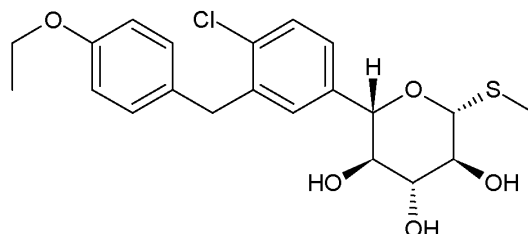
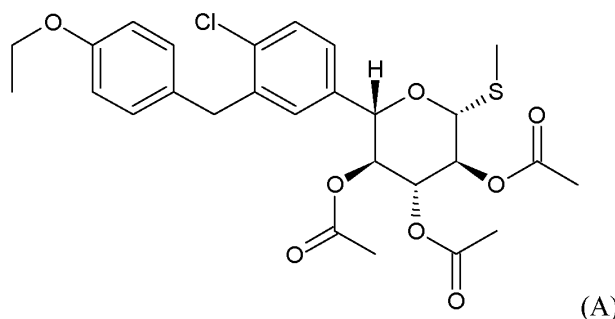


CLAIMS

1. A process for the preparation of the crystalline form II of sotagliflozin:



- 5 from the following compound of formula (A):



said process being continuously performed and comprising at least the steps of:

- a) performing in a reaction chamber the reaction of said compound of formula (A) in solution in toluene or in xylene or in mixture thereof, and at least sodium methoxide and methanol, at a temperature below the boiling point of methanol, to form sotagliflozin in mixture with sodium salts;
 - b) conducting in a crystallization chamber the crystallization of sotagliflozin formed in step a), in a non-aqueous solvent medium including at least toluene, or xylene, or mixture thereof, and free of sodium salts, at a temperature of crystallization of the form II of sotagliflozin; and
 - c) isolating the crystalline form II of sotagliflozin.
2. The process according to claim 1, wherein said compound of formula (A) in step a) is in solution in toluene.
3. The process according to claim 1 or 2, wherein the non-aqueous solvent medium in step b) includes at least toluene.

4. The process according to any one of the preceding claims, wherein the temperature in step a) is below 65°C, and preferably below 63°C, at the atmospheric pressure.

5. The process according to any one of the preceding claims, wherein the time of residence in the reaction chamber is of at least 10 minutes, in particular of at least 15 minutes, preferably of at least 20 minutes and more preferably of at least 30 minutes.

6. The process according to any one of the preceding claims, comprising additional steps between steps a) and b), of removing sodium salts from the medium obtained at the end of step a) by aqueous washing of said medium, and followed by dehydration of said medium.

7. The process according to the preceding claim, wherein the medium is dehydrated by evaporation.

8. The process according to any one of the preceding claims, wherein the temperature in step b) is from 60°C to 70°C, preferably from 62°C to 67°C, and is more preferably 65°C, at the atmospheric pressure.

9. The process according to any one of the preceding claims, wherein the crystallization chamber in step b) is sown with pre-existing crystalline form II of sotagliflozin.

10. The process according to any one of the preceding claims, wherein the time of residence in the crystallization chamber is of at least 10 minutes, in particular of at least 15 minutes, preferably of at least 20 minutes, and more preferably of at least 30 minutes.

11. The process according to any one of the preceding claims, wherein the medium obtained in the crystallization chamber is harvested, subjected to a wet milling, and fed back in said crystallization chamber.

12. The process according to any one of the preceding claims, comprising an additional step b'), between steps b) and c), of feeding a subsequent crystallization chamber with the medium obtained at the end of step b), at a temperature below the temperature in the preceding crystallization chamber.

13. The process according to the preceding claim, wherein the temperature in step b') is from 20°C to 30°C, preferably from 20°C to 28°C, and more preferably is 20°C, at the atmospheric pressure.

14. The method according to any one of the preceding claims, wherein the mixture obtained after step b) or after step b') is subjected to filtration and a washing, preferably with toluene or xylene, or mixture thereof, and more preferably with toluene.

15. The process according to the preceding claim, wherein the filtration and
5 washing are followed with a drying step.

16. The process according to the preceding claim, wherein the drying step is performed at a temperature from 45°C to 65°C, and in particular from 50°C to 55°C.

17. The process according to any one of the preceding claims, wherein said reaction and/or crystallization chamber(s) is/are continuous stirred-tank reactor(s).