Investigation of Electrostatic Properties of Pharmaceutical Powders using Phase Doppler Anemometry

Radu Beleca, *Member, IEEE*, Maysam Abbod, Wamadeva Balachandran, *Fellow, IEEE*, Paul R. Miller

Abstract— **Electrostatic properties of formulation component materials and blends play an important role in dry powder inhalation (DPI) products. Valid measurement of charge distribution will therefore lead to better control of powder behavior in DPI manufacturing processes. Ultra-fine powders are known to have bipolar charge, have non-spherical shapes and tend to be highly cohesive. Real time, non-invasive techniques need to be developed to obtain a precise and accurate measurement of electrically charged powders as they aerosolize from a DPI product. How this measure relates to materials behavior throughout the various steps of a manufacturing process e.g. from drug micronisation, blending with lactose, through to filling dose units, also needs to be addressed. A novel non-invasive technique which employs the Phase Doppler Anemometry (PDA) system for simultaneous measurement of size and charge of pharmaceutical powders is currently being considered. Previous research demonstrated the advantages of this technique in measuring the bipolar charge distribution on a population of liquid aerosols. These findings led to significant improvements in understanding the performance of inhaler formulations, manufacturing processes and development of new devices for inhaled drug delivery. This paper presents an investigation of electrostatic properties of lactose materials (typically used as a DPI excipient) using the PDA system. PDA calibration was checked using dry polystyrene microspheres, followed by an investigation of different grades of lactose. The PDA technique was used to track the motion of charged particles in the presence of an electric field. The magnitude as well as the polarity of the particle charge can be obtained by solving the equation of particle motion combined with the simultaneous measurement of its size and velocity. The results show the capability of the technique to allow real-time charge distribution and size measurement in the control of dry powder attributes that are critical to a better understanding of the manufacturing design space.**

Index Terms— **Dry powders; Particle Charge Measurement; Phase Doppler Anemometry.**

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I. INTRODUCTION

CHARACTERIZATION of pharmaceutical powders in terms of their electrical properties has become a subject of considerable research in the development of drug manufacturing and product performance. Electrostatic charge of dry powder for inhalation plays an important role in respiratory therapy. Inhalation of dry powders used to treat a variety of respiratory diseases has become a standard procedure especially for asthma and COPD (chronic obstructive pulmonary disease) affecting more than 300 million people worldwide [1]. Both theoretical and experimental studies have demonstrated that aerosols generated by inhalers for respiratory drug delivery acquire bipolar charge during the dispersion process [2-5]. The electrostatic charge distribution of the particles affects the efficiency of drug delivery by influencing both the transport and deposition of inhaled particles in the human lung due to space and image charge forces [6].

Powder mixing, coating, drying, transport and blending generates electrostatic charging which is attributed mainly to the process of triboelectrification [7-9]. The charge levels on particles could be affected by several factors related to the particle morphology such as size distribution, shape, surface roughness, purity, contaminants, contact area, as well as the inherent electrical and physical properties [10-13]. The atmospheric conditions such as: relative humidity, temperature, atmospheric pressure are known to affect charge generation and dissipation [14].

Accurate devices for measurement of the levels of charge resident on the pharmaceutical powders have to be developed with a measurement capability in the bipolar domain. Various techniques used for charge and size measurement of powder particles have been presented in [15]. The most common method used for charge measurements is Faraday pail. When a charged particle, of any form or conductivity, reaches the Faraday pail interior, an equal and opposite charge is induced on the inner wall and displayed on an electrometer. By dividing the measured total charge of the powder sample by the number of particles, the average particle charge can be obtained. However this technique can indicate only the net level and polarity of the charged powder sample and cannot be

used for a polydispersed powder.

Methods for powder charge measurement have been developed, based on optical techniques or electrostatic precipitation. Mazumder et al. [17] invented the Electrical-Single Particle Aerodynamic Relaxation Time (E-SPART) analyzer based on Laser Doppler Velocimetry (LDV), which measures both the size and charge of individual particles, at low particle flux rates. This proved to be an obstacle when characterizing highly charged, rapidly evolving, non-uniform aerosol clouds from inhalers.

Balachandran et al. [2, 3, 18, 19] promoted and developed new methods of bipolar charge measurement and particle characterization based on electrostatic precipitation techniques and Phase Doppler Anemometry (PDA) respectively. Bipolar Charge Aerosol Classifier in conjunction with aerodynamics was successfully used to obtain bipolar charge fractions and mobility classification of charged aerosols while it is also capable of measuring spatial deposition characteristics of an aerosol plume. The Multi Stage Precipitator developed by O'leary et al. [19] compliments the commercially available Electrical Low Pressure Impactor (ELPI). The net charge data obtained with ELPI is incomplete when calculating the charge of a bipolarly charged aerosol. Kulon et al. [2] developed PDA based bipolar charge measurement of liquid aerosols. PDA extends the capabilities of LDV, allows a real time simultaneous determination of particle size and charge distributions.

