

In-vitro capabilities to demonstrate Bio-Equivalence for Orally inhaled and nasal drug products as per FDA & EMA guidance

(Applicable to other global regulatory agencies as well)

List of In-vitro characterization studies for



Pressurized Metered Dose Inhalers (pMDIs)



Dry Powder Inhalers (DPIs)



Aqueous and Non-Aqueous Nasal Sprays



Nebulizer Formulations

Single actuation content (SAC)/
Delivered dose uniformity (DDU)



Aerodynamic particle size distribution (APSD)/
drug in small particles or droplets



Spray pattern



Plume geometry



Priming and Repriming



Droplet size distribution by laser diffraction



Mean nebulization time



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Aerodynamic particle size distribution (APSD)



SAC/DDU of OINDPs



Spray pattern and Plume geometry



Laser diffraction for aerosol droplet size distribution



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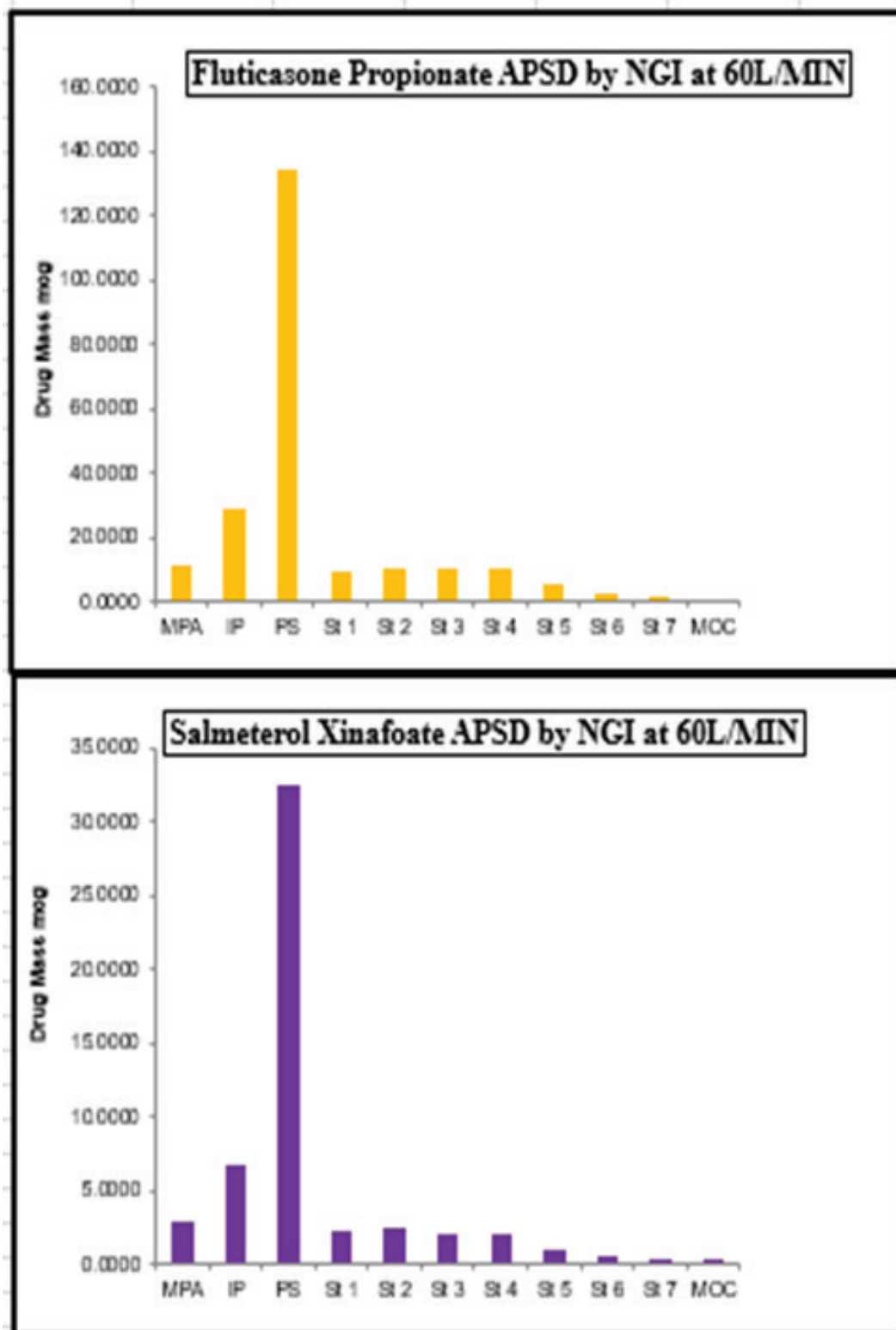
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APSD data for Advair Diskus DPI (250/50 microgram) using NGI at 60 liters per minute (Acquired at Raptim Research)



