



IOI OLEOCHEMICAL



LipoGalen[®] 144

The innovative
base for semisolid
formulations

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Expanding the legacy of WITEPSOL®
hard fats as the benchmark for
suppositories and ovules,
IOI Oleo GmbH introduces
LipoGalen® 144 as
innovative base
for ovules,
suppositories
and dermal
formulations.

THE
NEWEST
COOLEST
KID IN
TOWN

LipoGalen® 144



LipoGalen® 144 – The innovative new base for semisolid formulations

- Crystallizes in one stable modification in contrast to conventional hard fats
 - ✓ No post-hardening
 - ✓ Constant melting point over time
- 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



LipoGalen® 144 –

Typical values at a glance

Melting point:
36 – 39°C

Hydroxyl value:
150 – 200 mg
KOH/g

Acid value:
≤ 0.5 mg KOH/g

HLB: 5 – 6
Water uptake:
up to 40%
Ethanol uptake:
up to 10%

Melting point:
36 – 39°C



Regulatory and safety overview for LipoGalen® 144

Chemical name: Polyglycerin-4 Myristate

• EU

- ✓ Substance group of polyglycerin esters of edible fatty acids is authorised as food additive under Regulation (EC) No. 1333/2008; listed as E 475
- ✓ EFSA Safety Assessment (2017): no safety concern at reported uses; no genotoxic or carcinogenic effects resulting in potentially longer contact time

• US

- ✓ Substance group recognized under 21 CFR §172.854
- ✓ Considered safe (GRAS context) based on scientific consensus
- ✓ Supported by FDA guidance and historical use

• **Outlook: Medical Device Biocompatibility data**

- ✓ Testing for specific ISO 10993 chapters on pure substance to be done during H2 2026



Case study on lactic acid ovules with LipoGalen® 144

The product concept

- Ovules for support and maintenance of healthy vaginal microbiome were developed
- Based on LipoGalen® 144 with lactic acid/ sodium lactate as active system
- Similar concepts are successfully marketed as medical devices

Usability study

- Goal: Demonstrate comparable performance and identify potential benefits
- Compare performance and user experience of commercial benchmark with lactic acid ovules based on LipoGalen® 144

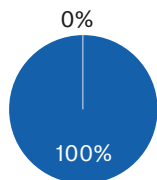
**Tested in a
human panel**



The new device demonstrated equivalent usability and high user satisfaction

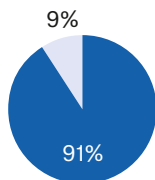
Usability study - results

- 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



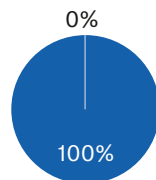
■ agree ■ disagree

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



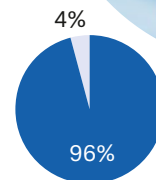
■ agree ■ disagree

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



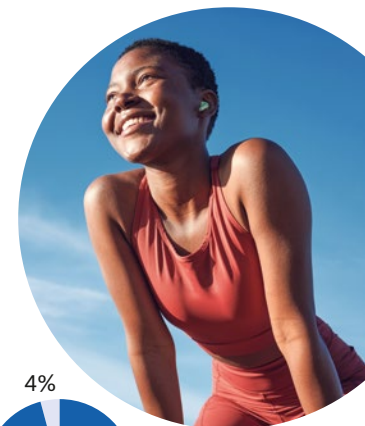
■ agree ■ disagree

- 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



Outcome

- Users reported that the new device felt pleasant and comfortable
- Comparable to reference product regarding comfort of insertion and during use
- Additional benefit: reduced discharge acknowledged in panel, LipoGalen® 144 based product may provide better suitability for daytime use

Growth opportunities in Women's Health

- Vaginal health and microbiome support are key innovation areas and growth contributors within Women's Health
- Patients seek comfortable and easy-to-use dosage forms
- LipoGalen® 144 enables differentiated ovule concepts for these segments





What comes next...?

LipoGalen® 144 can serve as a base for hydrophilic and lipophilic APIs, e.g.:

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

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

**No fat bloom
or post-hardening**

**No
surfactants
needed**



LipoGalen® 144: Enabling new ovules & suppositories

The alternative for conventional hard fats and PEG systems

Formulation flexibility

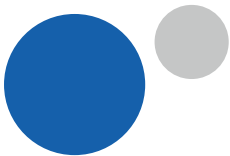
- Suitable for suspension and solution ovules/suppositories
- Compatible with wide range of APIs
- Processable on established manufacturing equipment

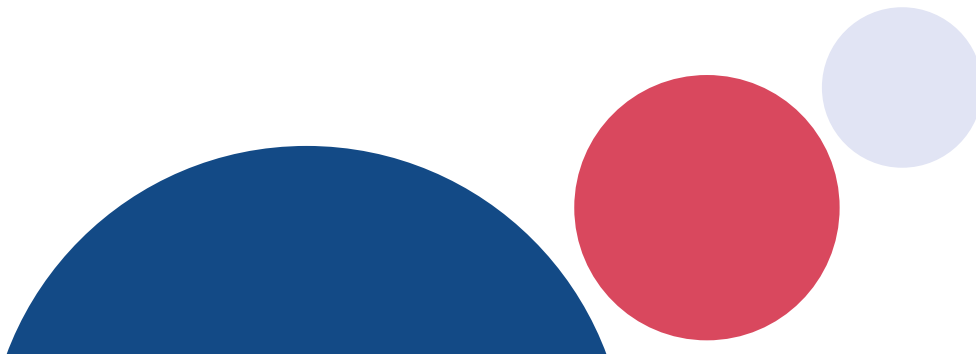
Differentiated performance

- Enables formulations that are challenging with conventional hard fats
- Opens application spaces traditionally addressed by PEGs/ Glycerine
- Reduced fat bloom and post-hardening effect

Market and positioning

- Plant-based alternative to petroleum-derived excipients and PEG
- Aligns with growing demand for plant-based origin in healthcare products
- Particularly attractive for women's health, microbiome and medical device concepts







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