The allulose developed by the inventors is in the form of granules, is compressible, and allows the preparation of tablets having hardness greater than 50 N.

There was no hint in the prior art suggesting allulose acting as a direct compression excipient. A fortiori, there was no hint in the prior art suggesting that this allulose needed to be in the form of granules.

## OBJECT

It was thus an object of the present invention to provide directly compressible compositions comprising significant amounts of allulose.

It was another object of the invention to provide tablets based on allulose, i.e. tablets exhibiting high amounts of allulose, and at the same time, satisfying hardness.

## BRIEF DESCRIPTION OF THE INVENTION

The present disclosure thus first relates to granules of allulose which are compressible in the sole presence of a lubricant, to form a tablet having a diameter of 13 mm, a thickness of 6 mm, an apparent density of 1.35 g/ml ± 0.02 g/ml, a cylindrical shape with convex faces with a radius of curvature of 13 mm, whose hardness is greater than 50 N.

The present disclosure also relates to the use of granules of allulose as disclosed herein as a direct compression excipient in a directly compressible composition.

In one aspect, the present disclosure relates to the use of granules of allulose which are compressible in the sole presence of a lubricant, to form a tablet having a diameter of 13 mm, a thickness of 6 mm, an apparent density of 1.35 g/ml ± 0.02 g/ml, a cylindrical shape with convex faces with a radius of curvature of 13 mm, whose hardness is greater than 50 N, preferably greater than 60 N, preferably greater than 70 N, preferably greater than 80 N, preferably greater than 90 N, preferably greater than 100 N, even more preferably greater than 110 N as a direct compression excipient in a directly compressible composition.

In another aspect, the present disclosure also relates to a directly compressible composition comprising the granules of allulose as disclosed herein.

In another aspect, the present disclosure also relates to a method for the manufacture of granules of allulose as disclosed herein, comprising:

- a step (a) of preparing a granulation liquid comprising allulose;
- a step (b) of granulating powdery allulose, by applying the granulation liquid obtained in step (a) onto moving powdery allulose;
- a step (c), preferably simultaneous with step (b), of drying the granules obtained in step (b);

- an optional step (c') of maturation of the granules obtained in step (c);
- a step (d) of recovering the granules obtained in step (c) or (c').

In a further aspect, the present disclosure relates to granules of allulose obtainable by the method as disclosed herein.

In another aspect, the present disclosure further relates to a method for the manufacture of a tablet, comprising the steps of: providing a directly compressible composition as disclosed herein; followed by directly compressing said composition to form the tablet.

In yet another aspect, the present disclosure relates to a tablet composed of a directly compressible composition as disclosed herein, or obtained by the method for the manufacture of a tablet as disclosed herein.

## DETAILED DESCRIPTION OF THE INVENTION

The inventors succeeded in obtaining compositions based on allulose, suitable for direct compression, as evidenced in Example 1. These directly compressible compositions allowed the preparation of tablets having hardness greater than 50 N. They comprised 99 % by weight of allulose, and no other direct compression excipient was required to obtain these results.

This allulose was obtained through a process of granulation that can be advantageously carried out by solely using water and allulose.

Granulation refers to the act or process in which primary powder particles are made to bind each other to form multiparticulate agglomerates called granules. It is the process of collecting particles together by creating bonds between them. The two principal types of granulation technologies are wet granulation and dry granulation.

In wet granulation, granules are formed by the addition of a granulation liquid onto a powder bed which is under the influence of an impeller (in a High or Low shear granulator), screws (in a twin screw granulator), a rotating device (for instance a rotating

pan or a rotating drum), or even preferably, air (in a fluidized bed granulator or in a spray-drier). The agitation and the wetting of the primary powder along the system results in the aggregation of the particles composing said primary powder to produce wet granules. The granulation liquid is removed by drying. The granulation liquid can be

**Claims**

1. Use of granules of allulose which are compressible in the sole presence of a lubricant, to form a tablet having a diameter of 13 mm, a thickness of 6 mm, an apparent density of 1.35 g/ml ± 0.02 g/ml, a cylindrical shape with convex faces with a radius of curvature of 13 mm, whose hardness is greater than 50 N, preferably greater than 60 N, preferably greater than 70 N, preferably greater than 80 N, preferably greater than 90 N, preferably greater than 100 N, even more preferably greater than 110 N as a direct compression excipient in a directly compressible composition.

2. The use of claim 1, wherein the granules of allulose are further used as a sweetener, and/or a low-calorie sweetener.

3. A method for the manufacture of granules of allulose , comprising:

- a step (a) of preparing a granulation liquid comprising allulose;
- a step (b) of granulating powdery allulose, by applying the granulation liquid obtained in step (a) onto moving powdery allulose;
- a step (c), preferably simultaneous with step (b), of drying the granules obtained in step (b);
- an optional step (c') of maturation of the granules obtained in step (c);
- a step (d) of recovering the granules obtained in step (c) or (c').

4. Granules of allulose obtainable by the method of claim 3.

5. A directly compressible composition, comprising the granules of allulose of claim 4.

6. The directly compressible composition of claim 5, wherein said granules of allulose represent at least 30 % of the directly compressible composition, preferably at least 40 %, preferably at least 50 %, preferably at least 60 %, preferably at least 70 %, preferably at least 80 %, preferably at least 90 %, typically between 90 and 99 %, even between 95 and 99 %, said percentage being expressed in dry weight, with respect to the total dry weight of said directly compressible composition.

7. The directly compressible composition according to any one of claims 5 or 6, comprising no more than 60 % of direct compression excipients other than said granules of allulose, preferably no more than 50 %, preferably no more than 40 %, preferably no more than 30 %, preferably no more than 20 %, preferably no more than 10 %, preferably no more than 5 %, more preferably no more than 2 %, and most preferably

0 %, said percentage being expressed in dry weight, with respect to the total dry weight of said directly compressible composition.

8. A method for the manufacture of a tablet, comprising the steps of: providing a directly compressible composition according to any one of claims 5 to 7; followed by directly compressing said composition to form the tablet.

9. A tablet composed of a directly compressible composition such as defined in any one of claims 5 to 7, or obtained by the method of claim 8.