlled group have controversial results. At present, we are looking into the results and a further study on the enhancement is being proceeded.

References

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