Thus, it is still desirable to provide a more efficient way to produce a bioactive containing sheet so as to allow the absorption of the bioactive agent. This is accomplished using a slab or sheet dosage form as put forth below.

BREIF SUMMARY OF THE DISCLOSURE~~INVENTION~~

The present disclosure~~invention~~ relates to a nonaqueous, extrudable composition comprising at least one thermoplastic polymer in an amount of more than 20 wt% of the whole composition and a bioactive agent.

In one aspect, there is provided a nonaqueous, extrudable composition comprising at least one thermoplastic polymer in an amount of more than 20 wt% of the whole composition, a bioactive agent other than tobacco and an ion exchange resin, the composition not containing polycarbophil.

The present disclosure~~invention~~ also relates to a pharmaceutical product comprising a sheet made by extruding or hot melt shaping a nonaqueous composition comprising at least one thermoplastic polymer and one or more bioactive ingredients, the sheet comprising a matrix comprising the at least one thermoplastic polymer and one or more bioactive ingredient(s) distributed in the matrix, the matrix being soluble in a user's mouth and resulting in sustained release of the bioactive to the user.

The present disclosure~~invention~~ also relates to a pharmaceutical product comprising a non aqueous composition comprising at least one thermoplastic polymer and one or more bioactive ingredients in a form that may be placed on any of the mucosa, e.g., oral (buccal, gingival, sublingual or palatal), nasal, rectal or vaginal of a user and having an average dissolution time of 5 to 50 minutes, measured for a composition in the form of a sheet having a surface area of approximately .25-1.5 in^2 and a thickness of approximately 10-70 mil, to dissolve fully.

The present disclosure~~invention~~ also relates to a pharmaceutical product comprising a matrix with one or more bioactive ingredients in an amount of less than 1000 mg, preferably less than 500 mg, more preferably less than 300 mg. The present disclosure~~invention~~ also relates to a method for making a pharmaceutical product, comprising extruding a nonaqueous composition comprising at least one thermoplastic polymer in an amount of more than 20 wt% the whole composition and one or more bioactive ingredients through an extruder to form an extruded slab or sheet of the nonaqueous composition.

In another aspect, there is provided a method for making a pharmaceutical product, comprising extruding a nonaqueous composition comprising at least one thermoplastic polymer in an amount of more than 20 wt% the whole composition, a bioactive agent other than tobacco and an ion exchange resin, the composition not containing polycarbophil, through an extruder to form an extruded sheet of the nonaqueous composition.

The present disclosure~~invention~~ also relates to a method for delivering super bioavailable bioactives from a pharmaceutical product containing one or more bioactives to a user, comprising providing a sheet comprising an extruded nonaqueous composition comprising at least one thermoplastic polymer and

such bioactive ingredient(s); and placing the sheet in the buccal mucosa of, or on the palate of or sublingual mucosa in the oral cavity of the user.

The present disclosure~~invention~~ also relates to a method for delivering super Bioavailable bioactives from a pharmaceutical product containing one or more bioactives to a user, comprising providing a sheet comprising an extruded nonaqueous composition comprising at least one thermoplastic polymer and ion exchange resins in conjunction with bioactive ingredient(s); and placing the sheet on any of the mucosa, e.g., oral (buccal, gingival, sublingual or palatal), nasal, rectal or vaginal or on or in a wound of the user.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a schematic diagram showing one example of a mixing process that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 2 is a schematic diagram showing one example of an extrusion process that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 3 is a schematic diagram showing one example of a small scale extrusion process that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 4 is a schematic diagram showing one example of a medium scale extrusion process that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 5 is a schematic diagram showing one example of a large scale extrusion process that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 6 is a schematic diagram showing one example of an extrusion process with optional compression rollers that can be used in the manufacturing method for the pharmaceutical product of the present invention.

Fig. 7 is a graph showing nicotine plasma concentration vs. time curves obtained on consumption of four different snus brands and a 2 mg nicotine chewing gum according to the Gothiatek cited Lunell study