This paper presents an experimental investigation of electrostatic charge of pharmaceutical lactose materials using a modified Phase Doppler Particle Analyzer (PDPA). The system was used to track the motion of the charged particles in the presence of a DC electric field. Solving the equation of a particle motion in a viscous medium combined with the simultaneous measurement of size and velocity of dry powders, the charge distribution on a particle population can be calculated.

II. Charged Powder Particle Motion in the Presence of DC Electric Field

Charged particles, in the presence of an electric field, experience a force exerted on them. The relative motion of a particle in a viscous medium leads to a drag force. When the drag force and the externally applied force are equal, then the particle is in mechanical equilibrium and a steady-state velocity of the particle relative to the medium results. The drag force F_{drag} for spherical particles moving through air is given by [2]:

$$F_{drag} = \frac{-C_d \pi \rho_{air} d^2 V^2}{8} \tag{1}$$

where C_d is the drag coefficient, V is the relative velocity between the gas and the particle, ρ_{air} is the air density, and d is the particle diameter. By equating drag resistance force and the electrical force $F_e = qE$, the charge q on an individual particle can be calculated as follows [2]:

$$\frac{-3\pi\eta V d}{C_c} = qE, \tag{2}$$

therefore,

$$q = \frac{-3\pi\eta V d}{C_c E} \tag{3}$$

where E is the electric field strength in the direction of particle drift velocity, η is the dynamic viscosity of air and C_c is the Cunningham slip correction factor.

III. Principles of PDA

The PDA technique measures the speed and size of particles without disturbing the electric field or the particle motion. The principle of the PDA is based on light scattering from two-plane light beams incident on the particle. The light from a laser is split into two parallel beams which are focused by the lenses to the measuring point. Each pair of beams is coherent and polarized so that when they intersect an interference pattern of light and dark fringes is formed. The phase shift between the signals from different detectors is proportional to the size of the spherical particle. According to Lorenz–Mie theory [16] the scattered light intensity in different scattering modes changes at different scattering angles, thus a linear relationship between the measured phase difference and the particle diameter only exists, if the detector is positioned such that one light scattering mode dominates. The phase shift between the two detectors depends on the scattering mode and is given by the following expression [2]:

For *reflection*

$$\Phi = \frac{2\pi \mathrm{d_p}}{\lambda} \frac{\sin\theta \sin\psi}{\sqrt{2(1-\cos\theta\cos\psi\cos\varphi)}} \tag{4}$$

for first-order refraction, see (5) at the bottom of the page, where λ is the wavelength of the laser light, θ is the angle between the incoming laser beams, φ is the scattering angle, ψ is the elevation angle, and n_{rel} is a particle relative refractive index. There is no calibration constant in these equations, therefore, no calibration is required providing that the particle refractive index as well as PDA optical parameters are known accurately. The velocity measurement is based on the Doppler effect and can be visualized using the fringe model. As a powder particle passes through the measurement region it scatters light at a frequency based on its velocity normal to the fringes and the spacing between the fringes.

$$\Phi = \frac{-2\pi d_p}{\lambda} \frac{n_{rel} \sin\theta \sin\psi}{\sqrt{2(1+\cos\theta\cos\psi\cos\phi)(1+n_{rel}^2 - n_{rel}\sqrt{2(1+\cos\theta\cos\psi\cos\phi)}}} \tag{5}$$

A receiving device measures the frequency of this scattering signal, and the spacing of the fringes is known based on the wavelength of the laser light and the angle between the beams. The relationship between the Doppler frequency (f_D) and particle velocity (V) is expressed as [1]:

$$f_d = \frac{f_s + V}{d_f} = \frac{f_s + V \cdot 2\sin\frac{\theta}{2}}{\lambda} \quad (6)$$

where d_f is the distance between the fringes and f_s is the frequency shift introduced to one of the beams to resolve the velocity directional ambiguity. The PDA technique is a well-established non-intrusive optical method for simultaneous measurement of the velocity as well as the size of spherical particles.

PDPA comes as an extension of the LDV technique, the photograph of the experimental arrangement and the schematic diagram of the measurement system are shown in Figs. 1 & 2 while the PDPA system characteristics are listed in Table I.

