

Examining an Intranasal Drug Delivery Device for Topical Treatment of the Nasal Passages and Sinuses

Summary

The RhinoClear Sprint is a battery-powered device that uses positive pressure to propel a saline or medicated solution into the nasal passages and sinuses. A nasal administration device like the RhinoClear Sprint may be used to deliver compounded medications for topical sinus therapy. Testing was performed in order to determine whether the RhinoClear Sprint is safe and effective for administering medicated solutions for this targeted treatment area. A major determinant of whether topical sinus therapy is safe and effective is pulmonary deposition of particles, which is determined by measuring the number of particles smaller than $10\mu\text{m}$. Testing showed that $< 3\%$ of the particles dispersed by the RhinoClear are smaller than $10\mu\text{m}$. It can be concluded that $> 97\%$ of the solution on average is deposited in the intended treatment area of the nasal passages and sinuses.

Particle Size Measurement of the RhinoClear Sprint

Woodland Hills Medical Supply commissioned testing from Spray Analytics, located in Lincolnshire, Illinois, to determine whether the particle size of a solution administered with the RhinoClear Sprint atomizer was sufficiently large to minimize pulmonary deposition and sufficiently small to penetrate into the sinuses.

The RhinoClear Sprint device was submitted to Spray Analytics for droplet size distribution testing. The Malvern Spraytec analysis tool was used for analysis. The Spraytec uses the technique of laser diffraction for measurement of the size of spray droplets and spray particles. It measures the intensity of the light from a laser beam as it passes through a spray. This method of measurement is recommended in FDA guidance for analysis in the development of locally acting nasal sprays.¹

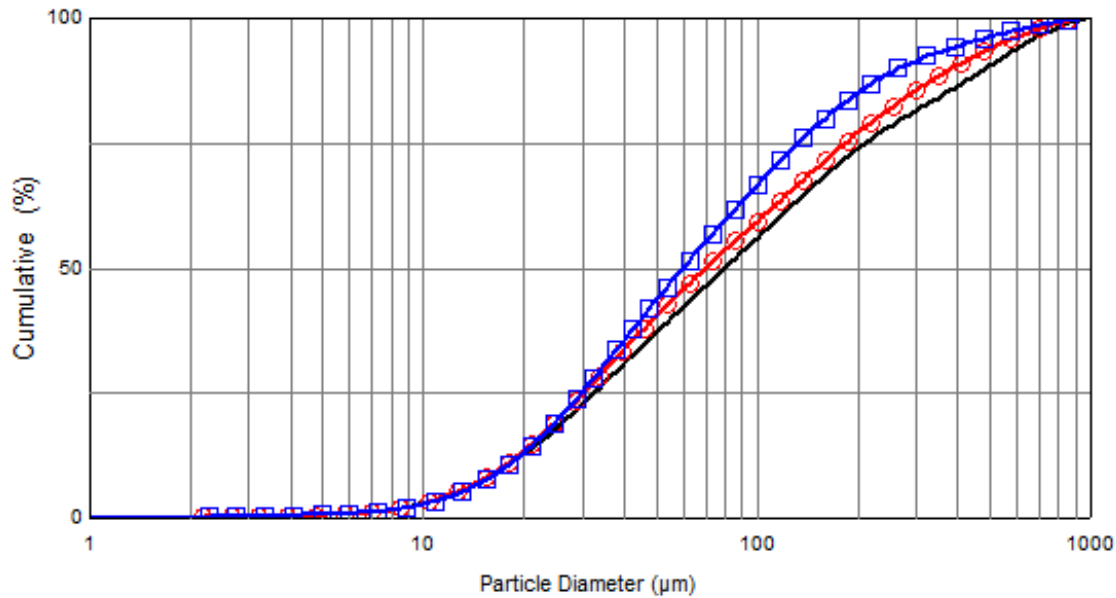
For the analysis, the atomizer was tested at 4cm from the detector beam and sprayed vertically. The sample was investigated for droplet size distribution and the final testing was performed as follows:

- Data was collected in triplicate for spray event of 5s with 300 mm lens



RhinoClear Sprint Atomizer with
Compounded Medicated Solutions

Overview of Three Samples



- The RhinoClear Sprint medication chamber was filled with RO water
- Data acquisition rate was set to 10Hz
- Refractive Index and Absorption Values of 1.33 and 0 were used
- Results were obtained by averaging the entire spray

The percent of particles measured that were less than 10µm in size averaged 2.912% over the three spray events. The median droplet size average for three sprays was 69.66µm.

Discussion

The term “atomizer” refers to a nasal drug delivery device that uses positive pressure to propel medication into the nasal passages. The term is in reference to the small size of the particles as they leave the device. The RhinoClear Sprint atomizer is designed to be used for regular saline nasal irrigation but it may also be used for delivering liquid medications to the nasal passages and sinuses.

The medication container on the RhinoClear Sprint has one chamber for holding medication or saline rinse and one for collecting discharge. The side that holds the solution can hold up to 15mL. The battery-powered device sends a spray of medication through a nasal adaptor, which is available in three different sizes to fit the individual’s nose.

Spray Analytics Testing Results

The percentage of spray by volume at droplet sizes of 10µm and less is thought to be inhalable and often requested in health and safety studies



Malvern Spraytec

for consumer goods. Less than 3% of the particles dispersed by the RhinoClear are smaller than $10\mu\text{m}$. This means that an insignificant amount of the medication can be deposited beyond the sinuses.

It is important to note that this percentage represents particles measured leaving the atomizer, not particles reaching the lungs. The actual sizes of particles that reach the lungs are between $5\mu\text{m}$ - $10\mu\text{m}$, with $10\mu\text{m}$ being used to provide a "safe" zone. This cut-off can vary between individuals.

A nebulizer intended for delivery of medication to the lungs must have a small particle size in order to avoid deposition in the nose. When the target treatment area is the nose and sinuses, however, a larger particle size is more desirable to prevent pulmonary deposition of the medication.² A larger particle size of $300\mu\text{m}$ will likely be retained in the anterior nasal passage or fall out. A smaller particle size of $20\mu\text{m}$ will travel further into the sinuses.

The nose is efficient at filtering particles out that may cause harm to the body through deposition in the lungs.³ This means that there is significant resistance to particles reaching further into the sinuses. The testing results showed that the RhinoClear Sprint atomizer produced a variety of particle sizes in the range from $10\mu\text{m}$ - $300\mu\text{m}$. A variety of particle sizes may be beneficial for intranasal drug administration as it allows for distribution of medication throughout the anterior and turbinate areas. When particles are uniformly small or large, they are more likely to be deposited in a similar region.

Positive Pressure and Distribution of Medication

It has been demonstrated that sinus rinse and nebulizer devices provide good sinus penetration.⁴ It has also been recognized that nasal irrigation is effective in the treatment of several acute and chronic sinonasal conditions.⁵ The use of positive pressure to propel medication into the nasal passages provides greater benefits than simply inhaling or using a nasal spray. With negative pressure, as is used when sniffing, the medication is not distributed as broadly in the sinuses. Positive pressure is needed to force the liquid medication into the nasal passages and distribute it more broadly into both the anterior and turbinate regions.

Conclusion

It should be noted that droplet size is not the sole determinant of whether a nasal spray will be distributed evenly throughout the sinuses.⁶ Equally important is the angle of administration (of the body in relation to the nasal spray tip) and the position of the nasal spray tip itself. One study concluded that "both the plume angle and administration angle are critical factors in determining deposition efficiency, while many other spray parameters, including particle size, have relatively minor influences on deposition within the nasal cavity." It is clear that particle size is not the only factor influencing deposition within the nasal region. However particle size measurements are a good determinant of whether particles are small enough to potentially be inhaled or be deposited broadly in the sinuses. Future testing and research on the RhinoClear Sprint

will include a more in-depth analysis of plume geometry and the angle of administration to account for these important distribution factors.

Research

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5. Principi N, Esposito S. Nasal irrigation: an imprecisely defined medical procedure. *Int J Environ Res Public Health.* 2017;14(5):E516.
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Contact Information

The RhinoClear Sprint is manufactured by Flaem Nuova in Italy and distributed to doctors and patients throughout the U.S. by Woodland Hills Medical Supply in California.

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For more information about the RhinoClear Sprint:

www.RhinoClearSprint.com