

APPLICATION NOTE

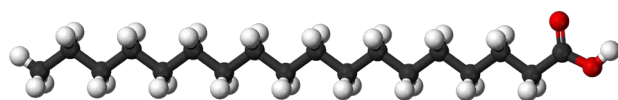
Pharmaceuticals – Differential Scanning Calorimetry

Reveal What Stearic Acid Really Is – Thermal Characterization by DSC for Reliable Quality Control

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Introduction

Stearic acid is a naturally occurring saturated fatty acid with a long carbon chain, present in both plant-derived oils and animal fats. It is widely used across various industry, including pharmaceuticals, cosmetics, food products, and household goods like candles and detergents. In pharmaceutical applications, however, pharmaceutical-grade stearic acid is not a single, chemically pure substance, but a mixture of fatty acids, primarily stearic and palmitic acid, the relative proportions of which may vary within defined specification limits. This compositional variability can influence key properties such as melting behavior.



1 Chemical structure of stearic acid, shown as a 3D ball-and-stick model [1]

Stearic Acid: Structure, Properties, and Applications

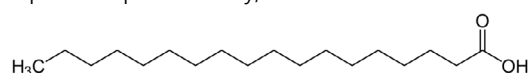
Stearic acid (also known as octadecanoic acid) is a hard, white to slightly yellowish crystalline solid and a long-chain saturated fatty acid ($C_{18}H_{36}O_2$, Fig. 1). Its structure consists of a linear hydrocarbon chain of seventeen methylene groups terminating in a carboxylic acid group, giving it an amphiphilic character, although it is predominantly hydrophobic due to its long nonpolar tail. The absence of double bonds confers high chemical stability and resistance to oxidation. It is poorly soluble in water, but readily soluble in organic solvents such as benzene, carbon tetrachloride, chloroform, and ether, with the polar head group enabling interfacial interactions.

Stearic acid readily undergoes esterification with alcohols to form esters, used as emollients and texture modifiers (e.g., octyl stearate, glyceryl stearate). It also forms

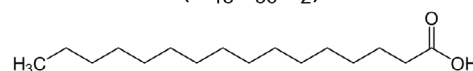
metal salts such as magnesium, sodium, and zinc stearates that are widely used as lubricants, stabilizers, and mold release agents.

In pharmaceutical and cosmetic formulations, stearic acid functions as an emulsifier, thickener, solubilizer, and emollient in topical products, and as a lubricant, binder, and release-modifying agent in solid dosage forms [2]. In the food sector, it is listed as E570 (EU) [3] and recognized as GRAS (Generally Recognized as Safe) by the FDA [4]. It serves as an anti-caking agent, emulsifier, and flavor carrier in products such as baked goods, ice cream, chewing gum, and confectionery.

Fatty acids differ in chain length and saturation, which govern their melting behavior and physical state. Short- and medium-chain acids (e.g., C8:0 - C12:0) have low melting points (16 to 32°C) and are liquid or semi-solid at room temperature, whereas longer saturated chains (C14:0 - C18:0) exhibit higher melting points (44 to 70°C) and are solid. Unsaturation lowers the melting point, as can be seen with oleic acid (C18:1, ~16 °C). Oleic acid also has 18 carbon atoms, but it contains one double bond. Compared to palmitic acid ($C_{16}H_{32}O_2$, hexadecanoic acid, Figure 2) – another fatty acid that occurs very frequently in nature – stearic acid provides slightly higher melting and contributes to firmer structures, while oleic acid disrupts the packing, resulting in softer systems with improved spreadability, but lower oxidative stability.



