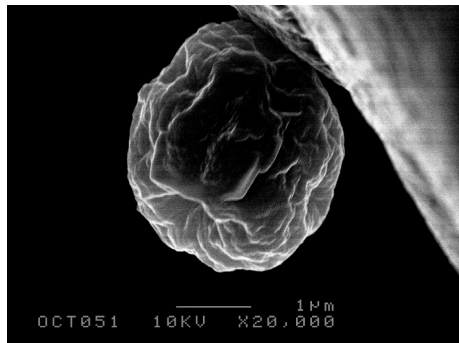


Highly respirable tobramycin microparticles for pulmonary administration

Prof. Paolo Colombo – University of Parma – Consorzio TEFARCO Innova

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 inhalable tobramycin is available on the market as a tobramycin solution for nebulization, TOBI®, and powder for inhalation, Tobi Podhaler®. Tobramycin micro-particles are 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
microparticle**



**Dry powder inhaler used during
the product development.
RS01/7 (Plastiap 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 tobramycin in dry form assuring the storage stability and the dose deposited into the lungs. Compared with the nebulisation, DPI system can reduce the dose administrated 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 increases the emitted fraction and protects the drug micro-particles from the humidity. The powder administered has a high antibiotic content (>90%).

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 application PCT/EP2008/059110

Technical and scientific publications

1. Chiara Parlati, Paolo Colombo, Francesca Buttini, Paul M Young, Handoko Adi, Alaina J Ammit, Daniela Traini. Pulmonary spray dried powders of tobramycin containing sodium stearate to improve aerosolization efficiency. *Pharm Res* (2009) vol. 26 (5) pp. 1084-92.
2. Chiara Parlati, Handoko Adi, Francesca Buttini, Paolo Colombo, Paul M Young, Daniela Traini. In Vitro Evaluation of Co-Processed Antibiotic for Inhalation. *Respiratory Drug Delivery 2008* (2008), Vol 3, pp 907-910. ISBN: 1-933722-23-1.
3. Francesca Buttini, Paolo Colombo, Chiara Parlati, Daniela Traini, Paul Young. A drug powder for inhalation administration and a process thereof. (Submission number 414699, PCT application number PCT/EP2008/059110, Applicant: Università degli Studi di Parma).

CONTACT

Consorzio TEFARCO Innova
c/o Dip.to di Farmacia, Viale delle Scienze 27/A, 43124 Parma - Italy
tefarco@nemo.unipr.it - Tel. 0521.905073