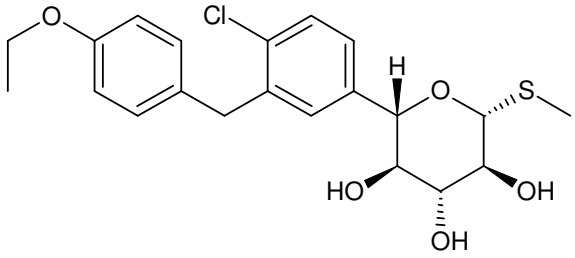
It also remains a need of a new process for the preparation of crystalline Form II of sotagliflozin which would be simple to implement, i.e does not request to carry out discontinuous steps.

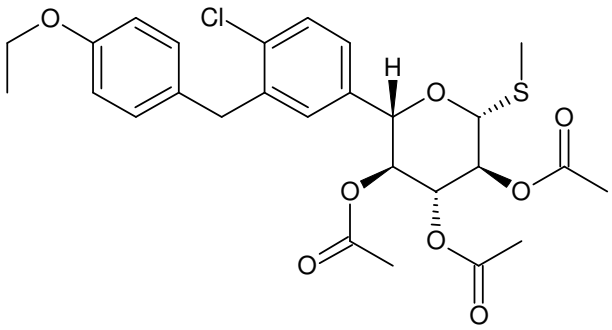
It also remains a need of a new process for the preparation of crystalline Form II of sotagliflozin which could be advantageously performed in a continuous way with the industrial preparation of the precursor of said form II of sotagliflozin.

SUMMARY

In one aspect, the present disclosure provides a process for preparing crystalline form II of sotagliflozin:



from a compound of formula (A):



(A)

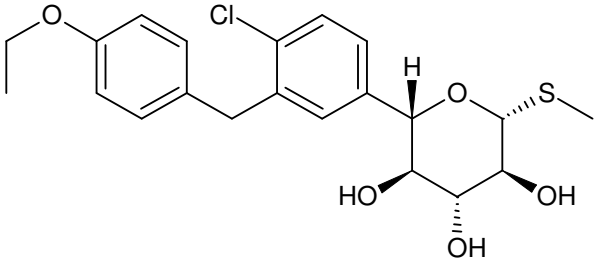
which process comprises:

a) reacting the compound of formula (A) with an alcohol in a non-aqueous solvent medium comprising a base and toluene, xylene, or mixture of toluene and xylene;
b) performing an aqueous washing of the solvent medium;
c) dehydrating the solvent medium;
d) crystallizing form II of sotagliflozin; and
e) recovering the crystalline form II of sotagliflozin;

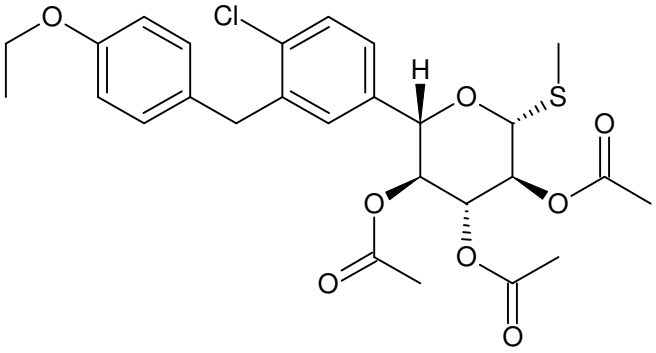
wherein crystalline form II of sotagliflozin has an XRPD pattern containing peaks at 4.4 ± 0.3, 4.8 ± 0.3, 14.5 ± 0.3, 14.7 ± 0.3, 15.5 ± 0.3, 21.2 ± 0.3, 22.1 ± 0.3 and 23.8 ± 0.3 degrees 2θ.

CLAIMS

1. A process for preparing crystalline form II of sotagliflozin:



from a compound of formula (A):



(A)

which process comprises:

a) reacting the compound of formula (A) with an alcohol in a non-aqueous solvent medium comprising a base and toluene, xylene, or mixture of toluene and xylene;

b) performing an aqueous washing of the solvent medium;

c) dehydrating the solvent medium;

d) crystallizing form II of sotagliflozin; and

e) recovering the crystalline form II of sotagliflozin;

wherein crystalline form II of sotagliflozin has an XRPD pattern containing peaks at 4.4 ± 0.3, 4.8 ± 0.3, 14.5 ± 0.3, 14.7 ± 0.3, 15.5 ± 0.3, 21.2 ± 0.3, 22.1 ± 0.3 and 23.8 ± 0.3 degrees 2θ.

2. The process of claim 1, wherein the base is sodium methoxide.

3. The process of claim 1, wherein the solvent medium further comprises methanol.

4. The process of any of the preceding claims, wherein step a) is performed at a temperature below the boiling point of methanol.

5. The process according to claim 4, wherein step a) is performed at a temperature below 65°C at atmospheric pressure.

6. The process of claim 5, wherein the temperature is below 63°C.

7. The process of any of the preceding claims, wherein step c) is performed by evaporation.

8. The process of any of the preceding claims, wherein step d) is performed at the temperature of the crystallization of form II of sotagliflozin.

9. The process of any of claims 1-7, wherein step d) is performed at a temperature of from 60°C to 70°C at atmospheric pressure.

10. The process of claim 9, wherein the temperature is from 62°C to 67°C.

11. The process of claim 10, wherein the temperature is 65 °C.

12. The process according to any of the preceding claims, wherein the formation of crystalline form II of sotagliflozin is initiated with pre-existing crystalline form II of sotagliflozin.

13. The process according to any of the preceding claims, wherein step d) is followed by filtration and washing.

14. The process of claim 13, wherein the washing is done with toluene, xylene, or a mixture of toluene and xylene.

15. The process of claim 13, wherein the filtration and washing are followed by a drying step.

16. The process according to claim 15, wherein the drying step is performed at a temperature of from 45°C to 65°C at atmospheric pressure.

17. The process according to claim 16, wherein the temperature is from 50°C to 55°C.