

SKRIPSI SARJANA FARMASI

**PEMBENTUKAN KO-AMORF TENOKSIKAM DAN
MEGLUMIN DENGAN METODE *SOLVENT DROP
GRINDING* SERTA KARAKTERISASI SIFAT
FISIKO KIMIA**



Pembimbing 1: Prof. Dr. apt. Erizal, M.Si
Pembimbing 2: apt. Lili Fitriani M.Pharm. SC

FAKULTAS FARMASI
UNIVERSITAS ANDALAS
PADANG
2020

ABSTRAK

PEMBENTUKAN KO-AMORF TENOKSIKAM-MEGLUMIN DENGAN METODE *SOLVENT DROP GRINDING* SERTA KARAKTERISASI FISIKO KIMIA

Oleh :

ZHAFIRAH ARIF

NIM : 1611013023

(Program Studi Sarjana Farmasi)

UNIVERSITAS ANDALAS

Tenoksikam merupakan obat antiinflamasi non stereroid termasuk kelompok oksikam. Tenoksikam termasuk ke dalam Biopharmaceutical Classification System (BCS) kelas II dengan kelarutan rendah dan permeabilitas yang tinggi. Tujuan dari penelitian ini adalah meningkatkan kelarutan dan laju disolusi tenoksikam dengan memodifikasinya menjadi bentuk ko-amorf dengan koformer meglumin (1:1). Pembentukan ko-amorf menggunakan meglumin yang memiliki berat molekul yang rendah dapat meningkatkan stabilitas, kelarutan dan laju disolusi tenoksikam. Pembentukan ko-amorf tenoksikam-meglumin dibuat dengan metode *solvent drop grinding*. Ko-amorf tenoksikam-meglumin dikarakterisasi menggunakan *Powder X-Ray Diffraction* (PXRD), *Differential Scanning Calorimetry* (DSC), spektroskopi FT-IR, mikroskop polarisasi uji kelarutan dan uji laju disolusi. Hasil karakterisasi terlihat adanya penurunan puncak endotermik ko-amorf tenoksikam-meglumin yang terlihat pada termogram DSC, penurunan intensitas puncak difraksi yang membentuk pola difraksi halo pada difraktogram PXRD. Hasil analisa gugus fungsi dengan spektroskopi FT-IR menandakan terbentuknya ko-amorf. Uji kelarutan dilakukan dalam air suling bebas CO₂. Ko-amorf tenoksikam-meglumin menunjukkan peningkatan kelarutan sebesar 42,71 kali dibandingkan tenoksikam murni. Uji disolusi dilakukan dengan alat uji disolusi USP tipe II dalam medium HCl 0,1 N dan air suling bebas CO₂. Ko-amorf tenoksikam-meglumin dengan metode *solvent drop grinding* menunjukkan kadar tenoksikam terdisolusi sebanyak 92,709% pada medium HCl 0,1 N dan 100% air suling bebas CO₂ pada menit ke-60 menit. Ko-amorf tenoksikam-meglumin menunjukkan peningkatan efisiensi disolusi tenoksikam sebanyak 3,05 kali pada medium HCl 0,1 N dan 9,12 kali air suling bebas CO₂.

Kata kunci: tenoksikam, ko-amorf, kelarutan, *solvent drop Grindng*, laju disolusi

ABSTRACT

FORMATION OF CO-AMORPHOUS TENOXICAM-MEGLUMIN BY SOLVENT DROP GRINDING TECHNIQUE AND CHARACTERIZATION OF PHYSICO-CHEMICAL PROPERTIES

By :

ZHAFIRAH ARIF

Student ID Number : 1611013023

(Bachelor of Pharmacy)

Tenoxicam is a thienothiazine derivat belonging to the oxamic acid class of non-steroidal anti-inflammatory drugs. Tenoxicam is classified as a BCS class II with poor solubility in water and good permeability. This study aimed to improve the solubility and dissolution rate of tenoxicam by modifying into a co-amorphous form with meglumine as coformer (1:1). Co-amorphous system using meglumine which has low molecular weight can improving stability, solubility, dissolution rate of tenoxicam. Co-amorphous tenoxicam-meglumine were made by *solvent drop grinding* methods. Co-amorphous tenoxicam-meglumine were characterized by Powder X-Ray Diffraction (PXRD), Differential Scanning Calorimetry (DSC), FT-IR spectroscopy, polarization microscope, solubility study and dissolution test. Endothermic peak of co-amorphous tenoxicam-meglumine decreased as seen on DSC thermograms, intensity of diffraction peak also decreased, which form halo diffraction patterns on XPRD diffractograms. Functional group analysis with FTIR spectroscopy showed the formation the co-amorphous. The solubility test was carried out in CO₂-free distilled water. Co-amorphous tenoxicam-meglumine with *solvent drop grinding* methods showed an increase in solubility of tenoxicam 42.71 times higher than intact tenoxicam. The dissolution test was carried out using a USP type II dissolution test using 0.1 N HCl and CO₂-free distilled water were used as medium. Co-amorphous tenoxicam-meglumine with solvent drop grinding method showed the tenoxicam was dissolved 92.709 % on 0.1 N HCl medium and 100% CO₂ free distilled water at 60 minutes. Co-amorphous Tenoxicam-meglumine with solvent drop grinding method showed an increase in dissolution efficiency of tenoxicam as much as 3.05 times on 0.1 N HCl medium and 9.12 times on CO₂ free distilled water.

Keywords: tenoxicam, co-amorphous, solubility, *solvent drop Grinding* dissolution rate