

การแปรผันวัตถุติบซึ่งเป็นตัวยาสำคัญต่อคุณสมบัติของ
ยาเตรียมในรูปแบบเจลละตินแคปซูลชนิดแข็ง



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VARIATION OF ACTIVE RAW MATERIALS
ON PROPERTIES OF HARD GELATIN CAPSULE DOSAGE FORM



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พิมพ์ต้นฉบับบทคัดย่อวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

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การศึกษาคุณสมบัติทางกายภาพของวัตถุดิบที่ใช้เป็นตัวยาสำคัญ ได้แก่ Tetracycline Hydrochloride, Cimetidine และ Mefenamic Acid จากต่างแหล่งที่มา แสดงให้เห็นว่าไม่มีความแตกต่างกัน ยกเว้น bulk density, tapped density และ compressibility ส่วนการละลายของ Cimetidine ซึ่งเป็นตัวยาที่ละลายน้ำได้เล็กน้อย และ Mefenamic Acid ซึ่งเป็นตัวยาที่ไม่ละลายน้ำ ปรากฏว่าตัวยาจากต่างแหล่งที่มาแสดงอัตราการละลายที่มีความแตกต่างกัน แต่ Tetracycline Hydrochloride ซึ่งเป็นตัวยาที่ละลายน้ำได้ดีแสดงอัตราการละลายที่ไม่แตกต่างกันอย่างมีนัยสำคัญ

เมื่อนำตัวยาสำคัญทั้ง 3 ชนิดมาผลิตในรูปยาเตรียมเจลละตินแคปซูลชนิดแข็ง การประเมินคุณสมบัติทางกายภาพของยาเตรียมทั้ง 3 ชนิดแสดงผลอยู่ในเกณฑ์มาตรฐานที่กำหนดในแล็บซ์ดำรับ ในกรณีที่มีการเปลี่ยนแปลงแหล่งที่มาของวัตถุดิบที่เป็นตัวยาสำคัญ ปรากฏว่า Tetracycline Hydrochloride ยังคงให้ยาเตรียมที่มีคุณสมบัติทางกายภาพอยู่ในเกณฑ์มาตรฐานในแล็บซ์ดำรับ ส่วนการเปลี่ยนแปลงแหล่งที่มาของ Cimetidine และ Mefenamic Acid อาจทำให้ยาเตรียมมีคุณสมบัติทางกายภาพเปลี่ยนแปลงไปจนไม่อยู่ในเกณฑ์มาตรฐานของแล็บซ์ดำรับได้



ภาควิชาเภสัชอุตสาหกรรม.....
สาขาวิชา -
ปีการศึกษา 2534

ลายมือชื่อนิสิต พ.ศ. ๒๕๓๔
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พิมพ์ต้นฉบับบทความวิทยานิพนธ์ภายในกรอบสี่เหลี่ยมนี้เพียงแผ่นเดียว

SUPANG WONGKHAN, MAJ. : VARIATION OF ACTIVE RAW MATERIALS ON PROPERTIES OF HARD GELATIN CAPSULE DOSAGE FORM. THESIS ADVISOR : ASSOCIATE PROF. PREEYA ATMIYANAN, 141 PP., ISBN 974-579-844-4

The study of physical properties of Active Raw Materials Tetracycline Hydrochloride, Cimetidine and Mefenamic Acid from various sources showed no difference among the sources except bulk density, tapped density and compressibility. Cimetidine which is a water slightly soluble drug and Mefenamic Acid which is a water insoluble drug, showed statistically significant differences in dissolution rate while Tetracycline Hydrochloride which is a water soluble drug showed no difference.

Evaluation of the physical properties of the experimental capsules, results from this study showed that all the lots investigated conformed to the requirements of the pharmacopeias. When the source of active raw materials had been altered, the results showed that Tetracycline Hydrochloride Capsules still showed the physical properties within the pharmacopeia requirement. The variation of sources of Cimetidine and Mefenamic Acid may changed the physical properties exceed the compendial limit.



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ABBREVIATIONS

| | |
|------|-----------------------------|
| BP | British Pharmacopeia |
| cm | centimeter |
| °C | degree celsius |
| g | gram |
| GMP | Good Manufacturing Practice |
| mg | milligram |
| ml | milliliter |
| min | minute |
| mm | millimeter |
| M | Molarity |
| S.D. | Standard deviation |
| µm | micrometer |
| USP | United States Pharmacopeia |