Stearic acid ($C_{18}H_{36}O_2$)



Palmitic acid ($C_{16}H_{32}O_2$)

2 Chemical structure of stearic acid and palmitic acid

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Table 1 Relationship of structure, property and application of common fatty acids

Fatty Acid	Carbon Chain Length	Chain Type	Melting Point (°C) [5]	Typical Applications (Pharma, Cosmetics and Food Industries)
Caprylic acid	C8:0	Saturated medium	16.5	Antimicrobial agent, drug intermediate; protein stabilization; biopharmaceutical manufacturing aid [6]
Capric acid	C10:0	Saturated medium	31.6	Flavoring and solubilizing agent in pharmaceutical preparations, providing a citrus-like flavor; emulsifying agent [2]
Lauric acid	C12:0	Saturated medium	43.8	Emulsifying and solubilizing agent; food additive; lubricant; surfactant [2]
Myristic acid	C14:0	Saturated long	53.9	Emulsifying and solubilizing agent; skin penetrant; tablet and capsule lubricant [2]
Palmitic acid	C16:0	Saturated long	62.5	Emulsifying and solubilizing agent; skin penetrant; tablet and capsule lubricant [2]
Stearic acid	C18:0	Saturated long	69.3	Emulsifying and solubilizing agent; tablet and capsule lubricant [2]
Oleic acid	C18:1	Monosaturated	16.3	Emulsifying agent; skin penetrant [2]

The structure of fatty acids thus dictates their physico-chemical properties and applications in pharmaceutical, cosmetic, and food systems (see Table 1).

Effect of the Stearic-Palmitic Acid Composition on the Thermal Behavior

In pharmacopeial terms (USP–NF), stearic acid is defined as a mixture of stearic (C18:0) and palmitic (C16:0) acids, comprising not less than 40% stearic acid, with the combined content of these two saturated fatty acids being at least 90% (Figure 2). Consequently, commercially available pharmaceutical grades exhibit variability in the stearic-to-palmitic acid ratio, which directly influences their thermophysical properties. Given that fatty acid chain length governs both intermolecular van der Waals interactions and crystalline packing efficiency, compositional differences alter lattice stability and polymorphic behavior, resulting in distinct melting profiles. Higher proportions of stearic acid typically promote increased melting temperatures and enhanced crystalline order, whereas greater palmitic acid content may slightly reduce these parameters due to the shorter chain length. In this work, we analyzed two different samples of stearic acid, with different stearic acid-palmitic acid ratios.

Experimental

Two stearic acid samples were analyzed: one containing more than 95% stearic acid and a second containing 44% stearic acid; the first manufactured by Sigma-Aldrich and the second by Caelo. Differential scanning calorimetry (DSC) was employed to characterize the differences

in thermal behavior and to assess the impact of composition on melting transitions.

The samples were filled in aluminum crucibles (*Concavus*[®]), which were closed with pierced lids, and heated from 20°C to 160°C at a heating rate of 10 K/min under N₂ at a flow of 20 ml/min. Each sample was measured in triplicate, with average measured masses recorded as 2.57 ± 0.05 mg for stearic acid 95% and 2.46 ± 0.05 mg for stearic acid 44%, see Table 2.

