

NanoRam®-1064 Fast Facts: Botanical Verification

Before the technological advancements of science, botanical medicine laid the groundwork for pharmaceutical advantages that exist today. Botanicals are derived from plant materials and are used for their medicinal and therapeutic properties. They are the primary aspect of the dietary supplement market called nutraceuticals that is promoted to the public as a holistical alternative to typical pharmaceutical drugs. The nutraceutical market is not as heavily regulated by the U.S. Food and Drug Administration (FDA) as the pharmaceutical drug market. However, under the FDA nutraceuticals manufacturers of botanicals follow Good Manufacturing Practice (GMP) requirements to ensure identity, purity, quality, strength and, composition, which qualifies for necessary testing before

consumption.

Raman can be utilized in the testing of botanical samples. Each sample varies with different chemical components, and some fluoresce greater than others. A typical handheld Raman device with a 785 nm laser is unable to identify the grape seed extract due to strong fluorescence (Figure 1, red trace). B&W Tek's NanoRam®-1064 is able to minimize some of the fluorescence from the grape seed extract (Figure 1, blue trace), permitting visibility of a few peaks for quick handheld Raman analysis.

The NanoRam-1064 is a handheld Raman device fully compliant with all major pharmacopeias. Its records management software is 21 CFR Part 11 compliant with complete audit trail.

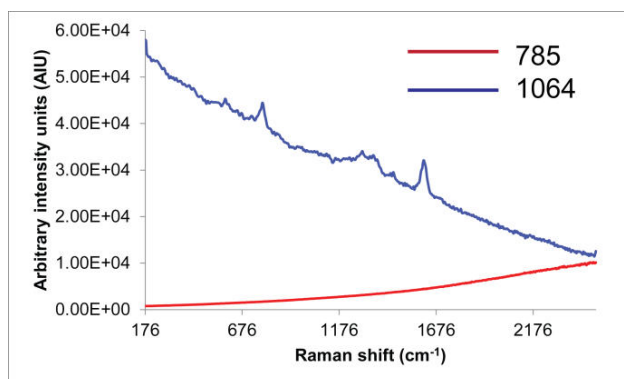


Figure 1. Raman spectra of grape seed extract collected with 785 nm and 1064 nm laser excitations.

A NanoRam-1064 with a point and shoot adapter was utilized to analyze four different types of botanical samples sealed in plastic sample bags (Figure 2). The samples include vitamin K2 and pomegranate, rhodiola rosea, and grape seed extracts. Laser power was set at 90% of the maximum power (~380 mW) for the Vitamin K2 sample with a yellow pigmentation. The laser power was set at 10% (~42 mW) for the remaining three samples because of

darker colored samples. For this case study the NanoRam-1064 Identification mode was utilized because it provides a robust algorithm based on a multivariate method. For each botanical sample an individual method was created. To create a method each sample was scanned five different times in alternate spots. All samples were tested against each method to prove validity.



Figure 2. Analyzing grape seed extract with 1064 nm laser with point and shoot adapter.

RESULTS

The validity of a method is dependent on each method having to prove its “specificity” via the correct sample passing and all other samples failing. The statistical significance (p-value) determines the samples passing or failing the method. The NanoRam-1064 p-value threshold is $p = 0.05$, which corresponds to the default significance level set for the botanical

methods. Calculated p-values over $p = 0.05$ are indicative of a “Pass” result, and p-values below $p = 0.05$ result in a “Fail” result. **Table 1** displays a matrix of pass/fail results for each individual botanical method. Each botanical method is able to selectively pass its own sample, while failing all other samples.

Method Sample	Vitamin K2	Rhodiola rosea ext	Pomegranate ext	Grape seed ext
Vitamin K2	PASS p=0.999996	FAIL p=0	FAIL p=0	FAIL p=0
Rhodiola rosea ext	FAIL p=0	PASS p=0.999971	FAIL p=7,79692 x10 ⁻⁴	FAIL p=0
Pomegranate ext	FAIL p=0	FAIL p=3.33067 x10 ⁻¹⁶	PASS p=0.999992	FAIL p=0
Grape seed ext	FAIL p=0	FAIL p=0	FAIL p=0	PASS p=0.999997

Table 1. Botanicals specificity matrix

CONCLUSION

The NanoRam-1064 is an effective pharmaceutical device for the minimization of fluorescence in raw materials identification. In this case study the NanoRam-1064 was able to reduce the fluorescence

in different botanical ingredients, allowing them to be analyzed and tested against each individual sample method for robust identification.

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CONFIGURATION



Spectromètre Raman portable NanoRam-1064

Le NanoRam-1064 est un spectromètre Raman portable hautes performances pour l'identification et la vérification non destructives des matières premières entrantes, telles que les IAP, les excipients et les produits intermédiaires, quelle que soit leur couleur. Compact et agile, le NanoRam-1064 peut être utilisé par des utilisateurs non techniques pour identifier rapidement des échantillons en entrepôt, sur rampe de chargement, sur le terrain ou en laboratoire, ce qui minimise les zones de quarantaine et permet aux matériaux de poursuivre plus rapidement leur cycle de vie de fabrication. Utilisant la technologie Raman, le NanoRam-1064 minimise la fluorescence et peut identifier une large gamme d'échantillons en distinguant les différentes qualités de cellulose, de polysorbate et Opadry®. Les tests rapides des matériaux entrants avec le NanoRam-1064 peuvent être effectués à travers des conteneurs transparents, tout en préservant le volume et l'intégrité de l'échantillon. L'unité offre également une bibliothèque intégrée complète et une validation de méthode, créant un flux de travail conforme pour le développement de méthodes et de bibliothèques.

Le NanoRam est entièrement conforme aux normes US FDA 21 CFR Partie 11 et Partie 1040.10, et peut jouer un rôle essentiel dans les installations conformes aux cGMP. Le NanoRam-1064 répond aux exigences des méthodes de spectroscopie Raman, y compris la pharmacopée américaine <858>, la pharmacopée européenne 2.2.48, la pharmacopée japonaise 2.26, ainsi que les directives de la pharmacopée de la République populaire de Chine sur la spectroscopie Raman. Raman est une méthode reconnue pour se conformer aux directives PIC/S et BPF concernant l'assurance d'identité à 100 % pour les matières premières. Une gamme complète de formations et de services d'assistance est disponible, y compris des services d'implémentation IQ/OQ/PQ/DQ, ainsi qu'une assistance au développement de méthodes et/ou de nouvelles bibliothèques.