IV. Experimental Procedure

The PDPA system comprises of an air cooled Argon-ion laser, a fibrelight multicolor beam generator with two fiber optic couplers, transmitting and receiving optics, signal processing unit with multiple velocity channels, a high-precision traversing system and a PC with interface board for data processing and storage. The experimental system of measurement consists of a TSI - PDPA system, a measurement cell with optical windows and a particle feeder, vacuum pump and the high voltage power supplies. The performance of a PDPA system is mainly determined by the properties of the beam configuration system (laser wavelength (λ), power (P), beam waist radius (ω), and beam crossing angle (θ)), the optical detection system (off axis angles (φ), elevation angles (ψ), detector field of view (Ω)), and the particle (size, shape and refractive index (n)).

Each pair of beams is coherent and polarized so that at their intersection point, a fringe pattern is formed. A particle which travels across the intersection volume of the incident laser beams of the PDPA system scatters light non-uniformly in all directions depending on the particle properties and refractive index. The light incident on a particle is partially reflected from the surface and partially transmitted and refracted in both forward and backward directions after one internal reflection.

The frequencies of the scattered fields are Doppler shifted. Interference between scattered waves on the detector aperture leads to a beat signal (PDPA burst). The beat of the Doppler frequency is a measure of the particle velocity. A time phase shift between the three detectors in the receiving optics is determined by the size and the optical properties of the scattering particle. A linear relationship exists between the measured phase difference and particle diameter only if the detector is positioned at a specific angle where a single light scattering mode dominates. The first-order refraction was selected as dominant scattering mode during the experiments

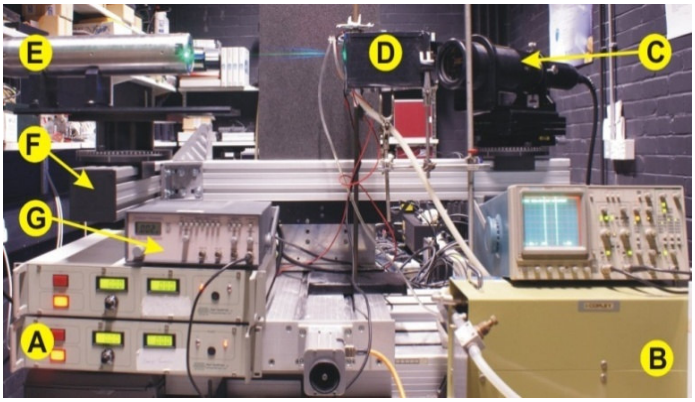

Fig. 1. PDPA experimental arrangement: A – dc high-voltage power supply; B – pump; C – receiving optics; D – measurement cell with particle feeder; E – transmitting optics; F – traverse system; G – function generator.

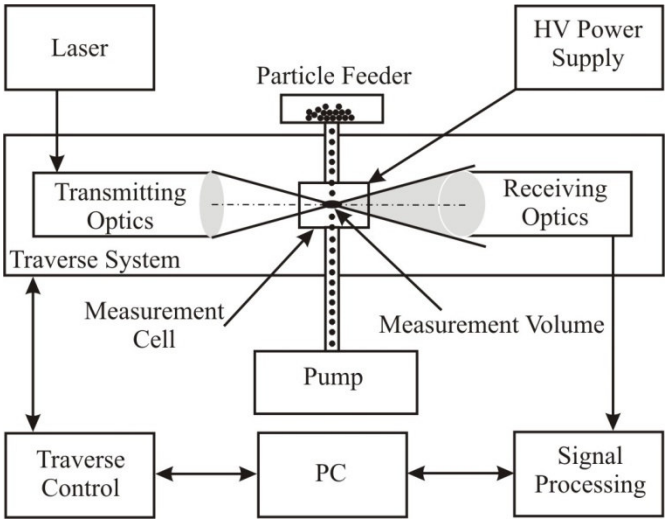

Fig. 2. Block Diagram of the measurement system.