Table 2 Experimental conditions

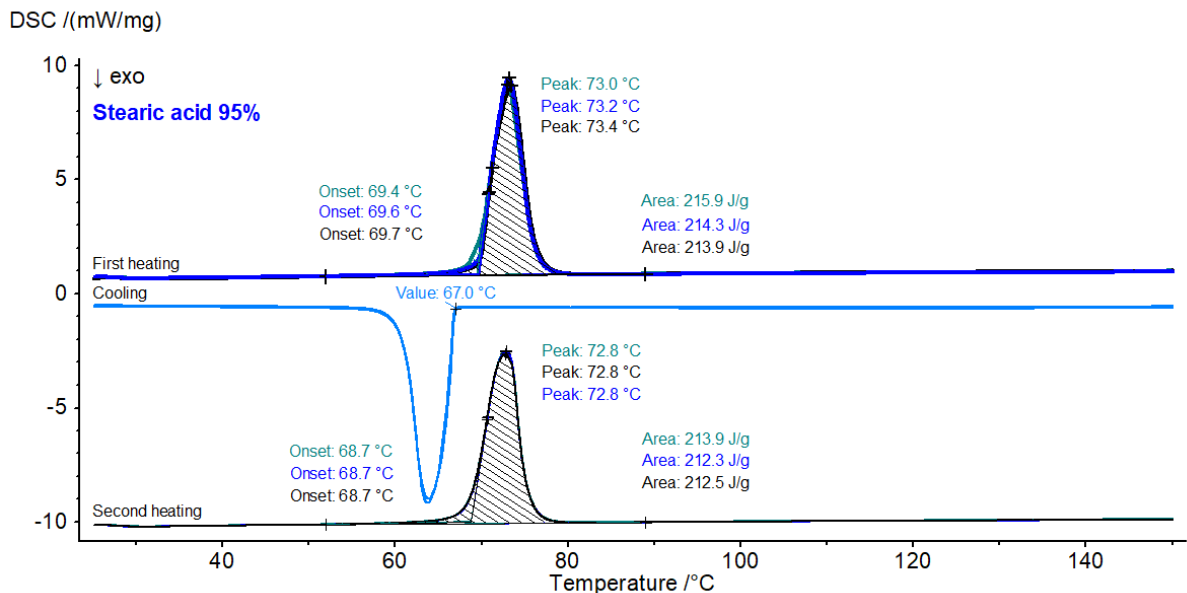
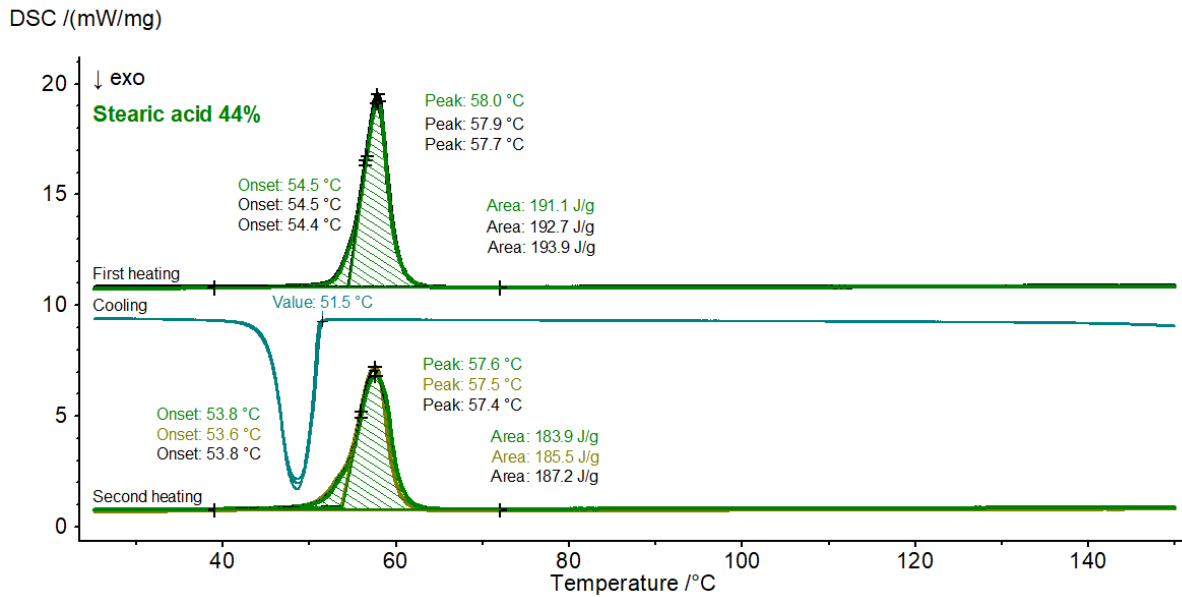
Parameter	Condition
Instrument	DSC 300 <i>Caliris</i> [®] <i>Supreme</i> , H-Module
Sample mass	2.41 to 2.61 mg
Sample type	Stearic acid (SA 44%, SA 95%)
Crucible	Aluminum crucible, pierced lid
Atmosphere	N ₂
Gas flow rate	20 ml/min (purge gas)
Temperature range	20°C to 160°C
Heating and cooling rates	10 K/min
Software	NETZSCH <i>Proteus</i> [®] <i>Protect</i> version 9

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Measurement Results

The DSC curves of stearic acid 44% (SA 44%) and stearic acid 95% (SA 95%), depicted in Figure 3, show melting peaks during both the first and second heating cycles,

as well as recrystallization during cooling with excellent reproducibility (Figure 3A and 3B, respectively). Based on the extrapolated onset melting temperatures (T_m), SA 44% melts at approximately 54 to 55°C, while SA 95% melts at about 69 to 70°C.