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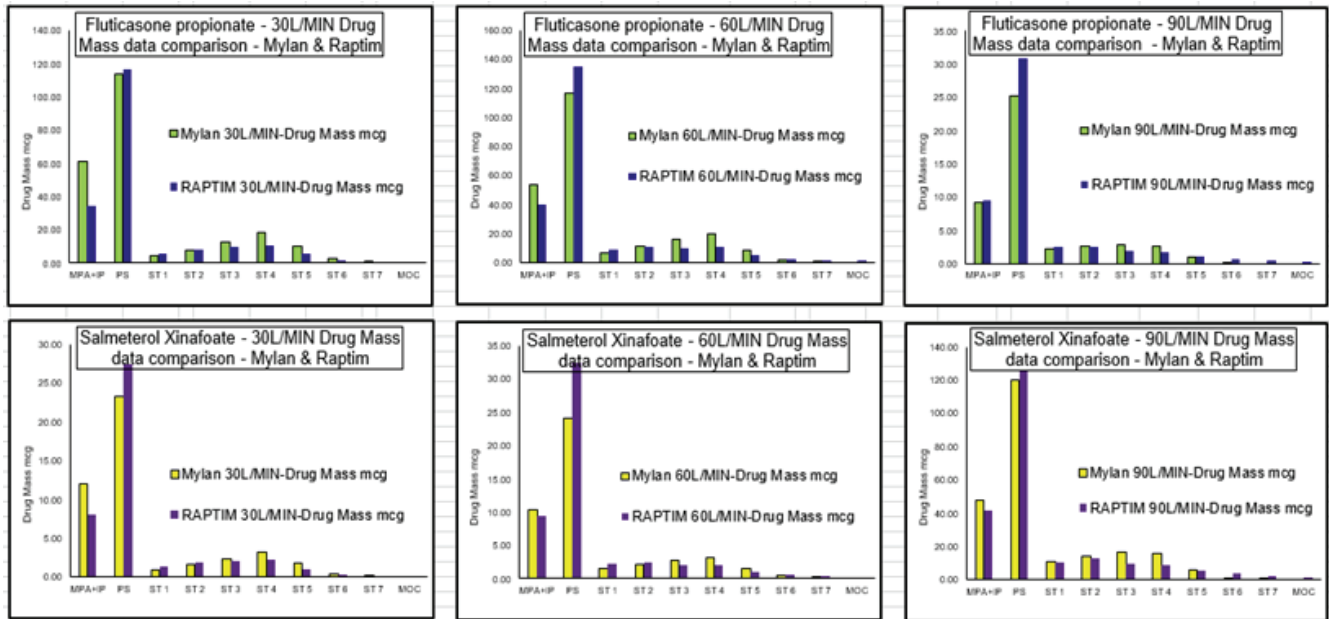
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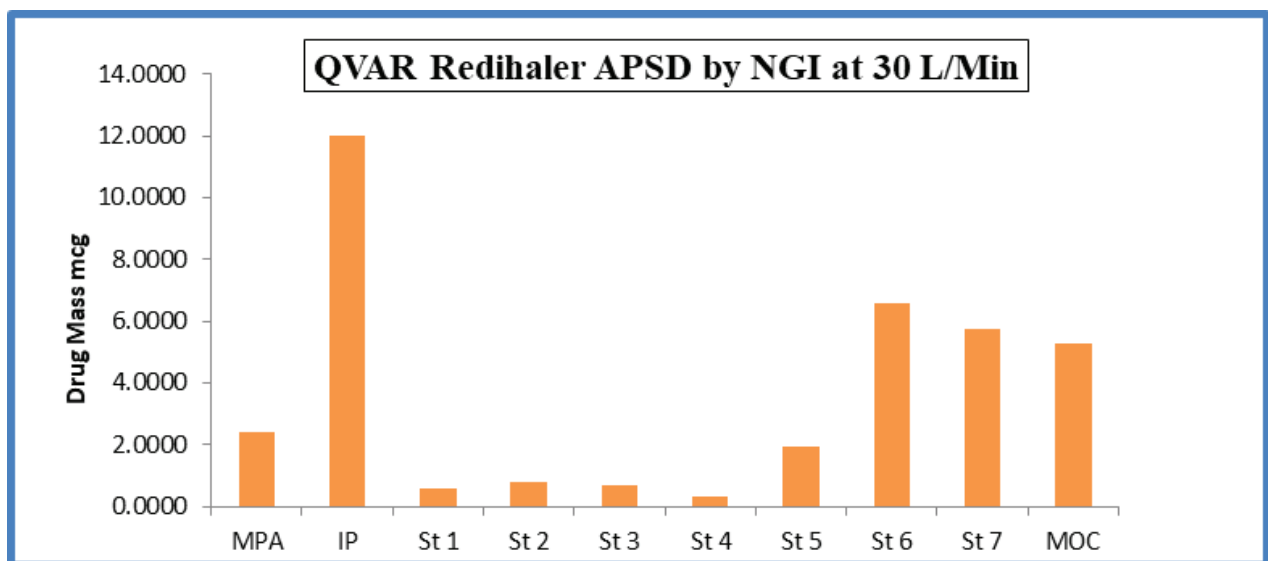
Comparison of Raptim acquired Advair Diskus DPI (250/50 Microgram) APSD data with Mylan acquired wixela inhub DPI APSD data using the NGI at different flow rates

