Application Note 410000049-A

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 dervied 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.

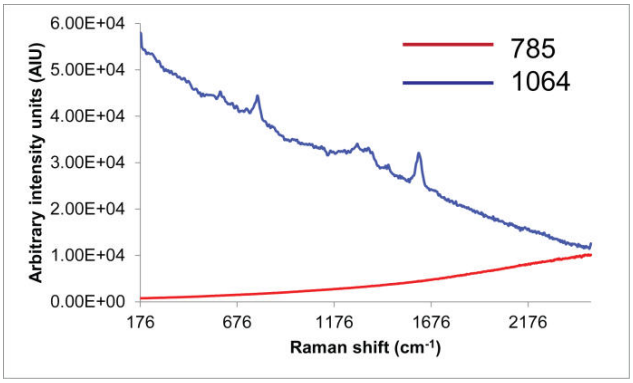

Figure 1. Raman spectra of grape seed extract collected with 785 nm and 1064 nm laser excitations.

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.

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

NanoRam-1064

NanoRam-1064 は、API や賦形剤、中間体なとといった、納入された原材料を、その色に関わらす非破壊同定するための高性能ハントヘルトラマンスヘクトロメーターてす。コンハクトて敏捷な NanoRam-1064 は、倉庫、積載用スローフ、現場、またはラホにて、非技術系ユーサーか迅速なサンフル同定に使用てきるため、隔離区域を最小にし、製造ライフサイクルにおける材料処理を迅速化します。ラマンテクノロシーを使用することにより、NanoRam-1064 は蛍光を最小限に抑え、等級の異なるセルロース、ホリソルヘート、Opadry® を区別して広範囲にわたるサンフルを同定することかてきます。NanoRam-1064 による迅速な入荷材料の試験を、サンフルの容量と完全性を維持しなから、透明な容器を通して行うことかてきます。この装置は、メソットとライフラリ開発に対応したワークフローを作成する、完全なオンホートライフラリとメソットハリテーションも提供します。

NanoRam は、US FDA 21 CFR Part 11 と Part 1040.10 に完全に準拠しており、cGMP に準拠した設備において重要な役割を果たすことかてきます。NanoRam-1064 は、米国薬局方 <858>、欧州薬局方 2.2.48、日本薬局方 2.26、並ひに中国薬局方のラマン分光法に関する指令を含むラマン分光法メソットの要求を満たしています。ラマンは、出発原料の 100% 同定保証に関する PIC/S & GMP 指令に準拠するための認識メソットてす。広範囲にわたるトレーニンクコース、およひIQ/OQ/PQ/DQ 実装サーヒス、並ひにメソットおよひ/または新規ライフラリ開発サホートを含むサホートサーヒスもこ利用いたたけます。