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FORMULATION, RELEASE AND STABILITY STUDIES
OF DICLOFENAC TOPICAL DOSAGE FORMS

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จากการศึกษาพบว่า ไดโครฟีแนคโซเดียม และไดโครฟีแนคไดเอทิลแอมโมเนียม มีรูปร่าง
และขนาดผลึกทางจุลภาค อินฟราเรดสเปกตรัม ค่าการละลาย ความคงตัวและปริมาณที่ถูกปลดปล่อยจากยา-
เตรียมแตกต่างกัน ลำดับความคงตัวของยา คือ พีเอช 9 > พีเอช 8 > พีเอช 7 ~ พีเอช 6 >> พีเอช
5 องค์ประกอบของส่วนน้ำมันในตำรับครีมชนิดน้ำมันในน้ำ ชนิดและปริมาณของสารก่อเจลในตำรับเจล
รวมทั้งปริมาณน้ำมันในตำรับครีมและเจลน้ำ-น้ำมัน มีผลต่อการปลดปล่อยตัวยาวอย่างมีนัยสำคัญ ไดโคร-
ฟีแนคโซเดียม ถูกปลดปล่อยจากตำรับครีมชนิดซี (ประกอบด้วย กรดลัเตอริก สเปอร์มาลิตี และ ไวท์ซีส์-
แวก) น้อยกว่าไดโครฟีแนคไดเอทิลแอมโมเนียมแต่ในเจลโซเดียมซีเอ็มซีจะถูกปลดปล่อยออกมามากกว่า
อย่างมีนัยสำคัญ ลำดับการปลดปล่อยตัวยาว จากยาเตรียมรูปแบบต่าง ๆ คือ เจลโซเดียมซีเอ็มซี >
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ลายมือชื่อนิสิต
ลายมือชื่ออาจารย์ที่ปรึกษา
ลายมือชื่ออาจารย์ที่ปรึกษาร่วม

##C375190 : MAJOR MANUFACTURING PHARMACY

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Diclofenac sodium (DS) and diclofenac diethylammonium (DE) were different in microscopic appearance, IR spectra, solubility, stability and the release from topical preparations. The general rank order of drug stability was pH 9 > pH 8 > pH 7 ~ pH 6 >> pH 5. The composition of oil phase in o/w creams, type and percent of gelling agent in hydrophilic gels significantly affected the release of drug. The percent of oil phase in o/w creams and oil-water gels also significantly affected the release. The release of DS from oil phase B cream containing spermaceti, stearic acid and white beeswax was significantly less than of DE but shown the reverse in sodium CMC gel. The general rank order of the release of drug was sodium CMC gel > commercial products (A, B and C) > oil-water gel ~ poloxamer gel > o/w cream.

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ลายมือชื่อนิสิต.....

ลายมือชื่ออาจารย์ที่ปรึกษา.....
Garnpimol C. Ritthidej

ลายมือชื่ออาจารย์ที่ปรึกษาร่วม.....



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ABBREVIATION

alc.	Alcohol
°C	Degree Cencius
Ceto. 1000	Cetomacrogol 1000
cm	Centimetre
DE	Diclofenac dietylammonium
DS	Diclofenac sodium
Ea	Energy of activation
g.	Gram
HLB	Hydrophilic-Lipophilic Balance
hr	Hour
IPA	Isopropyl alcohol
IPM	Isopropyl myristate
K	Kelvin (absolute temperature)
mcg	Microgram
mcl	Microlitre
MFA	Mefenamic acid
mg	Milligram
min	Minute
mL	Mililitre
mm	Milimetre
mh	Month
N	Normality
PHC	PEG-40-hydrogenated castor oil
PG	Propylene glycol
PP	Propyl paraben

Sor. Sol.	Sorbitol solution
Sodium CMC	Sodium Carboxymethylcellulose
TEA	Triethanolamine
Temp.	Temperature
wk	Week
WSP	White soft paraffin