Preparing diclofenac sodium sustained release tablets using bentonite by wet granulation

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This thesis was submitted in partial fulfillment of the requirements for obtaining a master's degree in pharmaceutical sciences.

College of Graduate Studies

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2019

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Acknowledgment

First of all praise be to Allah, most Gracious, most Merciful, for his unlimited support and favour.

I would like to express my thanks to Dr. Jamal Alyoussef Al –krad and Dr.Ahmad disi my supervisor and head of the department of pharmaceutics, for his wise advices, patience and encouragement throughout all stages of my study.

I am so thankful to college of pharmacy, university of Isra for offering this opportunity to continue my graduate study.

I would like also to express my grateful thanks to my family for their patience, support, help and love.

Finally, I would like to extend my thanks to all others who helped me to finish this work.

Saif A. Alkhalidi

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Abbreviation

AUC	**Area under the curve**
B	**Bentonite**
Cp	**Plasma concentration**
DS	**Diclofenac sodium**
DSC	**Differential scanning colorimetry**
hr	**Hour**
ICH	**International Comity for harmonization**
MPS	**Multi particulate system**
MTC	**Minimum toxic concentration**
MEC	**Minimum effective concentration**
MDT	**Mean dissolution time**
NSAID	**Non-steroidal anti-inflammatory drug**
PVP	**Polyvinylpyrrolidone**
PEG	**Poly ethylene glycol**

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Abstract

This study is designed to employ bentonite to develop and optimize multiparticulate drug delivery system by wet granulation method for preparing controlled release diclofenac sodium tablets. In this study the pharmacopoeial HPLC method were verified for analyzing diclofenac sodium according to International conference on harmonisation (ICH) guidelines (Q2 R1). Also, the use of different binders in preparing Multi particulate system (MPS) with sodium diclofenac was investigated to identify their impact on tablets properties including drug release. The, produced tablets were evaluated regarding their mechanical strength by measuring the hardness and the friability. Furthermore, the tablets were protected from gastric juice using enteric coating then the coating was assessed. Besides, the similarities of our enteric coated formulated tablets with a reference were calculated.

The formulated tablets complied with pharmacopeial requirements. Furthermore, we demonstrated sustained release for 16 hrs at least with similarity factor higher than 50% dissolve of the drug. The developed tablets using bentonite by wet granulation are good candidate for further in vivo evaluation.