TABLE I - PDPA System Characteristics

Optical Parameters	Transmitting Optics		Units
	Channel 1 [V_z]	Channel 2 [V_y]	
Laser wavelength	514.5	488	nm
Gaussian Beam diameter	2.65	2.65	mm
Beam separation at focus lens	50	50	mm
Focusing lens focal length	363	363	mm
Fringe spacing	3.74	3.55	μm
Number of fringes	34	34	μm
Measurement volume diameter	128.18	121.58	μm
	Receiving optics		
Scattering angle	30		deg
Collection lens focal length	363		mm
Particle refractive index	1.533		-

perpendicular polarization, with an optimum scattering angle of 30º. No calibration of the method is required, as the PDPA system is calibrated at the factory (based on phase difference relative to particle diameter). A few measurements were conducted using standardized polystyrene microspheres 5μm

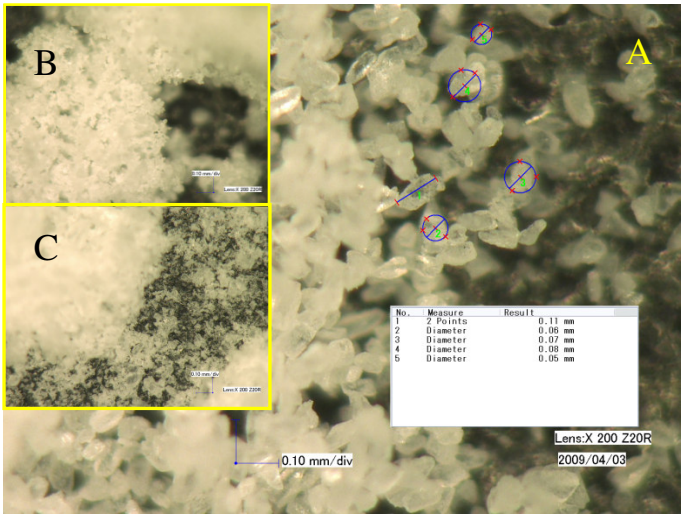

Fig. 3. Real-time view of the lactose samples (A, B, C) under investigation. The VXH Microscope was equipped with VH-20R, 200X zoom lenses (Courtesy Keyence Ltd.).

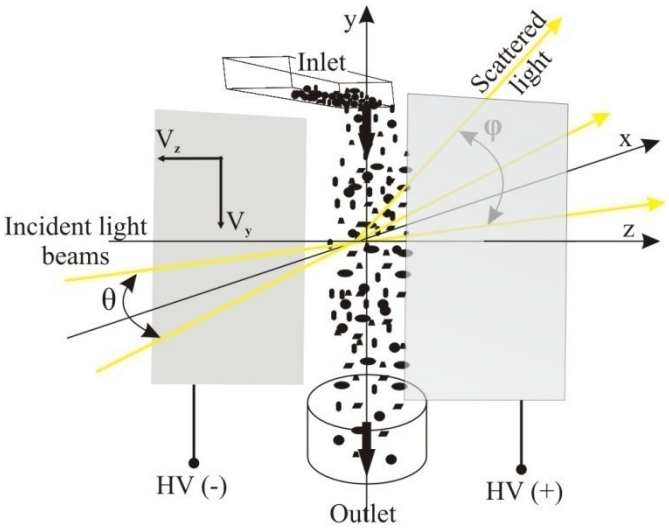

Fig. 4. Measurement cell. Two laser beams intersect in X-Y plane, φ is the scattering angle, θ is the angle between the incoming laser beams, and V_z and V_y are the horizontal and vertical component of the particle velocity measured by the PDPA [1]. V_y and V_z characteristics are presented in Table I.

in diameter (sourced from Duke Scientific Corporation) to check the PDPA calibration. These tests (not presented here) confirmed the overall applicability and accuracy of the technique in the expected size range of the measured dry powders.

The experimental investigation was performed on three samples of lactose grades (A, B, C), with size distributions in the range of 0.1 and 100μm. Micrographs of the powder samples taken using a Keyence VXH-600 Digital Microscope are presented in Fig. 3. Its built in software using advanced image processing methods can determine particle size while enabling Depth from Defocus (DFD) methodology, accurate 3D profiling of the samples can be obtained. Each lactose sample has specific characteristics in particle morphology, hygroscopicity and electrical charge, which made them very difficult to handle. Lactose B and C are very fine and proved to be highly hygroscopic while inter-particle forces enhanced agglomeration. In the case of agglomerated powder the speed and size measured by the PDPA will be of the whole agglomeration thus the charge on an individual particle cannot be determined.

The specially designed feeder allows a curtain of dry powder test sample to enter the measurement cell, which is drawn out through a tube by a suction pump as seen in Fig. 4. The cell has a triangular shape with optical windows, incorporating two parallel-plate electrodes. The electrodes are placed 20 mm apart and a potential difference of 5kV is applied between them during the charge measurement. The electrodes have rounded edges to ensure field uniformity within the cell and a low flow rate of 0.06 L/min was maintained during measurements to ensure a laminar flow. When the lactose samples enter the measurement cell they are deflected towards the appropriate electrodes based on the polarity of charge associated with the particles. The measurement volume generated at the intersection of the four laser beams was maintained in a fixed position. The scattered light signals were processed through a TSI-FSA 3500 8 bit signal processing unit connected via FireWire to a PC. The computer is equipped with an interface card and TSI FlowSizer 2.0.3.0 software for data acquisition and analysis.

