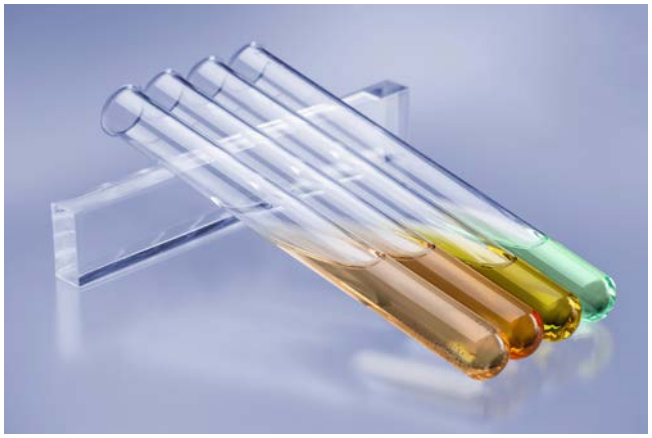
# Simple & compliant quality checks of natural oils for pharmaceutical and high-quality applications

**Relevant for: Producers of natural oils**

The properties of naturally derived oils in pharmaceutical and other high-quality products like cosmetics or food need to be checked and verified thoroughly.
Measuring the specific gravity is a key parameter in this quality control.



## 1 Introduction

Oils from plant and herbal sources are used since early history for various purposes.

Especially for medical purposes strict regulations on mandatory parameters to analyze and traceable documentation of the results are crucial.

Anton Paar density meters, specially the compact DMA 501 and DMA 1001 provide a well-designed, comprehensive set of technical and software features for these tasks and help simplify measurements as well as reduce measurement errors and time.

### 1.1 Typical fields of application

The most common applications for natural oils are:

- Excipients used as carrier oils in pharmaceutical cosmetic preparations and food.
- Active ingredients in natural medicine (like traditional & herbal medicine, Ayurveda products …), wellness products and nutraceuticals.
- General use as flavoring and scenting compounds.

### 1.2 Types of oils & production processes

Commonly natural oils can be differentiated by the way they are produced.

#### 1.2.1 Neutral oils

For neutral natural oils fat-containing seeds and plant material are pressed with high force to extract the oil. Sometimes this is done at elevated temperature.

Examples are olive oil, sunflower oil, canola oil, coconut oil, soybean oil or corn oil.

#### 1.2.2 Essential/aromatic oils

A further category are essential or aromatic oils. These oils are mostly produced by so called steam distillation of plant material which contains sensitive, otherwise hard to extract oils and fats, which are rich in aroma. Oils from roses, lemons, oranges or peppermint are typical examples.

#### 1.2.3 Scented/flavored oils

A simpler approach is scented/flavored oil where plant - often herbal plant - material is soaked for a long time in neutral carrier oil to extract lipid-soluble components.

For these of course high-quality neutral carrier oils are a pre-requisite.

#### 1.2.4 Further production steps & quality control parameters

After the initial extraction of the oil further purifying steps are done.

These can be as simple as leaving it for separation of also extracted water, filtration to remove solid plant material residues or more difficult chemical and thermal clarification processes separating the oil from non-lipid content like proteins or carbohydrates.

During these steps and most important at the end of these thorough quality control of the oil produced is necessary.

Simple physical parameters like specific gravity, refractive index and optical rotation as well as viscosity are the most commonly used and regulatory mandated ones.

Each supplier has to specify relevant physical parameters for their material certificates. This is true for all sizes of companies from the small, local company up to the global producer supplying to a whole range of different industries ranging from pharma, cosmetic and flavor & fragrance to food & beverages.

## 2 Quality regulations

Depending on the intended use and country of commercialization the oils have to be food- or pharma-grade.

This means the local and supranational (e.g. EU Commission) governmental regulations, the *Codex Alimentarius* apply. Of course, for regulated industries the various Pharmacopeia define the obligatory tests and test methods used.

Targeting the pharmaceutical industry as customer is a highly profitable market segment for any producer of natural oils. Thus, it comes with strict regulations to fulfill.

Measurements methods have to follow the requirements in Pharmacopeia and mandatory tests for the products are stated in each monograph as well.

| Parameter | Pharmacopeia reference |
|---|---|
| Specific Gravity | USP <841>, Pharm.Eu. 2.2.5, JP 2.56, ChP 2020 (Vol IV) 0601 |
| Refractive Index | USP <831>, Pharm.Eu. 2.2.6, JP 2.45 |
| Optical Rotation | UPS <781>, Pharm.Eu. 2.2.7, JP 2.49 |
| Rotational Viscosity | USP <912>, Pharm.Eu. 2.2.10, JP 2.53 |

*Table 1: Monographs for listed measured parameters*

Although regulations for the use in cosmetics, nutraceuticals or food may be less stringent, opting for the highest level of quality control always leaves the producer with the highest level of trust in the market and access to the complete range of customers.

### 2.1 Crucial factors for the pharmaceutical industry

For a lab instrument this means the following factors have to be considered:

- Excellent, state-of-the-art measuring technology compliant to relevant regulations.
- Technical & software features and functions simplifying measurements and avoiding handling errors.
- Electronic interfaces for simple and safe handling of data and metadata.
- All these factors combined with security functions according the requirements for complete traceability of actions and events following GxP guidelines.
- Review and approval possibility with electronic signature functions.

