

Description

The invention relates to a method of preparing a solid composition for the administration of lactulose and to the composition so obtained.

It is known that lactulose, an isomerisation product of lactose, is particularly suitable for the treatment of inter alia chronic constipation and hepatic coma. Usually lactulose in the form of a 50% solution of lactulose in water is used. However, the use of lactulose in the form of such a syrup is far from ideal.

Furthermore, the use of lactulose in a crystalline form is known. However, the crystallisation process of lactulose proceeds particularly laborious.

Finally British patent application 2,156,196 relates to compositions of therapeutic or dietetic use comprising vegetable fibre and lactulose. The two components should demonstrate a strong reciprocal synergic effect. Vegetable fibre or dietetic fibre as used in this composition contains between 11 and 22% of fibre, known as "active" fibre or "raw fibre". By means of a number of other components this known composition may be processed in the form of dietetic products, in particular in the form of biscuits.

It is the object of the present invention to provide an easy method for the preparation of a solid composition for the administration of lactulose.

It has been found that a solid composition for the administration of lactulose can be obtained by providing lactulose syrup on a moisture-absorbing fibre product as a carrier for the lactulose syrup. Conventionally used carrier materials for liquid medicines, for example, aerosil, lactose and CaHPO_4 have proved to be unfit for this purpose.

Also vegetable fibrous materials (i.e. raw fibre) cannot be used as a moisture-absorbing carrier for the preparation of a solid composition for the administration of lactulose.

It has been found in particular that the diet fibre product based on the husks of corn grains, which has a fibre content of more than 80% by weight, known as Fiberform® can very well be used as a carrier material in order to prepare in a simple manner a suitable solid composition for the administration of lactulose from lactulose syrup. Fiberform is used as an agent to control the intestinal activity. It is a granulate of a conditioned fibre-concentrate, manufactured from wheat bran through a selective three-stage enzymatic fermentation process. In phase 1 (proteolysis) the protein content is reduced with proteinase. In phase 2 (starch digestion) the product is treated with amylase to remove practically all starch. In phase 3 (removal of phytic acid) the naturally present enzyme phytase is activated to break down and re-

move over 90% of the phytic acid, which is known to bind essential minerals like iron, zinc, calcium and magnesium. The resulting granulate is of a standardized, reproducible pharmaceutical quality.

The solid composition for the administration of lactulose according to the invention is obtained in a simple manner by mixing the lactulose syrup with the Fiberform carrier material, spreading the mixture, drying it, crushing it and optionally sieving it to the desired grain size.

The preferred starting material is syrup comprising approximately 50% of solid lactulose. A quantity of 150-350 g, in particular 200-300 g, of Fiberform is used per litre of this syrup. The mixture is mixed for a few minutes and spread on a stainless steel plate. After drying for a few hours such as 6 hours at a temperature of 60-90°C, preferably approximately 80°C, the product thus obtained is crushed, for example, in an oscillating granulator, and finally sieved, if so desired, to the desired grain size.

No other auxiliary substances are necessary for the preparation of the solid composition of lactulose according to the invention, which is an advantage for a pharmaceutical product.

It is very surprising that a solid composition for the administration of lactulose can be obtained in such a simple manner.

EXAMPLE

7.5 kg of the diet fibre product Fiberform were mixed with 32 kg of lactulose solution (Duphalac®) in a Collette mixer for 5 minutes. The mixture was distributed over 20 "closed" drying plates and dried for 6 hours with an inlet air of 100°C. After drying for 2 hours and 4 hours respectively the mass was loosened. The dried mass was crushed by means of a Frewitt granulator having a sieve grating of 1.5 mm.

Claims

1. A method of preparing a solid composition of lactulose, characterized in that a lactulose syrup is mixed with the high fibre product Fiberform®, the mixture is spread, dried, crushed and optionally sieved.
2. A method as claimed in Claim 1, characterized in that a syrup comprising 50% of solid lactulose is mixed with a quantity of Fiberform® of 150-350 g per litre of lactulose syrup.
3. A method as claimed in Claim 2, characterized in that 200-300 g of Fiberform® are used per litre of lactulose syrup.



