There is therefore a need for a stable composition of duloxetine with a suitable release profile, which is obtainable in a simple, economical process.

It has been surprisingly found that stable enteric-coated compositions of duloxetine with bioavailability and release profile corresponding to the commercially available duloxetine compositions, can be prepared without exposing duloxetine to the contact with granulation liquids and without application of a separating coating. The present inventors have found, that it is possible to obtain enteric-coated tablets of duloxetine, wherein the core is directly coated with a single enteric coating and wherein the active ingredient remains stable throughout the period of storage, and which can be prepared in a simple and economical process.

The present invention provides an enteric-coated tablet of duloxetine consisting of:

- a core comprising duloxetine hydrochloride, which is blended uniformly without the use of any liquid with compressible sugar as defined in the monograph of the British Pharmacopoeia 2013, Volume II, pages 2117-2118, the amount of said compressible sugar being 60-85% by weight calculated on the total weight of the core, and optionally with one or more pharmaceutically acceptable excipients, and

- an enteric coating applied directly on the core and comprising methacrylic acid-ethyl acrylate copolymer (1:1) as the only polymer resistant to gastric acid and one or more pharmaceutically acceptable excipients.

The present invention also provides an enteric-coated duloxetine tablet consisting of:

- a core comprising duloxetine hydrochloride, which is blended uniformly without the use of any liquid with compressible sugar containing 95-98% by weight of sucrose and 2-5% by weight of maltodextrin or dry glucose syrup, the amount of said compressible sugar being 60-85% by weight calculated on the total weight of

the core, and optionally with one or more pharmaceutically acceptable excipients, and

- an enteric coating applied directly on the core and comprising methacrylic acid-ethyl acrylate copolymer (1:1) as the only polymer resistant to gastric acid and one or more pharmaceutically acceptable excipients.

In a preferred embodiment, the percentage of the compressible sugar is 65-70% by weight, and still more preferably 67% by weight calculated on the total weight of the core.

The compressible sugar, also described in the art as a directly compressible sugar or direct compacting and tableting sugar, in the context of this invention means a substance as defined in the monograph of the British Pharmacopoeia 2013, Volume II, pages 2117-2118. The compressible sugar is defined here as containing

Claims

1. Enteric-coated duloxetine tablet consisting of:

   - a core comprising duloxetine hydrochloride, which is blended uniformly without the use of any liquid with compressible sugar containing 95-98% by weight of sucrose and 2-5% by weight of maltodextrin or dry glucose syrup, the amount of said compressible sugar being 60-85% by weight calculated on the total weight of the core, and optionally with one or more pharmaceutically acceptable excipients, and

   - an enteric coating applied directly on the core and comprising methacrylic acid-ethyl acrylate copolymer (1:1) as the only polymer resistant to gastric acid and one or more pharmaceutically acceptable excipients.

2. Enteric-coated duloxetine tablet according to claim 1, **characterized in that** the compressible sugar is a spray-dried mixture of sucrose, invert sugar and maltodextrins, wherein the percentage of sucrose is 95-98% by weight, and the percentage of invert sugar and maltodextrins amounts in total 2-5% by weight, calculated on the total weight of the compressible sugar.

3. Enteric-coated duloxetine tablet according to claims 1 or 2, **characterized in that** the percentage of the compressible sugar is 65-70% by weight, preferably 67% by weight calculated on the total weight of the core.

4. Enteric-coated duloxetine tablet according to any of the claims 1 to 3, **characterized in that** the percentage of duloxetine hydrochloride is 15-30% by weight, preferably 23% by weight, calculated on the total weight of the core.

5. Enteric-coated duloxetine tablet according to any of the claims 1 to 4, **characterized in that** one or more pharmaceutically acceptable