

การผลิตสารเพิ่มปริมาณสำหรับวีซีตอกโดยตรงจากส่วนผสมของน้ำตาลทรายปนละ เอียด  
และแป้งมันสำปะหลังด้วยวิธีฟลูอิดไดซ์ เบดแกรนูลเลขื่น



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THE PRODUCTION OF TABLET DILUENTS FOR DIRECT  
COMPRESSION FROM POWDERED SUGAR-TAPIOCA  
STARCH MIXTURES USING FLUIDIZED  
BED GRANULATION TECHNIQUE



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## พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

เลขพล ปรี่ชากุล : การผลิตสารเพิ่มปริมาณสำหรับวิธีตอกโดยตรงจากส่วนผสมของน้ำตาลทรายป่นละเอียดและแป้งมันสำปะหลังด้วยวิธี ฟลูอิดไคซ์เบคแกรนูลेशन (THE PRODUCTION OF TABLET DILUENTS FOR DIRECT COMPRESSION FROM POWDERED SUGAR-TAPIOCA STARCH MIXTURES USING FLUIDIZED BED GRANULATION TECHNIQUE) อ.ที่ปรึกษา: ผศ.ดร.พจน์ กุลวานิช, 193 หน้า.

การศึกษาเกี่ยวกับการประเมินคุณสมบัติทางกายภาพของแกรนูล ซึ่งผลิตจากส่วนผสมของน้ำตาลทรายป่นละเอียด และแป้งมันสำปะหลังกับสารยึดเกาะที่เหมาะสมด้วยวิธีฟลูอิดไคซ์เบคแกรนูลेशन โดยมีวัตถุประสงค์เพื่อนำแกรนูลมาใช้เป็นสารเพิ่มปริมาณในการผลิตยาเม็ดที่ประกอบด้วยสารออกฤทธิ์ในปริมาณน้อย ๆ ด้วยวิธีตอกโดยตรง ให้นำส่วนผสมของน้ำตาลทรายป่นละเอียด และแป้งมันสำปะหลังในอัตราส่วนตั้งแต่ 1 : 9 ถึง 9 : 1 มาเตรียมเป็นแกรนูลโดยใช้สารยึดเกาะ 4 ชนิดคือ polyvinylpyrrolidone, gelatin, methylcellulose และแป้งมันสำปะหลัง

แกรนูลมีปริมาณความชื้นสูงชันสัมพันธ์กับปริมาณของแป้งมันสำปะหลังที่เพิ่มขึ้น แกรนูลมีลักษณะเป็นรูพรุน รูปร่างไม่สม่ำเสมอ มีการกระจายตัวของอนุภาคแคบ และความหนาแน่นต่ำ น้ำหนักเม็ดยามีความเบี่ยงเบนและความร้อนต่ำ มีความแข็งเป็นสัดส่วนกับแรงตอกอัด แต่เม็ดยาที่ผลิตจากแกรนูลที่ใช้ polyvinylpyrrolidone และ gelatin เป็นสารยึดเกาะ จะมีการแตกตัวเร็วกว่าเม็ดยาที่ผลิตจากแกรนูลซึ่งมี methylcellulose และแป้งมันสำปะหลังเป็นสารยึดเกาะ อัตราส่วนผสมของน้ำตาลทรายและแป้งมันสำปะหลังซึ่งมีผลให้แกรนูลมีคุณสมบัติทางกายภาพเหมาะสมที่สุด เปลี่ยนไปตามชนิดของสารยึดเกาะโดยมีอัตราส่วนผสมเป็น 1 : 1, 1 : 1, 9 : 1, 8 : 2 เมื่อใช้ polyvinylpyrrolidone, gelatin, methylcellulose และแป้งมันสำปะหลังเป็นสารยึดเกาะตามลำดับ นำแกรนูลทั้ง 4 ตัวรับนี้ มาผลิตเป็นยาเม็ด diazepam และ chlorpheniramine maleate ด้วยวิธีตอกโดยตรง พบว่า ยาเม็ดที่ผลิตจากแกรนูลซึ่งมี polyvinylpyrrolidone และ gelatin เป็นสารยึดเกาะเท่านั้นที่มีอัตราการละลายของตัวยาได้มาตรฐาน และเมื่อนำยาเม็ดเหล่านี้มาเก็บไว้ในสภาพธรรมดา และที่ความชื้นสัมพัทธ์ระดับต่าง ๆ กัน เป็นระยะเวลา 3 เดือนที่อุณหภูมิห้องพบว่า ความแข็งของยาเม็ดที่ผลิตจากแกรนูลซึ่งมี polyvinylpyrrolidone เป็นสารยึดเกาะจะลดลงอย่างมากที่ระดับความชื้นสูง ๆ แต่ยาเม็ดที่ผลิตจากแกรนูลซึ่งมี gelatin เป็นสารยึดเกาะยังคงคุณสมบัติเดิมได้ดี คุกความชื้นน้อยกว่าและพบว่า หลังจากเก็บแกรนูลไว้ในช่วงเวลา 3 เดือน ยังสามารถนำมาผลิตเป็นยาเม็ด diazepam และ chlorpheniramine maleate ที่มีคุณสมบัติได้มาตรฐานเหมือนเดิมทุกประการ

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จุฬาลงกรณ์มหาวิทยาลัย



พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

DETPON PREECHAGOON : THE PRODUCTION OF TABLET DILUENTS FOR DIRECT COMPRESSION FROM POWDERED SUGAR-TAPIOCA STARCH MIXTURES USING FLUIDIZED BED GRANULATION TECHNIQUE . THESIS ADVISOR : ASSIST.PROF. POJ KULVANICH, Ph.D., 193 pp.

This research is concerned with the assessment of the physical properties of granules prepared from powdered sugar-tapioca starch mixtures using fluidized bed granulation technique. The application of such granules compression process was demonstrated. The mixtures of powdered sugar-tapioca starch at various proportions in the ratio of 1:9 upto 9:1 were employed to prepare the granules by fluidized bed granulation using polyvinylpyrrolidone (PVP), gelatin, methylcellulose, and tapioca starch as the binders.

The moisture of the granules increased with increasing the amount of starch in the granules. Porous, irregular shape granules with narrow size distribution and low density were obtained. The hardness of the compacts increased with increasing the compressional forces. All granules gave low tablet weight variation and friability. But tablets made from sugar-starch-PVP and sugar-starch-gelatin granules showed faster disintegration times than those prepared from sugar-starch-methylcellulose and sugar-starch-starch granules. The mixtures of sugar and starch in the ratio of 1:1, 1:1, 9:1, and 8:2 provided the most satisfactory granule and tablet properties with PVP, gelatin, methylcellulose, and starch, respectively. When these four granule formulations were employed to make diazepam and chlorpheniramine maleate tablets by direct compression process, only the tablets prepared from sugar-starch-PVP and sugar-starch-gelatin met the compendial requirement for dissolution. After storage at room and various relative humidity conditions for three months, the tablets made from sugar-starch-PVP granules tended to be soften when exposed to high humidity. The tablet products prepared from sugar-starch-gelatin granules could retained required properties and exhibited lower moisture absorption during aging. It was also found that the storage granules could be used to produce the tablets with the same qualities of those made from freshly prepared granules.

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ศูนย์วิทยทรัพยากร  
จุฬาลงกรณ์มหาวิทยาลัย



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