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In vitro aerodynamic characterization of the dose emitted during nebulization of tobramycin high strength solution by novel and jet nebulizer delivery systems

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Background: Chronic infections with Pseudomonas aeruginosa are a leading cause of morbidity in patients with cystic fibrosis (CF). The aim of tobramycin inhalation therapy in CF patients with chronic pulmonary infection is to deliver high amounts of drug directly to the site of infection. TOBI® is a tobramycin nebulizer solution (300mg/5ml) approved by FDA for maintenance therapy for patient with CF. The 20% tobramycin sulfate solution was reported as the optimal and maximal concentration.

Methods: Nebulization of high strength tobramycin solution (20% tobramycin sulfate) (HSTS) has been assessed in this study by using different selected high performance nebulizer delivery systems: two different designs of jet nebulizers, and three new nebulizers based on vibrating mesh technology. The aerosol particle size distribution and output characteristics were measured for in vitro performance assessment of the nebulizer systems. The methodology was adapted from the current European standard, EN 13544-1:2001E.

Results: The particle size distribution characteristic measurements showed that all tested nebulizers may be suitable for inhalation of HSTS. The mean (SD) of highest percentage of fine particles (<5µm) was 77.64 (2.3)% for Sidestream®, at flow rate 16 L/min. The highest respirable inhaled mass was for Pari LC Plus® combined with PariBoyN® compressor, with mean (SD) 90.85 (8.6) mg. The mean (SD) of highest drug wastage percentage was 63.9 (3.9) % for Sidestream® jet nebulizer combined with compressed air cylinder at flow rate 16L/min, while the lowest was 2.3 (0.26)% for NE-U22 Omron® (high frequency).

Conclusions: The HSTS can be nebulized by all tested nebulisers but the high frequency NE-U22 Omron® and Aeroneb Go® are more efficient. When the HSTS compared to TOBI®, the respirable inhaled dose was increased to more than 73%.

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India pharmacovigilance status & scope to other Asian countries

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WHO initiated International Drug Monitoring Programme after thalidomide tragedy. To expand the drug safety surveillance programme internationally, 32 Asian countries has enrolled under WHO Programme of International Drug Monitoring (WHO-PIDM). Asia PV has become an important public health issue as Asian Continent carry maximum number of world population. Indian Pharmacopoeia Commission is functioning as National Coordination Centre for Pharmacovigilance Programme of India (PvPI) from 2011. Within a short span of time, by 2015, India has not only set up the system of pharmacovigilance but also has set the standards for its effective functioning. Comparing other countries in the Asian Continent, India is the first country which has launched the nationwide helpline (toll free), consumer reporting form in different vernacular languages & Android Mobile App to report ADR by the general public. India has also reported more than 100 thousand ADRs reaching the quality score 0.93 WHO scale as regulator. Comparing to other Asian countries, India has excelled by developing different ADR reporting tools to create awareness to enhance PV system. These methods can add scope to other countries so as to promote patient safety.

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