Development and optimization of sublingual films to enhance Oral bioavailability of agomelatine

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Abstract:

Agomelatine is a potent agonist at melatonin receptors and antagonist to serotonin 2c receptors, used to improve the quality of sleep metrics and also an atypical antidepressant. It has poor oral bioavailability i.e 1% because of extensive first pass metabolism. In this work, we aimed to improve the bioavailability of agomelatin by administering via sublingual route which is a promising approach to bypass the first pass effect. Here, agomelatin loaded sublingual films were developed using high water soluble polymers with appropriate levels of plasticizers to get good film properties. Further optimization studies were carried out using response surface methodology by selecting dependent and independent variables. The developed formulations were subjected for *invitro* and *invivo* evaluation, pharmacokinetic studies revealed that the bioavailability of agomelatine was enhanced 7.2 times upon sublingual administration when compared to oral route. These results indicate that fast dissolving sublingual films could be a promising delivery system to improve agomelatine oral bioavailability.

Keywords: Agomelatine, First pass effect, Sublingual route, Fast dissolving films