V. Results and Discussion

Initial net charge measurements using a Faraday pail (see Table II) revealed that the lactose powder samples were positively charged, while the *q/m* ratio increased with the finer lactose B and C. The feeder did not influence significantly the net charge of the lactose samples during transport. The measurements were performed at a temperature of 21ºC and a relative humidity of 48%. A quantity of 0.5 g lactose powder was used in each measurement. The difference between the values of the net charge obtained with lactose samples from the storage containers and the ones obtained from the feeder output are mainly due to powder handling.

TABLE II – Net Charge Measurements

Faraday pail		
Lactose sample	***q* [nC/g]**	***q* (using feeder) [nC/g]**
A	1.59	1.30
B	3.63	2.17
C	3.95	3.30

A sample of each type of lactose powder was spread on an electrically isolated metallic plate (20×20 cm) and the surface charge was monitored using a JCI 140 Static monitor at several locations, which revealed the bipolarity of the lactose powder samples (see Fig. 5). The JCI 140 is a compact electric field mill instrument that allows one to determine the voltage of a surface at a given distance. It is an electromechanical device which measures the strength of a static electric field. The readings from the JCI 140 static monitor are not direct values of the surface potential, but proportional to the surface potential. To convert the readings into the surface potential, a calibration was carried out which gave a linear relationship between the readings and the applied voltage.

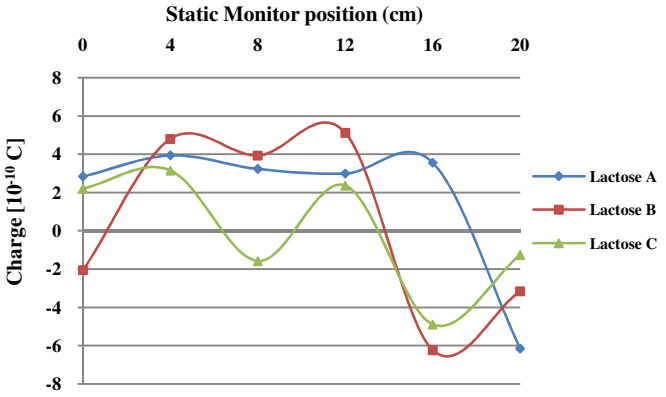

Fig. 5. Surface charge measurement of lactose powder samples under investigation.

The potential across the sample can then be estimated by:

$$V(t) = -\int_0^d E(x,t)dx \tag{7}$$

where d is the thickness of the sample. The surface potential is related to the charge density distribution $\sigma(x)$ by Poisson's equation as:

$$\frac{dE(x,t)}{dx} = \frac{\sigma(x,t)}{\epsilon_0 \epsilon_r} \tag{8}$$

where ε_0 is the permittivity of vacuum and ε_r is the relative permittivity of the lactose sample. The charge levels can be obtained from the surface charge density which is defined as the total amount of charge q per unit area A:

$$\sigma = q/A \tag{9}$$

Tests were conducted with the modified PDPA system (see Fig. 4) to assess its performance and capability of measuring bipolar charge of powder particles. Figure 6 a. shows the particle size distribution of ambient airborne particles obtained from the PDPA, ranging from 0-5 μm. The bipolar charge distribution of the ambient airborne particles that passed through the measurement volume is presented in Fig. 6. b. These tests were conducted at a temperature of 24.4ºC and a relative humidity of 32.3%. A potential of 5 kV was applied between the electrodes (see Fig. 4). The majority of particles carry between -6×10^{-17} C to +3×10^{-17} C and a total of 20 000 particles have been analyzed in this run.

An experimental investigation of electrostatic properties of lactose A was performed using the modified PDPA system. A real-time capture of the particle size and velocity distributions of lactose A are shown in Fig. 7. The diameter and speed values obtained from Fig.7 a. & b. are used to calculate the charge on a particle using (4).

