



IOI OLEOCHEMICAL



LipoGalenTM 144

A new Base for Ovules
and Suppositories –
a Case Study with
Lactic Acid Ovules

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LipoGalen™ 144 – The innovative new base for ovules and suppositories

Novelty

- ✦ Crystallizes in one stable modification in contrast to triglycerides
- ✦ New base is a “hydrophilic lipid”, thus
 - ✓ Hydrophilic character allows for stable water uptake which is unusual for lipid-based excipients
 - ✓ Lipidic character leads to better adhesion to the mucous membrane, resulting in potentially longer contact time





Case Study: LipoGalen™ 144 - A new base for lactic acid ovules

A case study in structured development and usability validation of a gynecological medical device



Goal

Development of a medical device with LipoGalen™ and lactic acid.

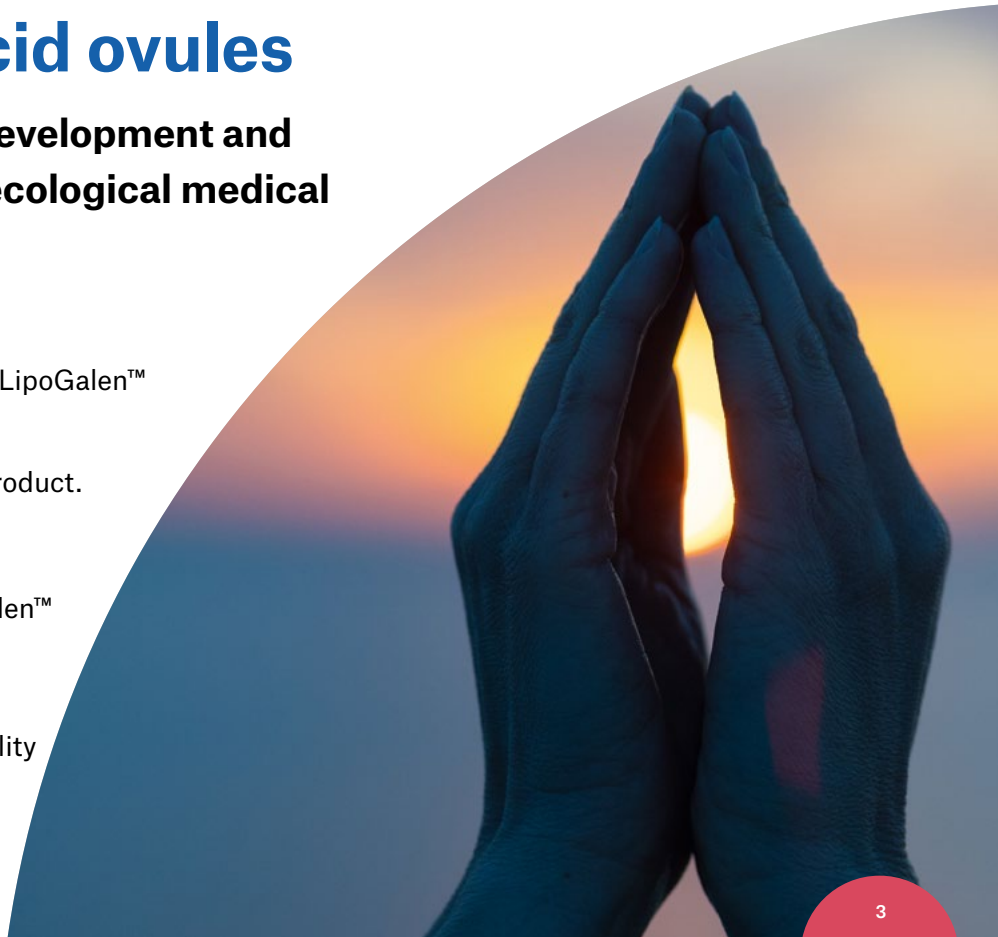
It shall be comparable to a reference product.



Focus

Formulation development with LipoGalen™ and lactic acid comparable to the commercial benchmark.

Evaluation of the application in a usability study to demonstrate comparable user experience and identify additional benefits.



