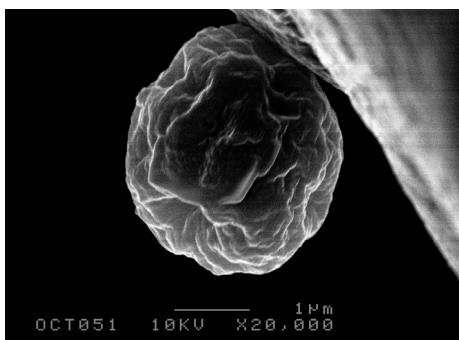


Highly respirable tobramycin microparticles for pulmonary administration

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The University of Parma has developed a novel micronized powder of tobramycin to be delivered to the lung by inhalation for the treatment of chronic infections of respiratory tract. To date the only inhalable tobramycin available on the market is TOBI®, a tobramycin solution for inhalation approved by the Food and Drug Administration. Tobramycin micro-particles could be a viable alternative to nebulisation for patients suffering of Cystic Fibrosis or Bronchiectasis. Dry powder inhaler (DPI) systems were explored from the University of Parma for the delivery of high amount of tobramycin directly on the site of infection.



Tobramycin micro-particle



**Dry powder inhaler used during the product development.
RS01/7 (Plastiapipe S.p.a.)**

1. Description of the product

The product is a flowable powder, made of micro-particles aerodynamically capable of producing pulmonary deposition. The respirable antibiotic powder was obtained by an original composition and technique based on the spray drying of a solution made by appropriate mixture of water solution of drug with alcoholic solution of fatty acids or their salt at 30°C. The process resolves the problems related to the difficulty of aerosolizing an antibiotic or chemotherapeutic powder in which the particles do not possess a useful aerodynamic behaviour.

2. Innovative aspect of the product

This product permits the pulmonary administration of the tobramycin in dry form improving the storage stability and the dose deposited into the lungs. Compared with the nebulisation, DPI system can reduce the dose administered and the administration time. The high respirability was obtained using a very low amount of lipophilic adjunct. The technique used is capable of produce a distribution of the adjunct on the surface of the micro-particles. The presence of the adjunct on the surface of the micro-particles increases the emitted fraction and protects the drug from the humidity. The powder administered has a high antibiotic content.

3. Main advantages of the offer

These powders have high respirable fraction (>80%). Micro-particles obtained have good flow properties which permit them to be easily charged in a device for the inhalation. The use of a lipophilic adjunct reduces the hygroscopicity and increases the physico-chemical stability of the micronized powder.

4. Technology key words

Tobramycin Micro-particles, 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

C.Parlati, H.Adi, F.Buttini, P.Colombo, P.M. Young, D.Traini, In vitro evaluation of co-processed antibiotic for inhalation, Respiratory Drug Delivery 2008.

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