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The preferred starting material is syrup comprising approximately 50% of solid lactulose. A quantity of 150-350 g, in particular 200-300 g, of Fiberform is used per litre of this syrup. The mixture is mixed for a few minutes and spread on a stainless steel plate. After drying for a few hours such as 6 hours at a temperature of 60-90°C, preferably approximately 80°C, the product thus obtained is crushed, for example, in an oscillating granulator, and finally sieved, if so desired, to the desired grain size.

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2. A method as claimed in Claim 1, characterized in that a syrup comprising 50% of solid lactulose is mixed with a quantity of Fiberform® of 150-350 g per litre of lactulose syrup.
3. A method as claimed in Claim 2, characterized in that 200-300 g of Fiberform® are used per litre of lactulose syrup.



4. A method as claimed in Claims 1-3, characterized in that the mixture of lactulose syrup and Fiberform® is mixed for a few minutes, is spread, dried at 60-90 °C for a few hours, the solid product is crushed and optionally sieved.
5. A method as claimed in Claim 4, characterized in that drying is carried out at 80 °C for 6 hours.
6. A solid composition of lactulose and Fiberform® obtainable by mixing a lactulose syrup containing 50% of solid lactulose with a quantity of Fiberform® of 150-350 g per litre of lactulose syrup, and subsequent spreading, drying and crushing of the mixture.

Patentansprüche

1. Verfahren zum Herstellen einer festen Lactulosezusammensetzung, dadurch gekennzeichnet, daß ein Lactulosesirup mit dem Hochfaserprodukt Fiberform® gemischt, die Mischung verteilt, getrocknet, zerkleinert und gegebenenfalls gesiebt wird.
2. Verfahren nach Anspruch 1, dadurch gekennzeichnet, daß ein 50 % feste Lactulose umfassender Sirup mit einer Menge von 150 bis 350 g Fiberform® pro Liter Lactulosesirup gemischt wird.
3. Verfahren nach Anspruch 2, dadurch gekennzeichnet, daß 200 bis 300 g Fiberform® pro Liter Lactulosesirup verwendet werden.
4. Verfahren nach den Ansprüchen 1 bis 3, dadurch gekennzeichnet, daß die Mischung von Lactulosesirup und Fiberform® einige Minuten gemischt, verteilt und einige Stunden bei 60 bis 90 °C getrocknet wird und das feste Produkt zerkleinert und gegebenenfalls gesiebt wird.
5. Verfahren nach Anspruch 4, dadurch gekennzeichnet, daß das Trocknen 6 Stunden bei 80 °C durchgeführt wird.
6. Feste Zusammensetzung von Lactulose und Fiberform®, erhältlich durch Mischen eines 50 % feste Lactulose enthaltenden Lactulosesirups mit einer Menge von 150 bis 350 g Fiberform® pro Liter Lactulosesirup und anschließendes Verteilen, Trocknen und Zerkleinern der Mischung.

Revendications

1. Procédé pour préparer une composition solide de lactulose, caractérisé en ce qu'un sirop de lactulose est mélangé avec le produit Fiberform ® à teneur élevée en fibres, le mélange est étalé, séché, broyé et éventuellement tamisé.
2. Procédé selon la revendication 1, caractérisé en ce qu'un sirop comprenant 50% de lactulose solide est mélangé avec une quantité de Fiberform ® de 150 à 350g par litre de sirop de lactulose.
3. Procédé selon la revendication 2, caractérisé en ce que 200 à 300 g de Fiberform ® sont utilisés par litre de sirop de lactulose.
4. Procédé selon les revendications 1 à 3, caractérisé en ce que le mélange de sirop de lactulose et de Fiberform ® est mélangé pendant quelques minutes, est étalé, séché à 60-90 °C pendant quelques heures, le produit solide est broyé et éventuellement tamisé.
5. Procédé selon la revendication 4, caractérisé en ce que le séchage est effectué à 80 °C pendant 6 heures.
6. Composition solide de lactulose et de Fiberform ® que l'on peut obtenir de 150 à 350g par litre de sirop de lactulose, et en étalant ultérieurement, en séchant et en broyant le mélange.