3 DSC curves of stearic acid 44% (top panel) and stearic acid 95% (bottom panel), showing the 1st heating, cooling, and 2nd heating cycles for three replicates of each sample.

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SA 44% exhibits a slight decrease in T_m between the first and second heating cycles. Similarly, for SA 95%, the second heating shows a T_m which is approximately 1°C lower than that observed during the first heating (see Table 3). These shifts may be attributed to several factors, including sample inhomogeneity during preparation, thermal history, polymorphism, or variations in recrystallization behavior under the applied cooling conditions.

In addition, practice-related aspects of sample preparation and measurement can contribute to this effect. During the first heating cycle, the sample is initially introduced as a solid with potentially limited and non-uniform contact with the crucible bottom. Upon melting, the material redistributes and forms a layer with improved contact to the crucible during subsequent cooling. In the second heating cycle, this enhanced thermal contact and possible spreading of the sample over a larger surface area facilitates more efficient heat transfer. As a result, the observed shift to slightly lower melting temperatures in the second heating cycle is commonly observed.

Another observation is the increase in peak width for SA 44% after the first heating from $4.0 \pm 0.2^\circ\text{C}$ to $5.0 \pm 0.2^\circ\text{C}$. In contrast, SA 95% exhibits only a slight increase of approximately 0.3°C in the average peak width (Table 3). While the peak width provides an indication of changes in melting behavior, the evolution of the

melting enthalpy (ΔH) is considered more significant. For SA 44%, a clear decrease in enthalpy is observed, from $188.0 \pm 1.8 \text{ J/g}$ in the first heating to $177.4 \pm 2.1 \text{ J/g}$ in the second heating. In contrast, the higher-purity SA 95% sample shows only a minor change in ΔH , from $215.2 \pm 1.3 \text{ J/g}$ to $213.4 \pm 0.9 \text{ J/g}$ (see Table 3). This behavior suggests that the higher content of palmitic acid in SA 44% affects molecular packing and recrystallization, leading not only to broader melting transitions, but also to measurable changes in the energetic characteristics of the phase transition, whereas the more homogeneous SA 95% remains largely unaffected.

It is important to note that both stearic acid and palmitic acid can exist in different polymorphic forms or recrystallize from the molten phase. The melting points of these forms are usually very close to one another; however, these different polymorphic forms can affect the DSC curve.

