DESIGN AND EVALUATION OF THE LOVELACE DRY POWDER AEROSOL GENERATOR

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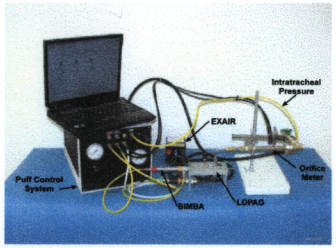
ABSTRACT

Recent advances in pharmaceutical powder technologies and scientific interests in bioaerosols have predicated the necessity of efficient laboratory scale aerosol generation devices for research purposes. We designed and developed the Lovelace Dry Powder Aerosol Generator (LDPAG) to deliver precise, known quantities of test article directly into the lung with a single breath. The LDPAG was tested with bulk pharmaceutical, medicinal vehicle and bacterial powders to determine their mass transfer, mass transfer efficiency and particle size distribution (PSD). Aerosol particles were collected on filters and by cascade impactors, then analyzed gravimetrically. Our results indicate that mass transfer, mass transfer efficiency and PSD are proportional to the amount and bulk size of the test article loaded into the LDPAG and to the physical properties of the powder. We generated aerosols in the respirable range (mass median aerodynamic diameter less than or equal to 10 microns) with a mass transfer efficiency of up to 66%. We have demonstrated the ability of the LDPAG to generate a variety of dry powder aerosols. However, their in-transit behavior is subject to many phenomena that affect particle size distribution and efficiency. Thus, we recommend that powders aerosolized with the LDPAG be fully characterized.

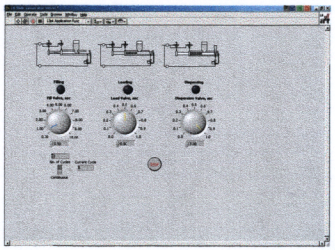
BACKGROUND

- The Lovelace Dry Powder Aerosol Generator is a pneumatic driven device that can be operated in continuous or single puff configuration.
- A slide bar is actuated into fill, load and dispersion positions.
- LDPAG volumetric airflows and pressures are set with a Puff Control System.
- Operational parameters are selectable and are controlled and monitored through a LabVIEW™ operating platform.
- Dispersion air is discharged with a EXAIR static neutralizer.
- Puff volumes are determined using a calibrated 0.318" cm diameter differential pressure orifice meter.
- Intratracheal pressure measured using a SETRA model 254 pressure transducer.
- An automated safety overpressure "kick-out loop" built into system.

Lovelace Dry Powder Aerosol Generator



LabVIEW Control Panel



METHODS

- Powders Tested:
  - Lyophilized Bacillus *globigii* (BG)
  - Dry powder pharmaceutical vehicle
  - Defatted western ragweed, Ambrosia *psilostachya*
- Bulk powders are charge neutralized using a MILTY ZEROSTAT 3 discharge gun and weighed.
- Weighed aliquots are transferred into the slide bar.
- LDPAG fill and load actuation times set at 0.5 seconds.
- LDPAG dispersion time set at 3 seconds (1.5 seconds for BG Procedure C).
- Filter samples and cascade impactor samples collected at the end of a 8.5 mm I.D. endotracheal tube.

BG

- Procedure A
  - Load three equivalent weight aliquots in LDPAG LDPAG flow rate: 15 L/min.
- Procedure B
  - Load three different weight aliquots in LDPAG LDPAG flow rate: 15 L/min.
- Procedure C
  - Load three equivalent weight aliquots in LDPAG LDPAG flow rate: 30 L/min.

Vehicle

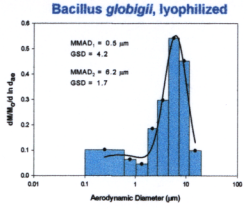
- Procedure A
  - Load three equivalent weight aliquots in LDPAG LDPAG flow rate: 15 L/min.
- Procedure B
  - Load three different weight aliquots in LDPAG LDPAG flow rate: 15 L/min.

Ragweed

- Procedure A
  - Load three equivalent weight aliquots in LDPAG
  - LDPAG flow rate: 15 L/min.

RESULTS

Bacillus *globigii*, lyophilized



BG Procedure A

LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
10.7	3.76	35.1
10.6	4.97	46.9
10.9	3.98	36.5
MEAN	4.24	39.5
STDEV	0.64	6.4
%CV	15.2	16.3

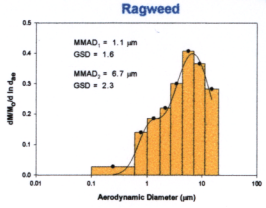
BG Procedure B

LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
10.1	4.09	40.5
20.5	8.39	40.9
30.2	13.97	46.2
MEAN	42.6	
STDEV	3.2	
%CV	7.5	

BG Procedure C

LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
10.6	5.70	53.8
10.5	5.52	52.5
10.1	5.87	58.1
MEAN	5.69	54.8
STDEV	0.18	2.9
%CV	3.1	5.3

Ragweed

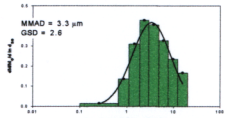


Ragweed

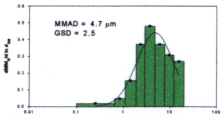
LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
26.4	15.95	60.4
26.5	15.20	57.3
26.7	15.16	56.8
MEAN	15.44	58.2
STDEV	0.45	2.0
%CV	2.9	3.4

Vehicle

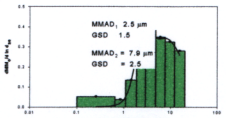
3 mg Load



5 mg Load



10 mg Load



Vehicle Procedure A

LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
5.1	2.55	50.0
5.4	2.81	52.0
4.9	2.68	54.8
MEAN	2.68	52.9
STDEV	0.13	3.5
%CV	4.8	6.6

Vehicle Procedure B

LDPAG Load (mg)	Mass Transfer (mg)	Transfer Efficiency (%)
5.3	3.78	71.3
10.1	5.39	53.3
15.9	13.30	66.3
MEAN	58.0	
STDEV	7.3	
%CV	12.6	

DISCUSSION

- Different dry powders are generated with different efficiencies by the Lovelace Dry Powder Aerosol Generator.
- Particle charging during dispersion causes agglomeration resulting in larger aerosol particle sizes than bulk compound.
- As a result, each material generated with the LDPAG must be characterized for size distribution and output efficiency