

# Determination of melting point of suppository bases and suppositories

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## Theory

The suppositories are solid, one-dose, plastic-deformable preparations for rectal, vaginal, or urethral administration. They melt at human body temperature (hydrophobic supp.) or dissolves at the site of application (hydrophilic supp.). They are intended for local or systemic drug administration. Suppositories contain one or more APIs dispersed or dissolved in a suitable suppository base. Suppository bases are hydrophobic (Hard fat - *Adeps solidus*, Cocoa oil - *Cacao oleum*) or hydrophilic (Macrogols, glycerogel of sodium soap).

Hard fats (triglycerides, eg Witepsol®) are produced by direct esterification of glycerol with selected fatty acids. They always contain a certain proportion of diglycerides and monoglycerides. They differ in melting point, polarity (hydroxyl number) and consistency. They are physiologically indifferent, non-irritating and the release of incorporated drug is optimal. The fast solidification, the minimal difference between melting and solidification temperature and the required volume contraction are other benefits.

## Materials and instrument

Suppository bases: Cacao oil, Hard fat, Witepsol W35, Witepsol H15

Aids: aluminum crucible for DSC

Instruments: DSC 200 F3 Maia®

analytical balance  $d = 0,0001$  mg

## Method

1. On an analytical balance, weigh an aluminum crucible with a lid and record the weight.
2. Weigh about 10 mg of suppository base/ suppository into a crucible and record the weight.
3. Calculate the weight of the sample material for DSC.
4. Place the measured and reference sample (empty crucible) in the instrument.
5. In the instrument SW, select a template for measurement with a suitable temperature mode (see Fig. 1).
6. Enter the required parameters and start the measurement.
7. Using SW *Protheus Analysis*, evaluate the melting temperature ( $T_m$ ) of the suppository base/ suppository.
8. Enter the  $T_m$  value and thermogram in the report.

Figure 1: Temperature modes



## Conclusion

Explain the importance of the melting and solidification temperatures of suppository bases and suppositories, and factors influencing the resulting temperatures.

# DSC measurement protocol

Student's name:

Instrument:

Sample:

weight of an aluminum crucible with a lid	
weight of an aluminum crucible with a lid and sample	
weight of the sample	

Temperature mode:

DSC scan: