Hound identifies foreign particles from dry powder inhalers

Introduction

Regulatory authorities require the evaluation of foreign particulate matter for respiratory drugs, including dry powder inhalers (DPI). Hound can be used to identify sub-visible and visible particulates (Figure 1). In this application note Hound is used to detect inhalable foreign particulate matter.

Methods

3 actuations of a dry powder inhaler were collected in a foreign particulate sampling tube. The powder was dissolved in 150 mL of 30% ethanol. The suspension was then filtered through a 0.8 µm filter round. The filter round was then loaded into Hound for automatic microscopy and Raman spectroscopy analysis. After morphologic analysis, Hound performed chemical identification with Raman spectroscopy for all particles >2 µm.

Results

Hound identified 514 particles larger than 2 µm (Figure 2). Particles were identified by comparing processed Raman spectra to an expandable reference library (Figure 3). Of the 514 particles

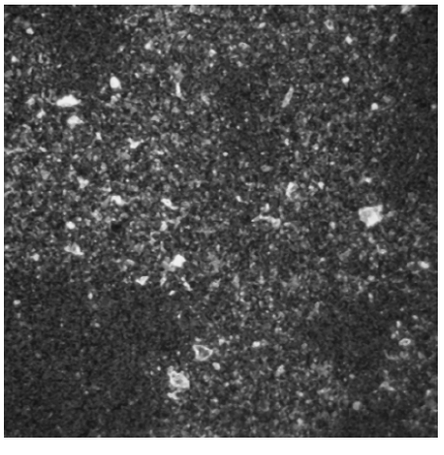

Figure 2: Dark field image of DPI particulates collected on the filter round.

Figure 1: Hound images, counts, sizes and identifies sub-visible and visible particles.

Hound identified, 480 were inhalable foreign particulates (<10 µm), while 34 were larger particles. The major product contaminants, including all particles >25 µm, were identified as polyester or carbon, with 160 and 141 particles respectively (Table 1). Polyamide and cellulose acetate were identified as additional impurities.

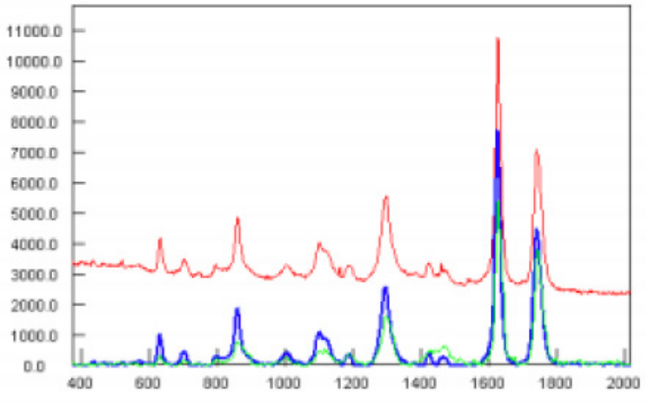

Figure 3: Chemical identities are confirmed by processing a raw Raman spectrum (red) to create a processed spectrum (blue) to match to an expandable reference library (green).

Substance	Number of particles	Size (µm)			
		2-5	5-10	10-25	≥25
Cellulose Acetate	41	32	6	3	0
Polyamide	95	78	12	5	0
Carbon	141	120	11	8	2
Polyester	160	132	17	7	4
Others (9 different species)	77	60	12	5	0
Total	514	422	58	28	6

Table 1: DPI particles >2 µm identified by Hound.

Summary

The fully automated identification of all foreign particles from DPI samples is a big advantage when the source of contaminant must be identified. The results obtained with the Hound enable statistically relevant and reliable conclusions about particle chemical composition.

Unchained Labs
6870 Koll Center Parkway
Pleasanton, CA 94566
Phone: 1.925.587.9800
Toll-free: 1.800.815.6384
Email: info@unchainedlabs.com

Rev A