agonist. The narcotic antagonist binds to a receptor in the brain to block the receptor, thus reducing the effect of the agonist.

One such combination of drugs has been marketed under the trade name Suboxone® as an orally ingestible tablet. However, such combinations in tablet form have the potential for abuse. In some instances, the patient who has been provided the drug may store the tablet in his mouth without swallowing the tablet, then later extract the agonist from the tablet and inject the drug into an individual's body. Although certain antagonists (such as highly water-soluble antagonists) may be used to help reduce the ability to separate the agonist, the potential for abuse still exists. It is desired to provide a dosage that cannot be easily removed from the mouth once it has been administered.

There is currently a need for an orally dissolvable film dosage form that provides the desired absorption levels of the agonist and antagonist, while providing an adhesive effect in the mouth, rendering it difficult to remove once placed in the mouth, thereby making abuse of the agonist difficult.

SUMMARY ~~OF THE INVENTION~~

According to one aspect, there is provided a film dosage composition comprising: (a) a polymeric carrier matrix; (b) a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; (c) a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and (d) a buffer in an amount to provide a local pH for said composition of a value sufficient to optimize absorption of said buprenorphine, wherein said local pH is from about 3 to about 3.5 in the presence of saliva.

According to another aspect, there is provided a method of treating narcotic dependence of a user, comprising the steps of: (a) providing a composition comprising: (i) a polymeric carrier matrix; (ii) a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; (iii) a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and (iv) a buffer in an amount to provide a local pH of about 3 to about 3.5 for said composition of a value sufficient to optimize absorption of said buprenorphine and also sufficient to inhibit absorption of said naloxone; and (b) administering said composition to the oral cavity of a user.

According to another aspect, there is provided an orally dissolving film formulation comprising buprenorphine and naloxone, wherein said formulation provides an in vivo plasma profile having a Cmax of between about 0.624 ng/ml and about 5.638 ng/ml for buprenorphine and an in vivo plasma profile having a Cmax of between about 41.04 pg/ml to about 323.75 pg/ml for naloxone.

According to another aspect, there is provided a use of a composition comprising: (i) a polymeric carrier matrix; (ii) a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; (iii) a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and (iv) a buffer in an amount to provide a local pH of about 3 to about 3.5 for said composition of a value sufficient to optimize absorption of said buprenorphine and also sufficient to inhibit absorption of said naloxone; for the manufacture of a medicament for treating narcotic dependence of a user, wherein said composition is to be administered to the oral cavity of the user.

In one embodiment of the present ~~invention~~disclosure, there is provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount to provide a pH of the composition of a value sufficient to optimize absorption of the buprenorphine.

In another embodiment of the present ~~invention~~disclosure, there is provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffer in an amount sufficient to inhibit the absorption of the naloxone when administered orally.

In still other embodiments, there may be provided a film dosage composition including: a polymeric carrier matrix; a therapeutically effective amount of buprenorphine or a pharmaceutically acceptable salt thereof; a therapeutically effective amount of naloxone or a pharmaceutically acceptable salt thereof; and a buffering system; where the buffering system includes a buffer capacity sufficient to