

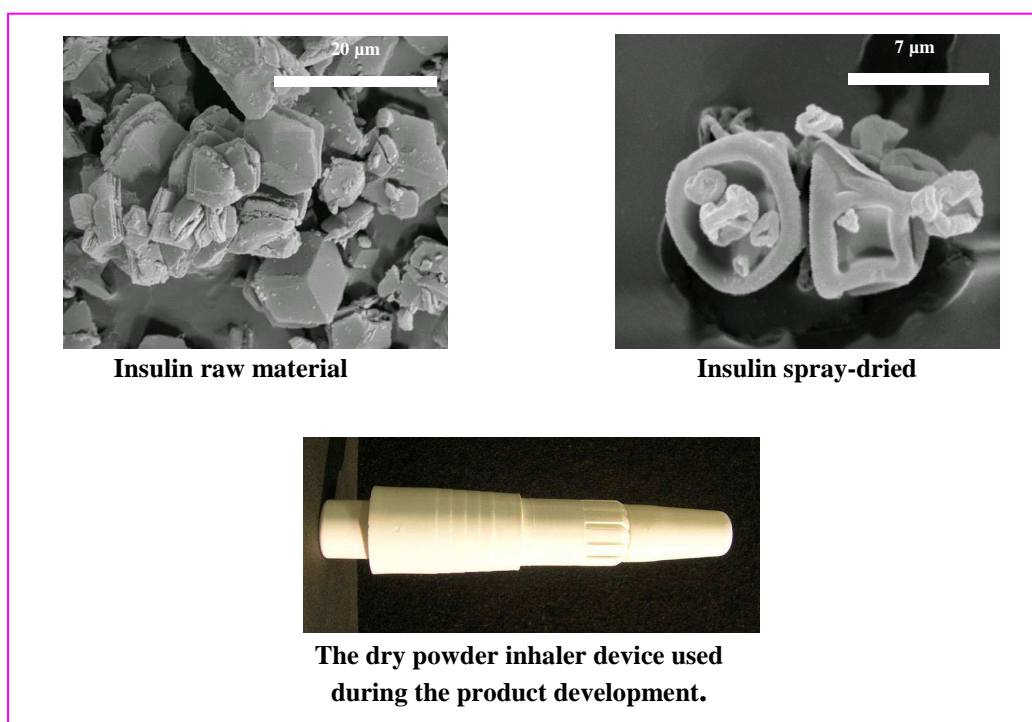
Highly respirable insulin microparticles for pulmonary administration

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The University of Parma has developed a novel micronized powder of insulin to be delivered to the lung by inhalation for the diurnal treatment of diabetes.

Inhaled insulin could be a viable alternative to prandial insulin administration for patients with diabetes because of its more favourable pharmacokinetic profile and less invasive route of administration. Dry powder inhaler (DPI) systems, which doesn't contain non-environmental friendly CFC or HFA propellants, were explored from the University of Parma for the delivery of insulin to the alveolar region.

These insulin pulmonary particles are characterized by a very high respirability due to a peculiar structure and shape and quick dissolution in aqueous solutions. The University is looking for industrial partnership for product development.



1. Description of the product

Drug delivery strategies for diabetes have included a wide range of scientific and engineering approaches, including molecular design, formulation and device design. Particle engineering has been applied to pulmonary formulations for delivery to the deep lung. The creation of novel drug delivery methods for the treatment of diabetes should remove barriers to insulin therapy and increase patient acceptance and compliance. The substitution of routine injections with insulin for inhalation may offer an increasingly attractive alternative.

To date several technologies have been used to produce highly breathable insulin powder with an irregular geometry, to allow the transport "in air suspension".

In addition inhalatory powders must be flowable, in order to be regularly dosed in the insufflation device. The product here described is insulin's micro particles aerodynamically useful for a deep pulmonary deposition and easy to dose in insufflation device. New way of preparation has been identified, finding the one able to give a breathable and bio-available powder mixture. The most relevant feature of this product is its good stability at room temperature.

2. Innovative aspect of the product

Insulin dry powders are manufactured by spray drying an aqueous acetic insulin solution, with a pH of lower than isoelectric point of the hormone. The volatilization of the acid during the production process led to an increased pH value of the powders compared to the pH of the medium prior spray drying to make them more stable, manageable and high respirable.

Particles obtained have corrugated surface characteristics. They have good flow properties which permit them to be easily charged in a device for insufflation. Very surprising is the fact that these powders, when aerosolized, produce aerosol with breathable fractions of 80-90%, higher if compared with the ones commonly used in medical aerosols (20-40%).

However, the major advantage is the room temperature stability that allows the product to be stored in non-refrigerated conditions.

3. Main advantages of the offer

By this formulative approach insulin crystals are transformed in micro-particles constituted essentially of pure peptide. The product does not contain excipients, so reducing the potential side effects associated to them. This insulin powder can be used as a generic version of the recently marketed pulmonary insulin, adding the improvement not to have excipients in the inspired particles.

4. Technology key words

Insulin Microparticles, Dry Powder Inhaler, Pulmonary Administration

5. Current Stage of Development

Work in progress – Tested in laboratory- Scale up needed

6. Intellectual Property Rights

The product is covered by a patent

Technical and scientific publications

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