Lipogalen™ 144

- A new base for lactic acid ovules

The Product

- IOI lactic acid ovules are a medical device designed to support and maintain a healthy vaginal microbiome
- Their innovative formulation enables a potentially longer contact time and thus a longer-lasting release of lactic acid

Advantages

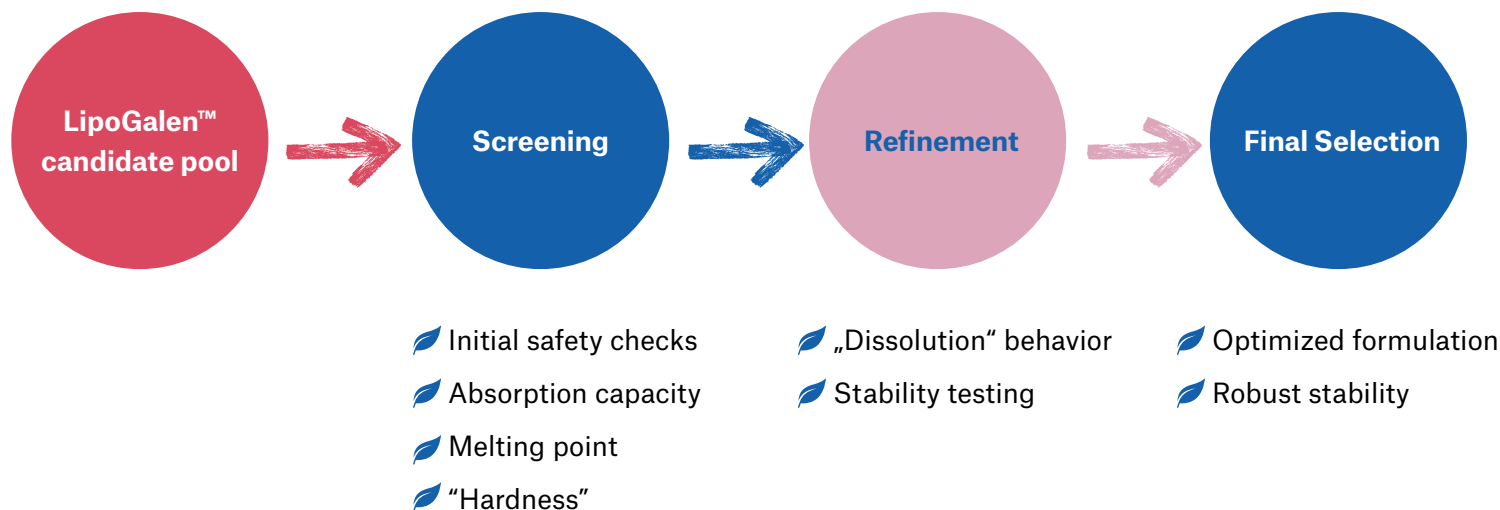
- Natural. Effective. Long-lasting. Vegan.
- Next-generation vaginal ovules: Petroleum- and PEG-free, patented base*, slow melting behavior
- High demand (CAGR: 4.6%): Meets growing consumer preference for natural intimate care products

**Usability Study
Tested**



Product development strategy

Systematic evaluation identified a safe, stable, and user-friendly device



Green light for usability study
with ovules made with LipoGalen™ 144

Head-to-head usability study compared the new device against the commercial benchmark

✿ Usability study - Objective:

- ✓ Collect data to demonstrate the comparability of IOI Oleo lactic acid ovules with the reference product

✿ Study methods:

- ✓ Structured questionnaires to be answered after the application of the ovules

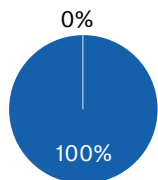




The new device demonstrated equivalent usability and high user satisfaction

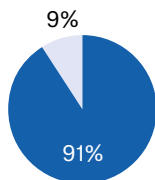
Usability Study - Results

- ✓ Safety: no device-related issues
- ✓ Users reported that the new device felt pleasant and comfortable
- ✓ Comparable to reference product
- ✓ Additional benefit: new product may also be suitable for daytime use because of improved mucoadhesive properties



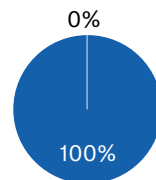
■ agree ■ disagree

- ✓ 100% of the users did not feel any itching or rated it as rather not disturbing or not disturbing



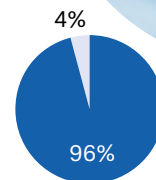
■ agree ■ disagree

- ✓ 91% of the users agree that the ovule gives a pleasant and comfortable feeling



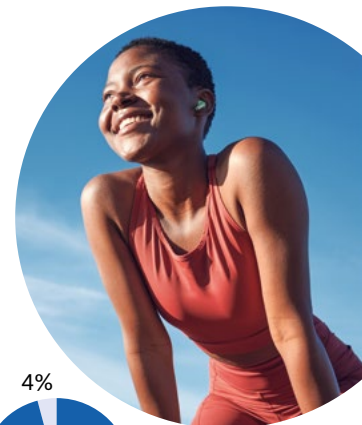
■ agree ■ disagree

- ✓ 100% of the users did not feel any burning sensation or rated the burning sensation as not bothersome or not bothersome at all



