At day 0 and appropriate time intervals until the final dose was dispensed and the lock-out mechanism of the inhaler was activated, the following parameters were assessed: water content, degradation products, content per cartridge, delivered dose (DD), fine particle dose (FPD) and microbial growth. All results, notably DD and FPD (Figure 1), were within the expected range and well inside the specifications applied during development. More precisely, the mean results of DD for aclidinium bromide were between 370 µg and 451 µg (specification 320–480 µg) and for FPD between 139 µg and 182 µg (specification ≥80µg), while the mean values of DD for formoterol fumarate dihydrate were between 10.1 µg and 13.1 µg (specification 9.6–14.4 µg) and for FPD between 2.5 µg and 3.7 µg (specification ≥1.8 µg).

The studies show that stable pharmaceutical quality can be guaranteed under

in-use conditions for a period longer than the allowed 60 days after unpacking the drug product pre-stored even up to the end of shelf life.

*Registered trademark of AstraZeneca group of companies; for use within the USA as Pressair® and Genuair™ within all other licensed territories.

P292 PILOT STUDY TO ASSESS BRONCHODILATOR RESPONSE DURING AN ACUTE EXACERBATION OF COPD USING A VIBRATING MESH NEBULISER VERSUS JET NEBULISER FOR BRONCHODILATOR DELIVERY

B Cushen, A Alsaid, A Abdulkareem, RW Costello. *RCSI Beaumont Hospital, Dublin, Ireland*

10.1136/thoraxjnl-2016-209333.435

Introduction Recovery from COPD exacerbation is associated with increases in respirable lung volume. Accelerating these changes through improved bronchodilator delivery could hasten recovery.

Hypothesis Vibrating mesh nebuliser (Aerogen® Ultra) results in greater change in lung physiology compared to standard small volume jet nebuliser.

Methods Patients with an exacerbation of COPD were randomised to receive combined salbutamol 2.5 mg/ipratropium bromide 0.5mg via vibrating mesh (Active group) or standard hospital jet nebuliser (Control) on one occasion between day 2–7 of hospitalisation. Spirometry, body plethysmography and impulse oscillometry were performed pre-bronchodilator and at 1 hour post. Borg breathlessness score was measured.

Results Thirty-one patients have been recruited to date, 16 to the active group and 15 control group. Mean FEV_1 was 48 ± 18% predicted. Baseline demographics were comparable between groups. Both groups had significant improvements in FEV_1 and Inspiratory Capacity post-bronchodilator, with greater increases in FVC in the active group (0.40 ± 0.39 L vs 0.19 ± 0.19 L, p = 0.06). Significant changes in operating lung volumes and airway impedance were seen in both groups. There was no significant difference in Borg score.

Conclusion Bronchodilator administration, during a COPD exacerbation, results in significant improvements in spirometry, lung volume and airway impedance. Drug delivery by vibrating mesh nebuliser results in greater absolute increases in FVC. Further studies will assess whether this translates into accelerated exacerbation recovery.

P293 DRUG DELIVERY PERFORMANCE OF BUDESONIDE (BD), GLYCOPYRRONIUM (GP) AND FORMOTEROL (FF) TRIPLE COMBINATION (BGF) CO-SUSPENSION™ DELIVERY TECHNOLOGY MDIS

[1]V Joshi, [2]P Mack, [2]J Archbell, [2]G Li, [2]M Arent, [2]K Vang, [2]S Ivatury, [2]R Schultz, [2]D Lechuga-Ballesteros, [2]S Dwivedi, [2]M Riebe. *[1]Pearl Therapeutics Inc., Redwood City, USA; [2]Pearl Therapeutics Inc., Durham, USA*

10.1136/thoraxjnl-2016-209333.436

Introduction To assure consistency of clinical outcomes, orally inhaled products must have consistent *in vitro* delivered dose and aerosol properties. Achieving this consistency has been challenging with MDIs, particularly those that combine multiple drugs. Co-Suspension™ delivery technology has been developed for *in vitro* drug-drug interaction-free delivery of multiple drugs from fixed-dose MDI combinations. This versatile technology suspends the micronised drugs with spray-dried phospholipid porous particles in hydrofluoroalkane propellant. The objective of this study was to determine whether BGF MDI, the triple Co-Suspension delivery technology formulation of BD/GP/FF, displays *in vitro* drug delivery comparable to its constituent single and dual drug formulations.

Methods Single, dual and triple therapy MDIs of BD, GP and FF were prepared by suspending each drug's microcrystals with phospholipid porous particles in HFA propellant. *In vitro* drug delivery was assessed by comparing delivered dose uniformity and aerodynamic particle size distribution.

Results BD, GP and FF formed stable suspensions in the presence of phospholipid porous particles, despite differences in drug physicochemical properties and doses. A consistent and comparable delivered dose and aerodynamic particle size distribution was observed whether emitted from a single, dual or triple therapy MDI.

Conclusion The single, dual and triple drug MDI formulations demonstrated comparable aerosol characteristics which should enable patients to transition across the continuum of these MDI therapies without *in vitro* drug-drug interaction impacting drug delivery and clinical outcomes.

P294 BENEFITS OF TIOTROPIUM/OLODATEROL OVER TIOTROPIUM AT DELAYING CLINICALLY SIGNIFICANT EVENTS IN PATIENTS WITH COPD CLASSIFIED AS GOLD B

[1]R Buhl, [2]L McGarvey, [1]S Korn, [3]GT Ferguson, [4]L Grönke, [4]C Hallmann, [4]F Voß, [5]KF Rabe, [6]F Maltais. *[1]Pulmonary Department, Mainz University Hospital, Mainz, Germany; [2]Centre for Infection and Immunity, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, Belfast, UK; [3]Pulmonary Research Institute of Southeast Michigan, Farmington Hills, Michigan, USA; [4]Boehringer Ingelheim Pharma GmbH and Co. KG, Ingelheim, Germany; [5]LungenClinic Grosshansdorf, Grosshansdorf, Germany; [6]Centre de Recherche, Institut Universitaire de Cardiologie et de Pneumologie de Québec, Québec, Canada*

10.1136/thoraxjnl-2016-209333.437

Rationale The once-daily combination of tiotropium (T), a long-acting muscarinic antagonist, and olodaterol (O), a long-acting β_2-agonist, has demonstrated efficacy and safety in COPD. Two large clinical studies (TONADO®1 + 2) have also demonstrated the benefits of T/O compared to the monocomponents in patients with moderate to very severe COPD. This *post hoc* analysis investigated whether T/O is more effective than T at delaying