## 3 Analytical references

| Oil | Specified Specific Gravity range (USP) |
|---|---|
| Neutral oils | |
| Almond oil | 0.910 – 0.915 |
| Canola oil | 0.906 – 0.920 |
| Sesame oil | 0.912 – 0.921 |
| Castor oil | 0.957 – 0.961 |
| Essential/aromatic oils | |
| Cardamom oil | 0.917 – 0.947 |
| Caraway oil | 0.900 – 0.910 |
| Clove oil | 1.038 – 1.060 |
| Coriander oil | 0.863 – 0.875 |
| Eucalyptus oil | 0.906 – 0.927 |
| Fennel oil | 0.953 – 0.973 |
| Lemon oil | 0.849 – 0.855 |
| Orange oil | 0.842 – 0.846 |
| Peppermint oil | 0.896 – 0.908 |
| Rose oil | 0.848 – 0.863 |

*Table 2: Specific gravity ranges specified in USP 43-NF 38*

Additionally, USP Monograph <401> *„Fats and fixed oils“*, which is commonly referred to for the test procedures of natural oil products, lists USP <841> *“Specific Gravity”* as one of the for routine quality checks and verifications.

## 4 Measuring challenges & technical solutions of Anton Paar density meters

Since specific gravity is one of the mandatory parameters to be determined, digital density measurement poses a number of benefits for day-to-day analytical challenges in the laboratory.

### 4.1 Measuring time & samples volume

Traditional, manual methods like pycnometers and hydrometers are in generally more prone to errors, breakage and a single measurement takes a lot of time. Reliable and consistent results need careful and experienced handling by the operator

The **time needed for one measurement** including filling, thermostatting of the sample, measurement and cleaning takes 20 minutes or longer.

A digital density meter reduces this time to 3-5 minutes per sample without having to worry about the measuring temperature once set correctly.

An added benefit is that the needed **sample volume** as well as the volume of cleaning solvents is significantly lower. As little as 1-2 ml of sample is sufficient for a proper measurement and the sample can easily be recovered back into the syringe if needed.

Especially for the precious essential oils a low sample volume is an advantage, considering that each of the small production batches has to be measured and certified.

### 4.2 Sample viscosity & air bubbles

The higher viscosity of the oils poses difficulties when filling traditional measuring vessels due to necessary time for leveling and also due to possible inclusion of air bubbles.

The measuring cell of a digital density meter itself is easier to fill than any pycnometer or hydrometer. In addition, the automatic **FillingCheck™** based on the oscillation characteristics of the U-tube in combination with **U-View™** – a complete, zoomable, live picture of the whole U-tube - help detecting and avoiding filling errors. Plus, the pictures can be saved with each result for complete review.

The viscosity itself can also influence a measurement in a digital density meter using an oscillating U-tube Automatic **viscosity correction** is mandatory as of US Pharmacopeia requirements for samples with viscosity higher than 10 mPa·s. The patented **Pulsed Excitation Method** used in all Anton Paar benchtop density meters uses advanced viscosity correction over the whole measurement range to provide the correct values.

### 4.3 Data integrity & traceability

Aside technical challenges manual methods show a lack of traceability.

For example, the transcription of results by hand is error prone. Digital instrument with modern user interfaces and software features virtually eliminate such problems.

A **user** and **role management** permits setting individual permissions of allowed actions on the instrument.

In combination with a **complete audit trail** and the **electronic signature function** all actions on the instrument are tracked and can be review and approved.

This provides a complete log for later audit purposes and avoids non-compliance.

Simple and **standardized data export** possibilities through network share over ethernet or USB allow easy storage of measurement and meta-data and integration in existing file systems.

## 5 Density meters & market segments

The **broad portfolio of density meters** from Anton Paar provides a solution for each producer of natural oils.

The **DMA 501 and DMA 1001** with 0.001 g/cm³ respectively 0.0001 g/cm³ accuracy cater to local producers stepping-up from manual methods to digital, fully compliant measurements for small budgets and in-frequent measurements.

The compact instrument saves space in the lab without sacrificing technical features.

Figure 1: DMA 501 & DMA 1001

**DMA 4101, DMA 4501 and DMA 5001** with its advanced connectivity as well possible automation are the solution for larger sites with multiple material sources as well as increasing sample numbers.

Furthermore, Anton Paar's benchtop density meters offer modularity, adding parameters like refractive index or optical rotation is simple.

This modularity allows measurements of multiple parameters in one run, which makes a **Modulyzer** system ideal for quality control of international trading companies and flavor and fragrance houses.

Figure 2: Example Modulyzer configuration

## 6 Summary & conclusion

The specific gravity of natural oils – neutral oils or essential oils - is one critical parameter to be measured and certified for sale and use of these products in regulated industries like the pharmaceutical and for high quality applications like cosmetics or food.

All Anton Paar benchtop density meters incorporate technical and software features helping the lab personnel to achieve good results, minimizing measurement errors and working in a compliant manner.

Furthermore, specific gravity is only one quality parameter important analysis of these oils.

For routine analytics additional Anton Paar instruments, like the MCP polarimeters, Abbemat refractometers or the ViscoQC rotational viscometer have similar technical and software features providing a complete package of parameters.

## 7 Other application reports

D22IA022EN – Refractive Index of Fats, Oils and Essential Oils

XOTIA024EN – Fats and Oils – Important Parameters

D22IA018EN – Refractometric Determination of Oleic and Linoleic Acid Content in Peanut Oil

## 8 References


Monographs in US Pharmacopeia USP 43-NF38, Pharm.Eu. 10.5, Japanese Pharmacopeia 17th edition and Chinese Pharmacopeia 2020 (Volume VI)

Publications of the CBI (Centre for the Promotion of Imports from developing countries of the Ministry of Foreign Affairs of the Netherlands) on Natural Ingredients for Cosmetics (https://www.cbi.eu/market-information/natural-ingredients-cosmetics)

European Commission directives on Hebal medicinal products (https://ec.europa.eu/health/human-use/herbal-medicines_en)



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