The bipolar behavior of this type of lactose was investigated under three different experimental conditions. Firstly, the powder's inherent charge distribution was measured immediately after being dispersed from the feeder. The

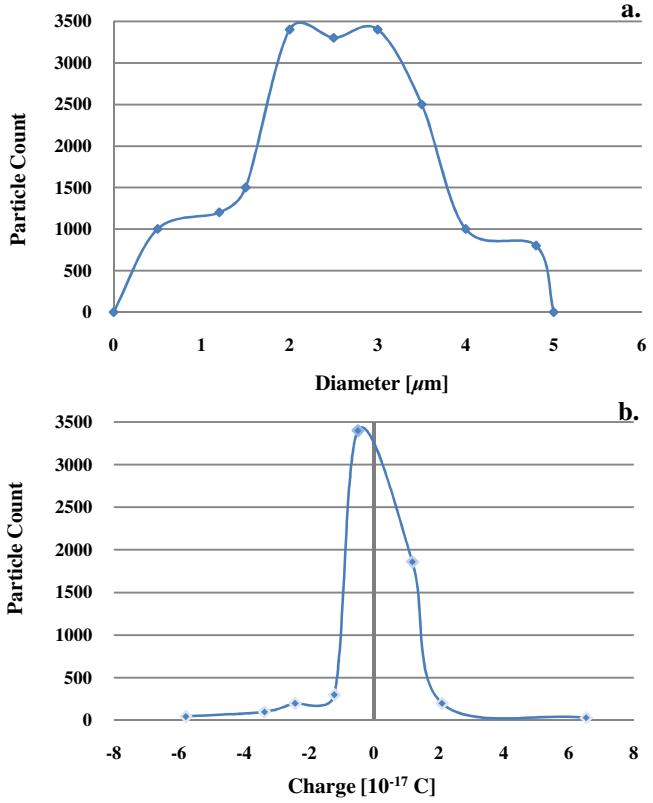

Fig. 6. PDPA test showing the diameter (a) and the bipolar charge (b) distributions of airborne particles in ambient air.

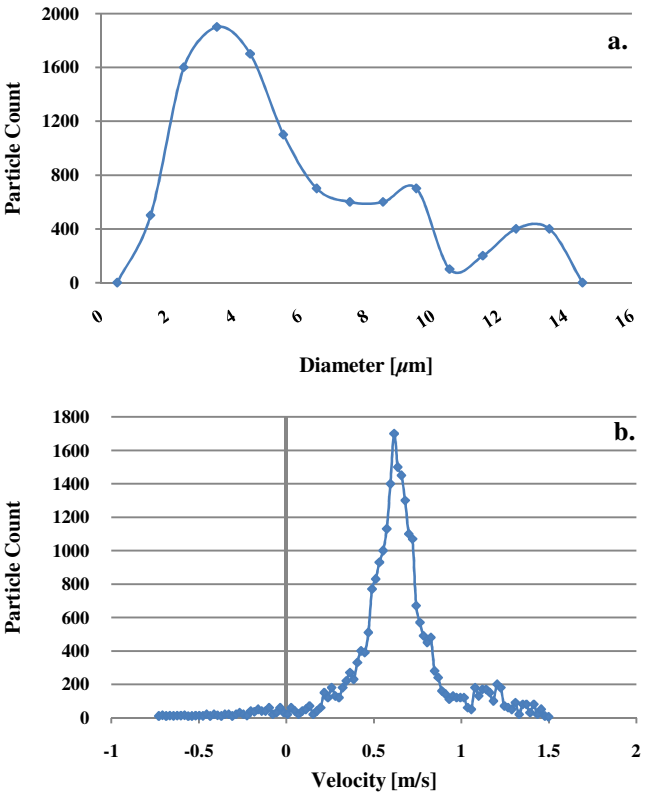

Fig. 7. Lactose A real-time diameter (a) and speed (b) distributions using PDPA system.

measured values of the bipolar charge distribution are shown in Fig. 8.a. A total number of approximately 35,000 particles were analyzed per each run. The data was collected in the centerline of the electrode set-up as seen in Fig. 4. The charge distribution varies between -8×10^{-15} C and $+5\times10^{-15}$ C. For comparison purposes, the charge distribution on lactose particles precharged with positive and negative corona was examined. The corona charger used in the experiment employed a coaxial electrode arrangement. It comprises of a coaxial wire with the radius of 0.025 mm, maintained at high potential of 5 kV. Corona charging has eliminated effectively one polarity of charge and produced predominantly unipolarly charged lactose particles.

The overall charge distribution (Fig. 8. b & c) for positive corona ranged from approximately 0 C to $+7\times10^{-15}$ C per particle, while for negative corona from 0 C to -10×10^{-15} C.

The particle charging mechanism is probabilistic in nature, therefore, the charge accumulated by the particles is not uniform and shows a certain distribution. Figure 8, reflects the most probable charge levels acquired by the majority of the particles. These charge levels depend on a number of factors such as the lactose particle size, particle residence time within the charging zone, the inter-particulate collisions, particle morphology, temperature, humidity, etc.

