

Raman spectroscopy

European cosmetics industry faces new test in GMP compliance

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Raw material identification

Raw material identification (RMID) is critical for verification of purchased products and raw materials. The GMP guide published by the European Federation of Cosmetic Ingredients clearly states that there should be procedures for the approval and release of each raw material used in the production of cosmetic ingredients.

Upon receipt, raw materials should not be used prior to acceptance. Verification should include a supplier certificate of analysis and, wherever feasible, an identification test. Testing schedules should be organized to separate those tests that are routine from those that are performed infrequently or only for new suppliers.

Sampling activities should be conducted under defined conditions, in accordance with a sampling method, using procedures designed to prevent contamination of the raw material.

Deliveries made by bulk tankers should have appropriate controls to assure material purity and freedom from contamination. Controls should include a certificate of cleaning, analytical testing, or audit of the supplier.

The European GMP guide also specifies production instructions and recording requirements. The guide clearly states that records should include, where critical to cosmetic ingredient quality,



The Thermo Scientific™ TruScan™ Handheld Raman Analyzer can provide raw material identification in seconds.

documentation of each significant step in the manufacturing, packing, or batch-holding process. Required details include:

- Date and time each step was completed
- Identification of individual major equipment and lines used in processing
- Specific identification of each batch of component or in-process material
- Weights and measures of components used in the course of processing
- In-process and laboratory control results
- A record of the inspection of the packaging and labeling area before and after use
- A statement of the actual yield or quantity produced
- A statement of the percentage of theoretical yield
- Labeling control records
- Description of cosmetic ingredient containers and closures
- Description of sampling performed
- Identification of persons performing and directly supervising or checking each significant step in the operation
- A record of investigations made for failures and discrepancies
- Results of final product inspection

A handheld solution to achieve compliance

Designed to meet the stringent requirements of current good manufacturing practices (cGMP), Thermo Scientific™ handheld analyzers provide manufacturers with a portable solution to achieve quality initiatives throughout the manufacturing process. The Thermo Scientific™ TruScan™ RM and Thermo Scientific™ TruScan™ GP are based on Raman spectroscopy and enable on-the-spot, actionable PASS/FAIL results within seconds. These analyzers enable manufacturers to obtain fast, accurate material identity verification with considerable ease and convenience.

The Thermo Scientific analyzers perform identification through sealed packaging to minimize the risk of contamination and exposure. Reports in various formats are available when the data is synchronized to the company network.

RMID in cosmetics manufacturing

The main raw materials used in the cosmetic industry are:

- **Preservatives:** organic acids, alcohols, aldehydes, phenolic compounds, esters, surface active agents, miscellaneous compounds like vanillin, ethyl vanillin, and etramethylthiuram disulfide

Baby products	Bath products	Eye makeup products	Skin care products
Cetyl Alcohol	Cocamide DEA	Alcohol Denat.	Allantoin
Dimethicone	Cocamidopropyl Betaine	Ammonium Acrylates Copolymer	Cetyl Alcohol
Dipropylene Glycol	Dipropylene Glycol	Ascorbyl Palmitate	Dimethicone
Glycerine	Glycerin	Copernicia Cerifera (Carnauba) Wax	Glycerin
Glyceryl Stearate	PEG-6 Laurate	Disodium Cocoamphodiacetate	Glyceryl Stearate
Isopropyl Palmitate	Polyquaternium-11	PEG-6 Sorbitan Oleate	Mineral Oil
Mineral Oil	Propylene Glycol	PEG-6 Sorbitan Stearate	Propylene Glycol
Myristyl Myristate	Sodium Carbonate	Squalane	Stearic Acid
PEG-100	Sterate Sodium Dodecylbenzenesulfonate	Tocopheryl Acetate	Stearyl Alcohol
Sorbitamstearate	Sodium Laureth Sulfate	Triethanolamine	Tocopheryl Acetate
Stearic Acid	Sodium Lauroyl Sarcosinate	Zinc Stearate	Triethanolamine
Stearyl Alcohol			

Table 1. Raw materials that can be measured with the Thermo Scientific TruScan RM and the Thermo Scientific TruScan GP.

