

Such a concentrated application of an active pharmaceutical ingredient directly onto the mucous membrane can be achieved with dosage forms which contain the active pharmaceutical ingredient in a sheet like, in particular film shaped, foil shaped or wafer shaped preparation, in particular as a so-called wafer. Drawbacks of conventional wafers are, particularly, that known wafers dissolve partially or completely before the site of action and in particular for e.g. intestinal, rectal or vaginal wafers no contact with the mucous membrane can be guaranteed. Moreover, for e.g. intestinal, rectal and vaginal multilayered wafers no contact with the correct site of the wafer and in particular no sufficiently long contact with the mucous membrane can be guaranteed.

Summary

In one aspect, the present invention refers to a pharmaceutical dosage form for the application to a gastrointestinal, in particular an esophageal, mucous membrane, comprising at least one sheet-like preparation comprising an active pharmaceutical ingredient, a release mechanism and a trigger mechanism, wherein the trigger mechanism is adapted to trigger, at a predetermined site of action of the gastrointestinal tract, the release of the sheet-like preparation by the release mechanism, wherein the pharmaceutical dosage form further comprises a shell, wherein the shell contains the sheet-like preparation comprising the active pharmaceutical ingredient, and wherein the shell comprises at least one aperture configured such that the sheet-like preparation is releasable from the shell through the aperture upon release of the sheet-like preparation, wherein the aperture is formed as a slit and/or the aperture is at least partially covered by the trigger mechanism, wherein the aperture forms a part of the release mechanism configured to allow said preparation to leave the shell, such that the sheet-like preparation is unrolled or unfolded while the dosage form moves down the esophageal mucous membrane and leaves the shell through the aperture.

Detailed Description

It is an object of the present invention to provide a pharmaceutical dosage form that overcomes the aforementioned drawbacks.

It is a further object of the present invention to provide a pharmaceutical dosage form that enhances the bioavailability of active pharmaceutical ingredients contained in dosage forms which are administered, in particular orally, vaginally or rectally.

It is yet a further object of the present invention to provide a pharmaceutical dosage form, in particular a dosage form containing the active pharmaceutical ingredient in a sheet like, in particular film shaped, foil shaped or wafer shaped, preparation, preferably a wafer, in which a release of the active pharmaceutical ingredient at its predetermined site of action is achieved and the amount of the active pharmaceutical ingredient available for resorption is increased, and/or an enhanced bioavailability and/or an enhanced rate of resorption is achieved.

In particular, it is an object of the present invention to provide a rapidly releasing dosage form with a systemic effect. Finally, it is yet a further object of the invention to provide a dosage form that makes it possible to apply active pharmaceutical ingredients, which cannot be administered orally due to poor bioavailability, at a predetermined site of action.

Especially, the present invention relates to a pharmaceutical dosage form for the application, preferably to an upper gastrointestinal tract such as throat, esophagus, cardia and/or stomach, and particularly to the respective mucous membranes, that

Claims:

1. A pharmaceutical dosage form for the application to a gastrointestinal, in particular an esophageal, mucous membrane, comprising
5 at least
one sheet-like preparation comprising an active pharmaceutical ingredient,
a release mechanism and
a trigger mechanism, wherein
10 the trigger mechanism is adapted to trigger, at a predetermined site of action of the gastrointestinal tract, the release of the sheet-like preparation by the release mechanism,
wherein the pharmaceutical dosage form further comprises a shell, wherein the shell contains the sheet-like preparation comprising the active
15 pharmaceutical ingredient, and wherein the shell comprises at least one aperture configured such that the sheet-like preparation is releasable from the shell through the aperture upon release of the sheet-like preparation, wherein the aperture is formed as a slit and/or the aperture is at least partially covered by the trigger mechanism,
20 wherein the aperture forms a part of the release mechanism configured to allow said preparation to leave the shell, such that
the sheet-like preparation is unrolled or unfolded while the dosage form moves down the esophageal mucous membrane and leaves the shell through the aperture.
25
2. The pharmaceutical dosage form according to claim 1, wherein
the trigger mechanism is adapted to trigger the release of the sheet-like preparation by the release mechanism after a contact of the pharmaceutical dosage form with a key stimulus and/or
30 the trigger mechanism is adapted to trigger the release of the sheet-like preparation by the release mechanism in a time controlled manner or immediately and/or

the release mechanism is adapted to release the sheet-like preparation in a time controlled manner or immediately after triggering of the trigger mechanism.

- 5 3. The pharmaceutical dosage form according to any one of the preceding claims, wherein:

the sheet-like preparation provides, after its release by the release mechanism, a relatively large surface area, and comes into contact with a relatively large surface area; and/or

- 10 the release mechanism is adapted to release, at least partially, the sheet-like preparation while moving along the mucous membrane.

4. The pharmaceutical dosage form according to any one of the claims 1 to 3, wherein:

- 15 the release mechanism comprises a string member;

the string member being expandable from a compact form, which is a folded, collapsed, rolled or coiled up form, to an expanded form, which is an unfolded, spread out, opened up, elongated, stretched, unrolled or oblong form, upon activation of the release mechanism; and

- 20 the string member comprises, at least in the compact form, the sheet-like preparation, or wherein:

the release mechanism is an expansion mechanism and an elongation mechanism adapted to unfold, elongate, uncoil, unroll or unwind the sheet-like preparation by leveraging an external movement, force or pressure.

25

5. The pharmaceutical dosage form according to any one of the claims 1 to 4, wherein the trigger mechanism is a holding device that is a part of or is attached to the sheet-like preparation.

- 30 6. The pharmaceutical dosage form according to claim 5, for oral administration, wherein the trigger mechanism and the holding device are adapted to be fixed in an oral cavity and/or to be held in a hand during administration of the pharmaceutical dosage form.

7. The pharmaceutical dosage form according to any one of the preceding claims, for oral administration, wherein, at least during the release of the sheet-like preparation, the released portion of the sheet-like preparation and the dosage form move relative to each other thereby defining a movement path (PM) of the dosage form, and the enveloping cross-sectional area (AD) of the dosage form, viewed in the direction of the movement path is larger than the enveloping cross-sectional area (AP) of the released part of the sheet-like preparation.
8. The pharmaceutical dosage form according to any one of the preceding claims wherein the sheet like preparation is film shaped, foil shaped or wafer shaped.
9. The pharmaceutical dosage form according to claim 1, wherein in an initial state of the dosage form, the sheet like preparation is in a compact form.
10. The pharmaceutical dosage form according to claim 1, wherein the release mechanism is formed by the part of the sheet like preparation that is inside the shell and the aperture.
11. The pharmaceutical dosage form according to claim 5, wherein the holding device is adapted to be fixed in an oral cavity by gluing it to buccal mucosa.
12. The pharmaceutical dosage form according to claim 5, wherein the holding device is connected to the sheet-like preparation or is a broadened part of the sheet-like preparation comprising mucoadhesive polymers.