(Reference-<https://doi.org/10.1089/jamp.2019.1584>)



The above figure demonstrates that Raptim acquired data matches well with that acquired by Mylan, indicative of high quality of Raptim's in-vitro analysis

APSD Data for QVAR redihaler (40 microgram) using NGI at 30 liters per minute (Acquired at Raptim Research)

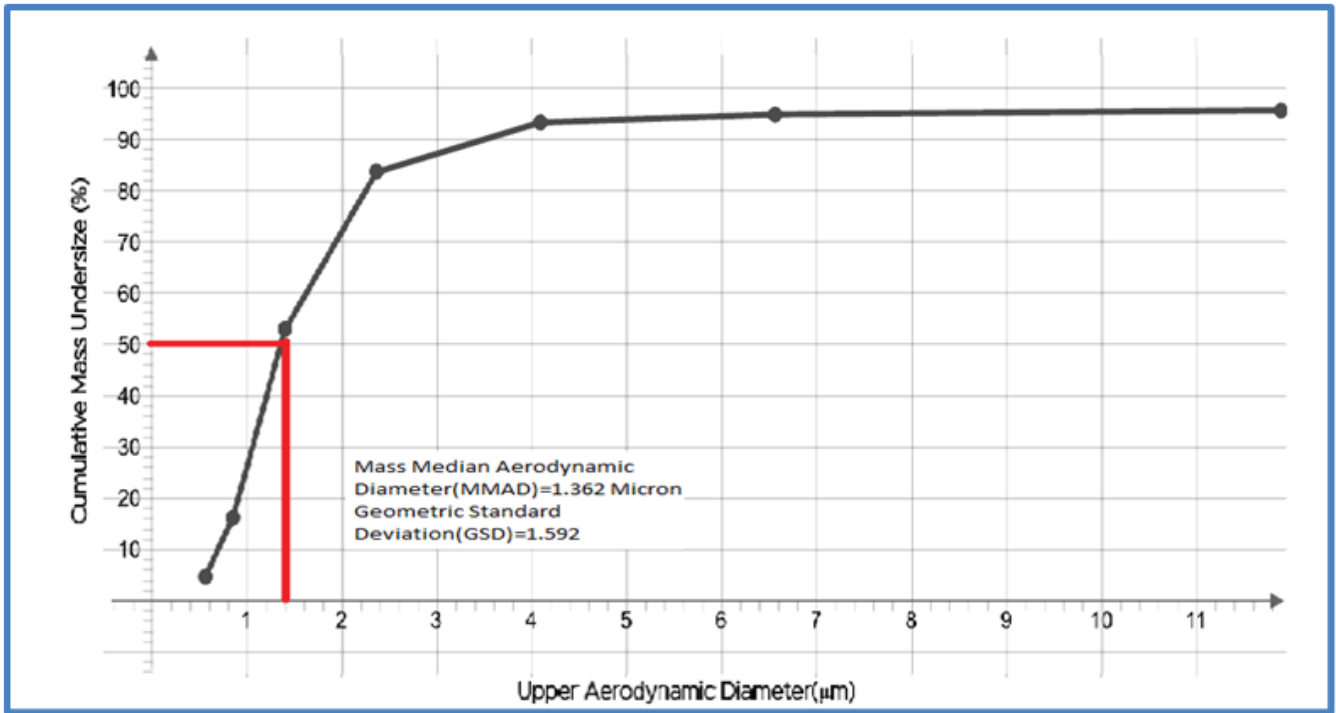


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MMAD and GSD values for beclomethasone dipropionate pMDI (200 Micrograms) estimated by NGI at 28.3 liters per minute



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Examples of inhalation products tested in Raptim Research Pvt Ltd

Sr.No	Name of the Product	API	Type of Inhaler
1	Advair Diskus	Fluticasone Propionate (250mcg) and Salmeterol Xinafoate (50mcg)	DPI
2	Symbicort	Budesonide(80mcg) and Formoterol Fumarate(4.5mcg)	DPI
3	Symbicort	Budesonide(160mcg) and Formoterol Fumarate(4.5mcg)	DPI
4	QVAR Redihaler	Beclomethasone Dipropionate(40mcg)	Breath Actuated pMDI
5	QVAR Redihaler	Beclomethasone Dipropionate(80mcg)	Breath Actuated pMDI
6	Seroflo	Fluticasone Propionate (250mcg) and Salmeterol Xinafoate (25mcg)	pMDI
7	Foracort	Budesonide(200mcg) and Formoterol Fumarate(6mcg)	pMDI
8	Beclate	Beclomethasone Dipropionate(200mcg)	pMDI
9	Asthalin	Albuterol Sulfate(100mcg)	pMDI

Raptim Research is now ready to perform in-vitro characterization of orally inhaled and nasal drug products for bio-equivalence

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