Soft agglomerates for the administration of powders through non-invasive routes

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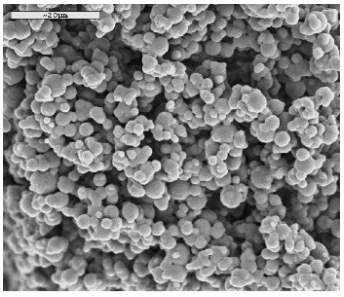
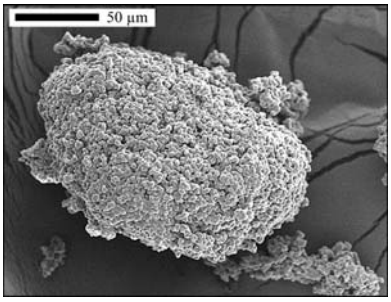
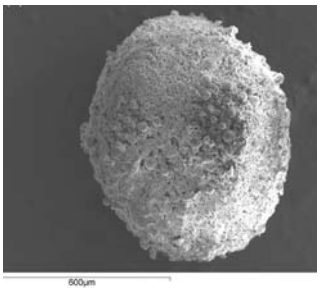
The University of Parma has developed a new dosage form as a powder able to satisfy different technological requirements related to preparation and administration of powders through non-invasive routes (oral, buccal and nasal). The powder is made of agglomerates of microparticles strong enough to be handled during the metering into the device, but weak to be fragmented by air turbulence. The agglomerate fragments have suitable size for deposition and are promptly deaggregated and dissolved by water on humid mucosa.



Microparticles

Soft agglomerates at optic microscopy





Soft aglomerates at scanning electronic microscopy

1. Description of the product

The agglomerates are made of primary microparticles, obtained by spray-drying process of an aqueous or hydro-alcoholic solution of drug and excipients. Successively, the primary microparticles are agglomerated by placing them on the top of the sieve stack which is vibrated on a vibratory laboratory sieve shaker. Agglomerates between 106 and 850 µm are collected.

In the case of insufflation, the agglomerate dimensions are useful for the dose metering of the powder into the insufflation device. After the insufflation, due to turbulence of air flow, agglomerates are broken into fragments of appropriate dimensions for nasal or buccal administration which are rapidly deaggregated in the primary microparticles by water.

2. Innovative aspect of the product

The soft agglomerates can be useful for the preparation of drug powder formulations characterized by high physico-chemical and microbiological stability. Moreover, these systems are able to satisfy the different

technological requirements related to dose preparation, administration and rapidly dissolution of the drug through non-invasive routes.
The soft agglomerates are very versatile since it is possible to prepare formulations of different therapeutic class by varying the composition of the microparticles.

3. Main advantages of the offer

Due to the characteristic of soft agglomerates, the new dosage form have the advantage to compromize the dimension of agglomerates, suitable for manipulation during dosage form preparation, with the dimension of microparticles, appropriate for rapid dissolution of the drug.

4. Technology key words

Soft agglomerates, nasal administration, buccal administration, oral administration

5. Current Stage of Development

Scale up phase - Laboratory tested - Available for demonstration

6. Intellectual Property Rights

The product is under patents owned by University of Parma: "Powder for nasal administration of drugs" (PCT n. WO2003035034A3); "Composition in powder from made of soft agglomerates of a micronized drug and of a two-components excipients, and process for their preparation" (PCT/EP2007/061559).

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