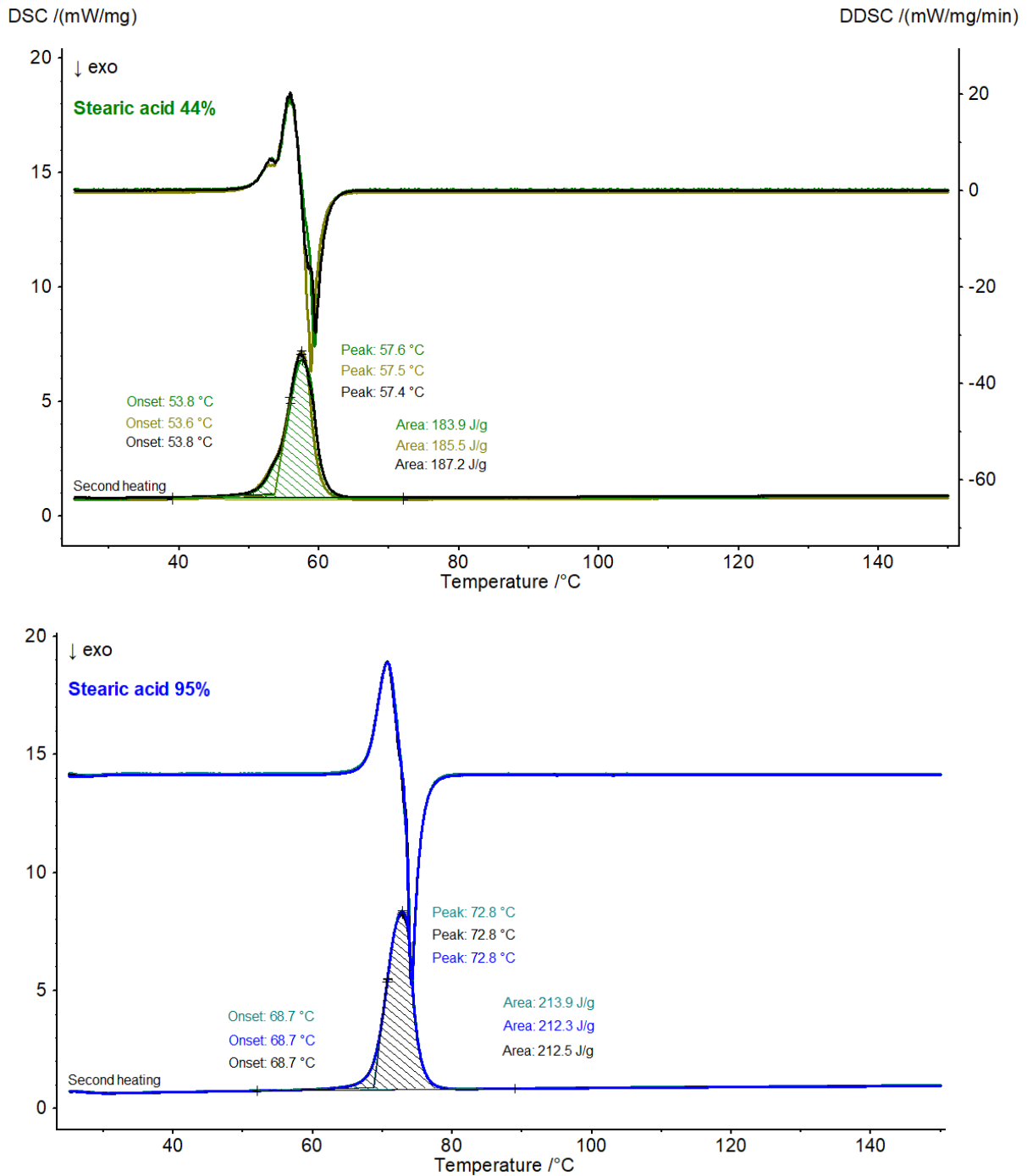
Table 3 DSC results for stearic acid 44% and stearic acid 95%

Complex peak	Stearic acid 44% 1 st heating	Stearic acid 44% 2 nd heating	Stearic acid 95% 1 st heating	Stearic acid 95% 2 nd heating
Extrapolated onset T_m ($^\circ\text{C}$)	54.5 ± 3.0	54.0 ± 0.1	69.6 ± 0.2	68.7 ± 0.1
Peak maximum ($^\circ\text{C}$)	57.9 ± 0.2	57.5 ± 0.1	73.2 ± 0.2	72.8 ± 0.0
Enthalpy (J/g)	188.0 ± 1.8	177.4 ± 2.1	215.2 ± 1.3	213.4 ± 0.9
Peak Width ($^\circ\text{C}$ at 37.0%)	4.0 ± 0.2	5.0 ± 0.2	4.6 ± 0.1	4.9 ± 0.1

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In addition, the presence of multiple thermal events during the second heating of SA 44% is indicated by a distinct shoulder in the first derivative (DDSC) signal (Figure 4A), which is not observed for SA 95%. This feature can be more clearly evaluated on the basis of the DDSC

curve, where the shoulder becomes more pronounced. This further supports the presence of compositional heterogeneity and more complex crystallization behavior in the lower-purity sample.