- **Humectants:** organic humectants like ethylene glycol, propylene glycol, glycerol, and PEG
- **Surfactants:** sodium oleate, alkyl trimethyl ammonium salts, alkyl polyglycol ethers, acryl peptides and betains
- **Oils, fats and waxes:** almond oil, arachis oil, castor oil, olive oil, coconut oil, oleic acid, fatty alcohols like lauryl alcohols, myristyl alcohols, fatty acid esters like glyceryl monostearate, ethylene glycol monostearate, bees wax, plant wax, mineral wax, and synthetic waxes
- **Perfumes:** most are distilled essential oils from flowers, fruits, seeds, wood, leaves, etc.
- **Colors:** cochneal, saffron, chlorophyll, henna, beet extract, caramel and also permitted inorganic colors

The Thermo Scientific TruScan RM and the Thermo Scientific TruScan GP analyzers can identify many of these raw materials used in the industry, as shown in Table 1.

Case study

The effectiveness of TruScan RM in the identification of pure distilled oils & common oils

Using oil ingredients commercially available from Holland and Barrett, Thermo Scientific researchers collected samples of juniper oil, lavender oil, sweet orange oil, tea tree oil, white camphor bark oil, clove bud oil, vitamin E oil (dltocopheryl acetate), almond oil, oil blend, and extra virgin olive oil.

Methods were created with samples in clear glass vials and then analyzed with a Thermo Scientific TruScan RM device for selectivity. Each sample was tested three times against the method to determine PASS or FAIL, and then tested against the nearest neighbor to determine whether there were any mismatches between the closest neighbors.

Figures 1 & 2, generated in TruScan software, show spectra of all oils exported in SPC and viewed using spectroscopy software.

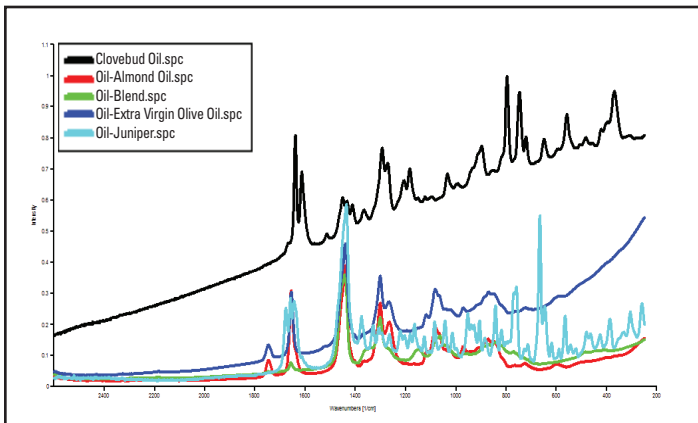


Figure 1. Spectra of five raw materials.

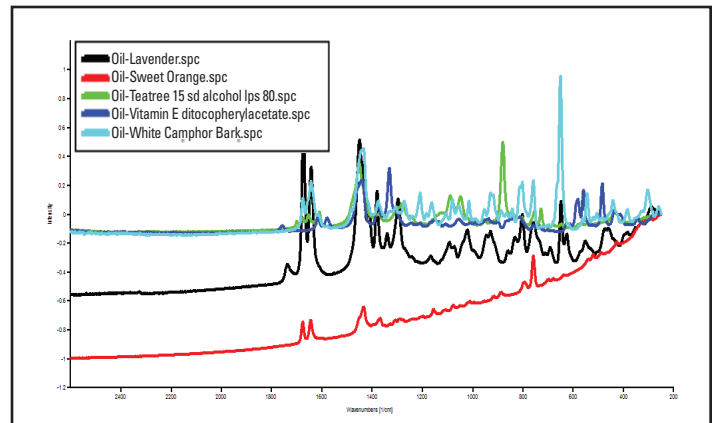


Figure 2. Spectra of five raw materials.

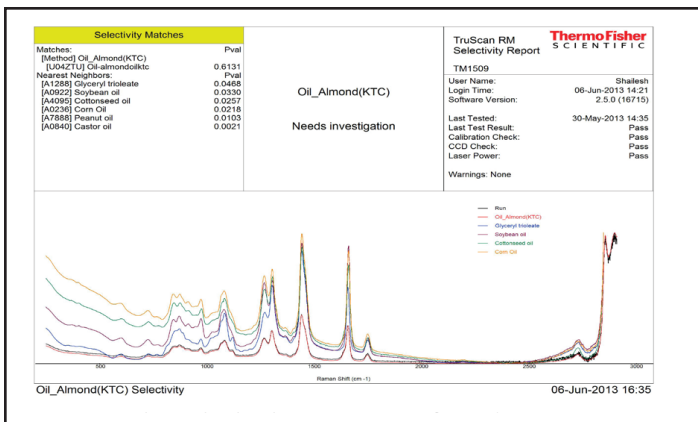


Figure 3. Almond oil selectivity report from the TruScan RM analyzer.