■ agree ■ disagree

- ✓ 96% of the users did not feel the ovule while wearing it or rated wearing as rather not bothersome or not bothersome



Conclusion and outlook

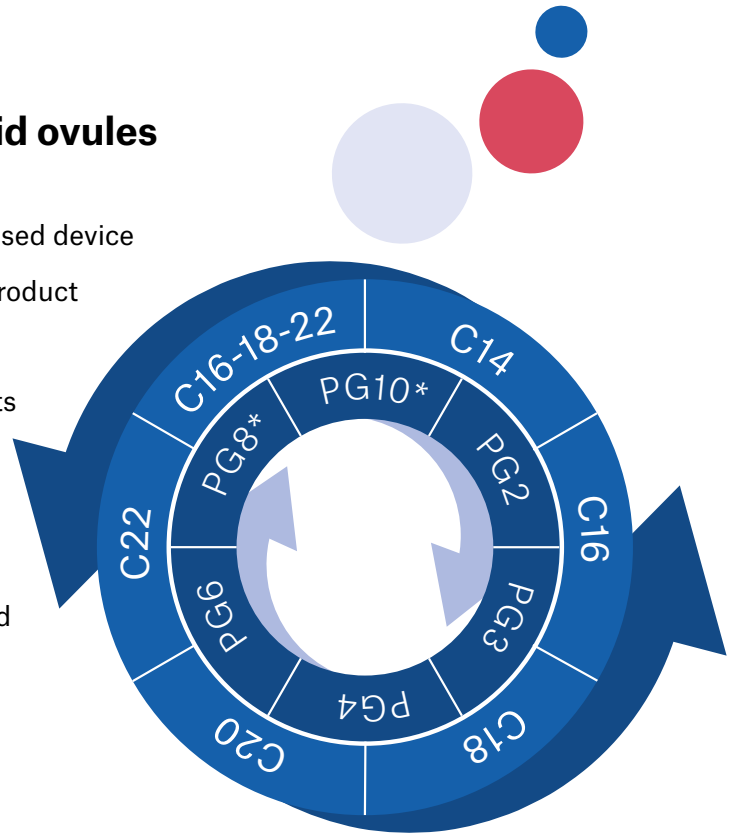
LipoGalen™ 144 as new base for lactic acid ovules

- Structured development ensured robust and patient-focused device
- New device shows equivalent usability to the reference product
- Additional claims:
 - ✓ Natural & sustainable: petroleum-free, PEG-free, meets growing consumer preference for natural intimate care products
 - ✓ Innovative base design ensures longer contact time between the product and the mucous membrane, which can lead to a longer-lasting release of lactic acid

Next steps

- Regulatory submission
- Potential collaborations

But there is even more ...





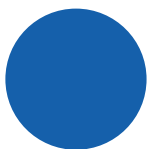
IOI ovules and beyond ...

LipoGalen™ 144 can serve as a base for a variety of APIs, e.g.:

- ✦ Nonsteroidal anti-inflammatory drugs and other analgesics / antipyretics
- ✦ Hormones
- ✦ Anti-hemorrhoidal agents
- ✦ Anesthetics
- ✦ Cannabinoids
- ✦ Acids such as hyaluronic acid or boric acid
- ✦ ... your product???

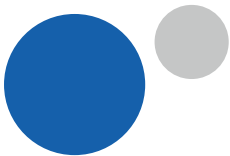
**Also,
suppositories
are possible
as finished
dosage form**

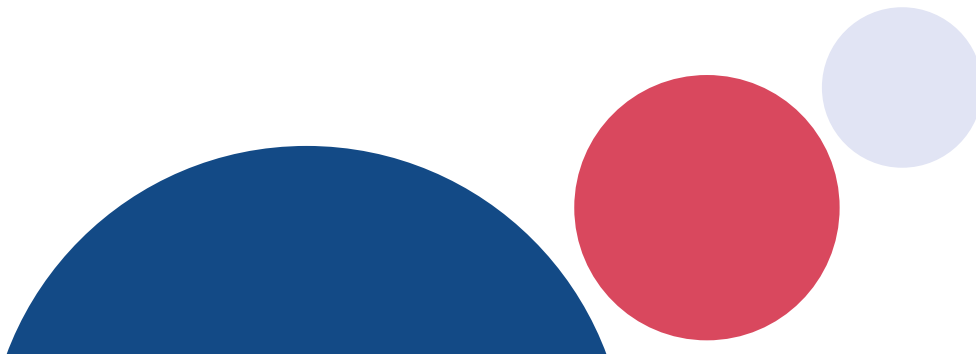
**Since the base is
peroxide-free, it may
favor its use also for
sensitive APIs**



Handwriting practice lines consisting of ten horizontal dashed lines.









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