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Developing controlled release tablet of Ibuprofen using bentonite as an excipient

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Dedication

I dedicate this thesis for my Parent, My mother who was the Candle in my dark way, who accompanied me with her prayers until I succeeded, The unknown soldier is My father, my only hero, the reason to achieve my dreams, I am proud that I am your daughter and because my father is you, I hope to be a pride for you. In addition, those closest to me from my soul to those who share my mother's bosom, and draw my strength from them, they are my brothers. Also, for my closest person who whenever I lost hope, he never hesitated to help me and did not stop supporting me, Diyar. Finally for all pray for me and who love me honestly without complaining.

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Developing controlled release tablet of Ibuprofen using bentonite as an excipient

Prepared by Sind Mohammed Rashid

Supervisor Dr. Jamal Alyoussef Alkrad

<u>Abstract</u>

Introduction: This study used bentonite in developing and optimizing a controlled release multiparticulate drug delivery system of Ibuprofen (Ibu). Different granules were prepared using different binders as well as using water only without binder. The flowability of granules was evaluated before compression.

Materials and method: The compatibility between the different components of granules was evaluated using Fourier Transform Infrared Spectroscopy (FTIR). Then, the prepared tablets of these granules were evaluated regarding their mechanical strength and weight uniformity. The dissolution behavior was established in 0.1N HCl medium and phosphate buffer 7.2 pH using HPLC method.

Results and discussion: The granules showed good flowability. Also, FTIR-spectra did not show any interaction between the different components. Furthermore, the prepared tablets complied with their compendia requirements. The tablets released Ibu at constant rate for 16 hr. at least. This behavior was altered after subjecting the tablets to acidic media. However, protecting the tablet by enteric coating using Eudragit could maintain their sustained release behavior.

Conclusion: Bentonite was successfully used in preparing sustained release tablets containing Ibu. However, the enteric coating is important to maintain the gel structure of bentonite by shielding it from the destructive effect of acidic gastric juice.

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List of abbreviations

AUC	Area under the curve
Ben	Bentonite
Ср	Plasma concentration
Ibu	Ibuprofen
fig	Figure
hr	Hour
HCL	Hydrogen chloride
MSC	Maximum safe concentration
MEC	Minimum effective concentration
MDT	Mean dissolution time
NSAID	Non-steroidal anti-inflammatory drug
COX-1 & COX-2	Cyclooxygenase 1 & Cyclooxygenase 2
PEG	Poly ethylene glycol
MCC	Microcrystalline cellulose
HPLC	High Performance Liquid Chromatography
ОТС	over-the counter
FDA	Food and Drug Administration
SR	Sustained release
SB	Sodium bentonite
DSC	Deferential Scanning Calorimeter
USP	United States Pharmacopeia
CI	The CAR's index
HR	Hausner Ratio
UPM	United Pharmaceuticals Manufacturing
r	Correlation coefficient
SD	Standard deviation
Mg	Milligram

L	liter
g	gram
ml	Milliliter
Kg	Kilogram
mm	Millimolar
F	Friability
W	Weight
NaOH	Sodium hydroxide
°C	Celsius
РН	Scale used to specify how acidic or basic a water-based solution
cm	Centimeter
S	Seconds
min	Minute
bar	Metric unit of pressure
FTIR	Fourier Transform Infrared Spectroscopy
р	p-value or probability value
H2O	Water
N	Newton
mm	Millimeter
nm	Nanometer
PVP	Polyvinylpyrrolidone