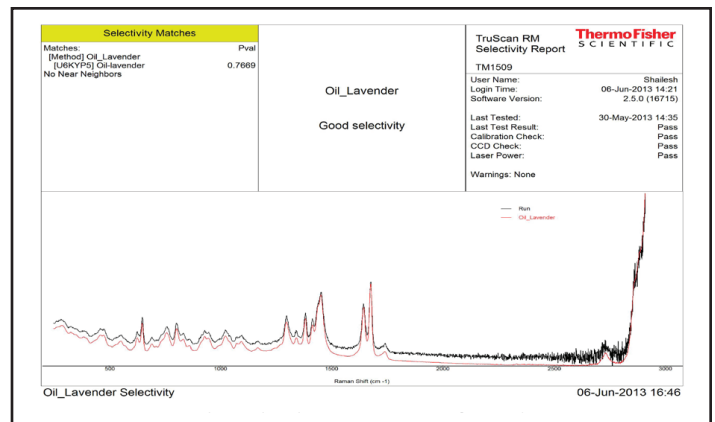


Figure 4. Lavender oil selectivity report from the TruScan RM analyzer.

Results with TruScan RM

The selectivity table (Table 2) shows that specific oils pass for that selected oil only and fail for all of the others (shown in the green color across the diagonal). All of the off-diagonal squares in red indicate that the method is selective for which it is calibrated and non-selective for all of the others, which results in a FAIL. It is also seen that common oils like almond oil and extra virgin olive oils were differentiated from castor, soyabean and peanut oils. The displayed selectivity report shows the nearest neighbors.

The Selectivity Tool on the TruScan RM analyzer helps a method developer easily find the nearest neighbor. For example, in Figure 3, the data suggests that almond oil needs investigation. This means that all of the nearest neighbors listed in the report should be tested against the almond oil method to make sure that this method is selective for only almond oil while all other oils listed in this study will result in a FAIL.

The lavender selectivity report in Figure 4 shows that there are no nearest neighbors. This shows that the lavender oil method is selective only for that oil and is highly selective as it has no neighbors. This would in turn mean that only positive testing will have to be done during validation of this method.

Conclusion

The Thermo Scientific portable TruScan products can help the European cosmetics industry meet the challenge of GMP compliance. The instruments feature Raman spectroscopy, which has been used for QA/QC applications in the pharmaceutical industry for well over a decade.

The case study discussed in this paper illustrates that the Raman technique can also be used in cosmetics manufacturing, where the raw materials would include essential oils of natural origin. The TruScan RM used in the study obtained 100 percent specificity on the raw materials tested. Further, TruScan instrumentation also allows a user to check the formulations at various stages in the manufacturing process.

Advantages of the TruScan RM and TruScan GP include:

- Easy-to-use handheld technology that can be used anywhere in the facility
- Fast return on investment through rapid implementation and savings generated due to non-sampling activity
- Identity testing through packaging, increasing the speed of analysis
- Minimal training required to build the methods and for routine measurements
- No consumables required.

	Almond oil	Extra virgin olive oil	Blend oil	Juniper	Lavender	Sweet Orange oil	Tea Tree oil	White Camphor bark oil	Clove bud oil	Vitamin E oil
Almond oil	Green	Red	Red	Red	Red	Red	Red	Red	Red	Red
Extra virgin olive oil	Red	Green	Red	Red	Red	Red	Red	Red	Red	Red
Blend oil	Red	Red	Green	Red	Red	Red	Red	Red	Red	Red
Juniper	Red	Red	Red	Green	Red	Red	Red	Red	Red	Red
Lavender	Red	Red	Red	Red	Green	Red	Red	Red	Red	Red
Sweet Orange oil	Red	Red	Red	Red	Red	Green	Red	Red	Red	Red
Tea Tree oil	Red	Red	Red	Red	Red	Red	Green	Red	Red	Red
White Camphor bark oil	Red	Red	Red	Red	Red	Red	Red	Green	Red	Red
Clove bud oil	Red	Red	Red	Red	Red	Red	Red	Red	Green	Red
Vitamin E oil	Red	Red	Red	Red	Red	Red	Red	Red	Red	Green

Table 2. Results indicate that the various oils were clearly differentiated.

References

1. EN ISO 22716: 2007 Cosmetics – Good Manufacturing Practice (GMP) - Guidelines on Good Manufacturing Practices
2. European Cosmetics Regulations (EC) No 1223/20092
3. http://www.efeci.org/assets/files/EFfCI_GMP_2012.pdf
4. <http://www.cosmeticsinfo.org/index.php>

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