The finer lactose samples B and C proved to be highly cohesive in nature, which encouraged particle agglomeration and cohesion. This strongly influenced the ability to feed the test samples into the measuring cell by the feeder. Very few measurements were validated by the system, and the rest were discarded by the signal processing unit. The low data rate could not be used to calculate charge distribution for these samples, as the number of measurements were statistically insignificant.

VI. Summary and Further Work

This experimental study has enabled a better understanding of the dry powder properties and fundamental physical inter-particle mechanisms involved in acquisition of electrostatic charge, retention and neutralization. The results demonstrate the capability of this technique to allow real-time simultaneous determination of particle size and charge. The charge on analyzed particles can vary in a range from $(0 - 10^4)$ times the electronic charge. The accuracy is depending on the velocity and particle size measurement. In the case of highly agglomerated and highly charged lactose powders the error caused by the electric field induced by the space charge has to be taken into account. Further development of the PDPA measuring cell and sample feeding mechanism is essential to accommodate cohesive, small particle size samples, like micronised lactose. Optimized electrode system, DC and AC electric field simulations in conjunction with air flow aerodynamics will hopefully lead to a better detection and validation of non-spherical dry powders using advancements in the PDPA system. It is clear from the analysis of previous simulations and other experimental work that device efficiency for drug delivery to the lungs can be strongly influenced by critical powder attributes like electrostatic bipolar charge distribution. Therefore, the effort to develop valid measurement techniques will prove to be of significant benefit in controlling dry powder processes in the pharmaceutical industry.

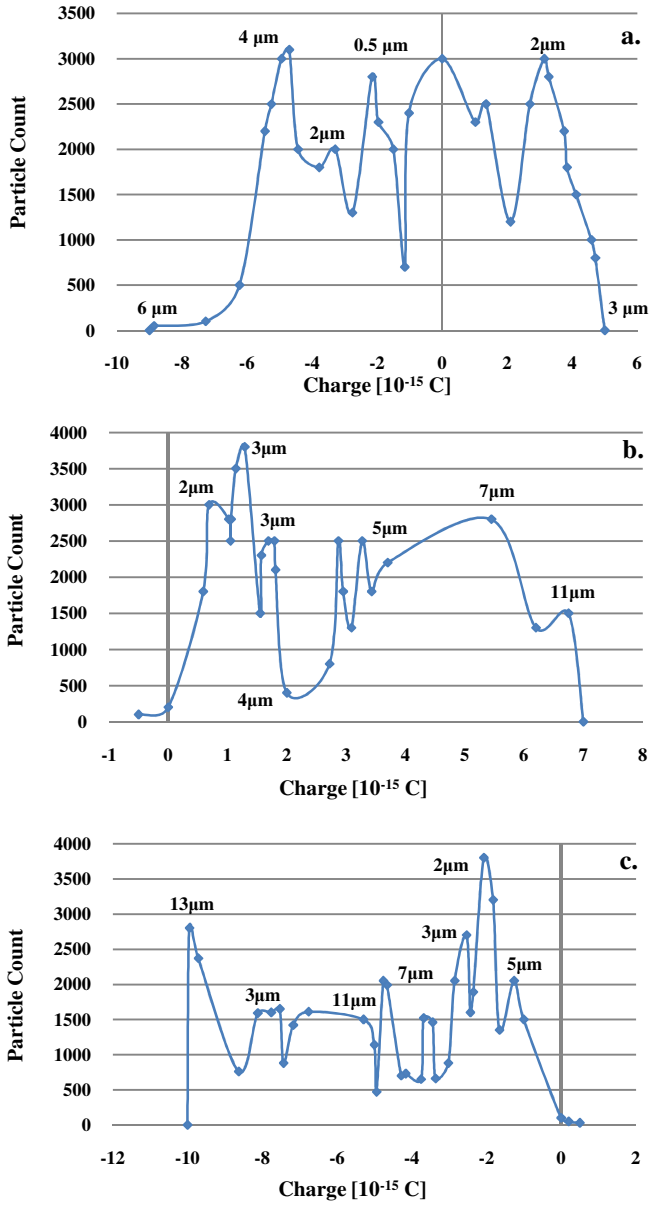

Fig. 8. Lactose A charge distribution. (a) Random lactose sample. (b) Positive corona discharge V=5 kV. (c) Negative corona discharge V= -5 kV.