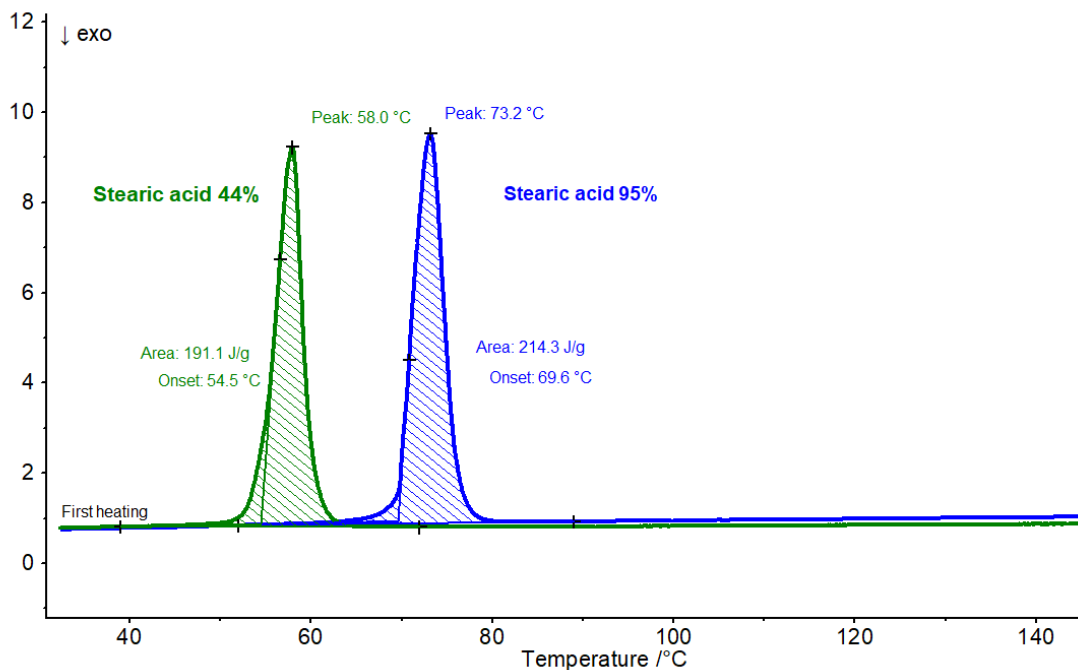


4 DSC curves of stearic acid 44% (top panel) and stearic acid 95% (bottom panel), showing the second heating cycles of three replicates of each sample and their corresponding first derivatives.

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When the first heating curves of both samples are displayed in a single graph, the separation between their melting events becomes particularly evident. Figure 5 shows the first heating curves of SA 44% and SA 95%,

revealing narrow and well-defined peaks with excellent resolution. The clear difference in peak position reflects the variation in chemical composition and purity, as well as differences in crystalline structure.



5 DSC curves of stearic acid 44% and stearic acid 95%, showing the first heating cycles of a representative sample for each substance.

Conclusion

Overall, these results demonstrate that the DSC 300 *Caliris*® provides highly reproducible and well-resolved thermal data, enabling clear differentiation between samples with varying compositions and purities. Its sensitivity to changes in melting temperature, peak shape, and recrystallization behavior makes it a powerful and efficient tool for research and industry.

In pharmaceutical, cosmetic, and food applications, where raw material consistency and purity are critical, the DSC 300 *Caliris*® allows rapid identification of material differences, detection of impurities, and verification of batch-to-batch consistency, supporting both product development and routine quality assurance.

This study has shown that pharmaceutical-grade stearic acid may not always meet the expected composition of pure stearic acid, even though the material complies with the requirements of the pharmacopoeia monograph. Its properties, such as melting behavior, depend heavily on its composition. It is therefore recommended that the substance be properly characterized prior to any industrial use.

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Referenes

- [1] [Stearic-acid-3D-balls - Stearic acid - Wikipedia](#)
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- [4] Substances Added to Food (formerly EAFUS)
- [5] <https://pubchem.ncbi.nlm.nih.gov/>
- [6] <https://www.sciencedirect.com/topics/biochemistry-genetics-and-molecular-biology/caprylic-acid>

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Key Results and Benefits

- √ Distinct melting temperatures
→Fast identification of raw materials

- √ Narrow, well-resolved peaks
→Reliable quality control decisions

- √ Detection of multiple events
→Early detection of impurities

- √ Excellent measurement reproducibility
→Reduced batch-to-batch variability