CONTROLLED RELEASE DOSAGE FORM COMPRISING QUETIAPINE

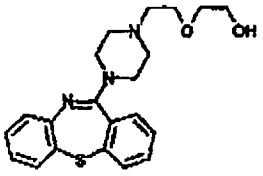
~~PHARMACEUTICAL DOSAGE FORM~~
~~CONTAINING AN ANTIPSYCHOTIC AGENT~~

FIELD OF THE INVENTION

The present invention relates to a novel dosage form and a process for the manufacturing the same. More specifically, the present invention relates to a controlled release oral dosage form comprising an antipsychotic agent.

BACKGROUND OF THE INVENTION

Quetiapine, chemically designated as 2-[2-(4-dibenzo[*b,f*][1,4]thiazepin-11-yl-1-piperazinyl) ethoxy]ethanol (also known as 11-[4-[2-(2-hydroxyethoxy)ethyl]-1-piperazinyl]dibenzo-[b,f][1,4] thiazepine), is a compound of formula (I):



(I)

Quetiapine has been employed as an antipsychotic or neuroleptic agent in the treatment of schizophrenia and bipolar mania, due to its antidopaminergic activity, as well as depressive episodes associated with bipolar disorder. As a combined serotonin ($5HT_2$) and dopamine (D_2) receptor antagonist, quetiapine, including its fumarate salt, is also known for the effective treatment of psychiatric conditions. Quetiapine is a drug of the dibenzothiazepine class and belongs to a group of drugs known as "atypical" or second generation antipsychotics which have become increasingly popular alternatives to "typical" antipsychotics.

When administered orally, quetiapine is rapidly absorbed and generally reaches a peak plasma level within about 1.5 hours. Quetiapine is highly metabolized, with elimination occurring mainly through hepatic metabolism in the liver. The plasma half-life of quetiapine is typically about 5 to about 7 hours. Quetiapine is currently marketed as a