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From 2003 to 2007 he was with the High Intensity Field Laboratory, Technical University of Cluj-Napoca, Romania, and from 2006 to 2008 with Electronics and Electrostatics Research Unit, Laboratory of Automatics and Industrial Informatics & Laboratory of Aerodynamic Studies UMR6609, University of Poitiers & IUT Angoulême, France, where he took part in various research projects aimed at the study of applied electrostatics, electrohydrodynamics, tribocharging phenomena of fine powders and the development of novel electrostatic separation technologies for minerals and recycling industry. Currently as a member of the Centre for Electronic Systems Research, Brunel University, UK his research interests focus on characterization of pharmaceutical aerosols, charge particle dynamics, Phase Doppler Anemometry, medical electrostatics and nanotechnology.

Mr Beleca is member of the IEEE Industry Application Society, Institution of Engineering and Technology UK, Romanian Medical Association, TATE Galleries UK which include international modern and contemporary art and British art from 1500 to the present day.

Maysam Abbod was born in 1966. He has finished his BSc degree in electronics from the University of Technology, Baghdad in 1987 and PhD degree in Control Engineering for the University of Sheffield in 1992. His research work is of a multi-disciplinary nature ranging from biomedical applications to industrial applications. He has been a Research Fellow working for the Institute for Microstructural and Mechanical Process Engineering, The University of Sheffield (IMMPETUS) on modeling of material properties using hybrid modeling techniques. His research interests include intelligent systems for modeling and optimization. Currently he is a lecturer in Intelligent Systems in the School of Engineering and Design, Brunel University.

Dr Abbod is a member of the IET and Chartered Engineer. He has published over 40 papers in journals, 9 chapters in edited books, and over 50 papers in refereed conferences.

Wamadeva Balachandran (M'91-SM'96-F'04) is Professor of Electronic Systems and Director of the Centre of Electronic Systems Research at Brunel University, UK. He served as Head of Department of Systems Engineering at Brunel University from 1999 to 2004. His research interest spans several different disciplines: Electrostatics & Charge Particle Dynamics, Electrohydrodynamics, Micro/Nano particles and fibre generation, Transport of DNA using DEP force, Lab-on-a-chip, Electromagnetic Field Sensing, EM Interaction with Human Body, Dynamic Measurement Systems, Global Positioning Satellite System for Navigation and Medical Electronics. He has published over 300 papers and filed 14 patent applications.

Professor Balachandran was a Visiting Scholar at University of Georgia in 1993 & 1996, and in University of California, Los Angeles in 2004. He is a Visiting Professor at University of Mansoura, Egypt and University of Technology Dongguan, China. He is the recipient of IEEE John Melcher "Best Paper" award, IEEE "innovation and creativity award and three other best paper awards for presentations made at international conferences. He is also a recipient of Royal Academy of Engineering Global Research Award in 2004. He is a paper review manager of IEEE Transactions of Industrial Application Society. Prof. Balachandran is a member of the Editorial Board of the Journal of Atomization and Sprays, and the International Journal of Particle Science and Technology. He has been a Guest Editor for the Journal of Measurement & Control. He has organized and Chaired several international conferences and continue to serve as a member of several scientific and organizing committees. He is regularly invited to Chair sessions at IEEE, ICLASS, and several other meetings in the UK, Europe, USA and Asia. On a couple of occasions, Professor Balachandran's research has been featured on BBC World Service and TV Broadcasts.

He is a Fellow of IET (UK), IEEE (USA), Institute of Physics (UK), Institute of Measurements and Control (UK), and Royal Society of Arts (UK). He has a long experience of acting as a consultant in the fields of his research to over 30 companies worldwide.

Session 7: Biomedical

Paul R. Miller was born in Sussex, UK in 1957. He has worked at Upjohn, UK for 13 years before joining Pfizer, in Sandwich, Kent where he has developed his career in Inhalation Science over the past 19 years. His academic background is as a Chemist – his first degree was in Applied Chemistry and a Masters in Analytical Chemistry, at University of London, Chelsea College (1984).

Within his many roles at Pfizer, he has been responsible for building the Inhalation Analytics discipline, which has allowed him to cover many different avenues of Inhalation R&D. These areas range from License & Development to Regulatory science (as a founder member of the European Pharmaceutical Aerosol Group), Inhalation toxicology to Clinical scintigraphy studies & devices technology hunting, Materials science of respirable particles (micronisation processing, particle engineering and particle characterisation), to co-inventing aerodynamic particle sizing equipment and automating inhaler performance testing – are all areas he understands can be strongly influenced by electrostatic charge and therefore, has an equally strong interest in developing meaningful & valid measurement for bipolar charge distribution in controlling pharmaceutical powders and processes.

Mr Miller is a Member of the Royal Society of Chemistry, a Chartered Chemist and a Chartered Scientist.