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REVIEW ARTICLE

# Corn germ oil (Zea mays L.) in the development of dermatological semisolid dosage forms: composition, technological aspects and prospects for application

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## Abstract

**Introduction.** Corn germ oil (Zea mays L.) is of interest for the development of dermatological semisolid dosage forms because of its high content of unsaturated fatty acids, tocopherols and phytosterols. Its technological and functional properties depend on the composition of the raw material, the method of production, the degree of purification and oxidative stability.

**Objective.** To systematize current data on the composition, production methods and pharmaceutically relevant properties of corn germ oil and to assess prospects for its use in the development of dermatological semisolid dosage forms.

**Materials and methods.** A review of peer-reviewed scientific publications, predominantly from 2016-2026, was performed using PubMed, ScienceDirect, SpringerLink and open-access resources of scientific journals. Data on the composition and production technologies of corn germ oil, its potential dermatological application and Quality by Design (QbD) principles for topical semisolid dosage forms were analyzed.

**Results and discussion.** Corn germ oil is characterized by a predominance of unsaturated fatty acids, particularly linoleic and oleic acids, and contains tocopherols and phytosterols. Production and purification methods can influence its composition and oxidative stability. Available evidence supports considering the oil as a promising lipophilic component of dermatological semisolid dosage forms, although direct clinical evidence for finished medicinal products remains limited. Based on the literature analysis, key directions for further pharmaceutical development using QbD principles were proposed.

**Conclusions.** Corn germ oil is a promising component of dermatological semisolid dosage forms. Further application requires standardization of the source raw material and experimental confirmation of the characteristics of the developed formulation.

**Keywords:** corn germ oil; Zea mays L.; semisolid dosage forms; dermatology; linoleic acid; tocopherols; supercritical $CO_2$ extraction; Quality by Design

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## Introduction

Plant oils are of considerable interest for the development of dermatological and cosmetic systems because they combine technological and functional properties. In topical products, they may serve as the lipophilic phase, emollients or solvents for lipophilic compounds and may influence skin permeability. The properties of a particular oil are determined by its fatty-acid profile, the composition of the unsaponifiable fraction, oxidation status, production method and subsequent processing [1-4].

Corn germ oil is obtained from the germ fraction of Zea mays L. grain, which contains a substantial amount of lipids. Its fatty-acid profile is dominated by unsaturated fatty acids, particularly linoleic and oleic acids; the unsaponifiable fraction contains tocopherols, phytosterols and other minor lipophilic compounds [1,2,5]. These characteristics support interest in corn germ oil as a potential lipophilic component of topical pharmaceutical systems.

Linoleic acid is especially relevant to dermatological use because it participates in the formation of epidermal lipids and maintenance of the skin-barrier function. Contemporary reviews indicate that linoleic acid and plant oils rich in it can have beneficial effects on the skin barrier, but the magnitude and direction of the effect depend on fatty-acid composition, skin condition, concentration and use pattern [6-8]. Findings obtained for other plant oils therefore cannot be directly extrapolated to corn germ oil and require confirmation in a specific pharmaceutical formulation.

The potential value of corn germ oil in dermatological semisolid dosage forms is determined not only by chemical composition but also by the quality of the lipid raw material, production method, degree of purification and oxidative stability. Published information on composition, production technology, potential dermatological properties and requirements for topical-product development remains fragmented. Systematization is required to define pharmaceutically relevant characteristics and to establish a scientifically grounded approach to subsequent formulation development.

The aim of this review was to systematize current data on the chemical composition and production of corn germ oil, assess its technological potential for dermatological semisolid dosage forms and define key directions for further pharmaceutical development using Quality by Design (QbD).

## Materials and methods

The work was performed as a literature review. Scientific publications were searched in PubMed, ScienceDirect, SpringerLink and open resources of peer-reviewed journals. The principal search period was 2016-2026; earlier sources were used when they were foundational for oil-production methods or topical formulation development.

Search terms and combinations included “corn germ oil”, “Zea mays oil”, “corn germ extraction”, “supercritical $CO_2$ extraction”, “cold pressed corn oil”, “linoleic acid skin barrier”, “vegetable oils topical”, “topical semisolid formulation”, “Quality by Design topical semisolid”, “QTPP”, “CQA”, “CMA” and “CPP”.

Peer-reviewed studies were included when they provided data on the chemical composition of corn germ and corn germ oil, production methods, the influence of extraction technology on composition and quality indicators, the dermatological role of fatty acids, or principles of topical semisolid development. Publications primarily concerning agronomic characteristics, domestication history, food classification of maize varieties or other plant parts were excluded unless directly relevant to corn germ oil and its potential pharmaceutical use.

The extracted evidence was organized into four domains: (1) pharmaceutically relevant chemical composition of corn germ oil; (2) effects of the production method on composition and quality; (3) rationale for potential use in dermatological semisolid dosage forms; and (4) parameters for subsequent pharmaceutical development using QbD principles.

## Results

Chemical composition and pharmaceutically relevant characteristics. The literature indicates that corn germ is the principal lipid-containing fraction of Zea mays L. grain. Corn germ oil is dominated by unsaturated fatty acids, with linoleic acid representing the major fraction followed by oleic acid [1,2,5]. Quantitative ratios vary according to raw-material characteristics, cultivation conditions, germ separation, oil-recovery technology and subsequent refining.

In addition to triacylglycerols, the oil contains an unsaponifiable fraction that includes tocopherols, phytosterols and smaller amounts of carotenoids and phenolic compounds [1,2]. Their levels depend on the raw material and the processing technology.

Pharmaceutically relevant characteristics include the fatty-acid profile, tocopherol content, acid and peroxide values, moisture and impurities, and indicators of oxidative stability. Key components and quality indicators relevant to semisolid formulation development are summarized in Table 1.

**Table 1. Pharmaceutically relevant components and quality indicators of corn germ oil for topical semisolid dosage-form development**

| Component / indicator | Characteristics | Relevance to development |
|---|---|---|
| Linoleic acid | Major polyunsaturated fatty acid of corn germ oil; content depends on raw-material origin and production technology | Participates in epidermal lipid formation and skin-barrier maintenance; the high degree of unsaturation requires control of oxidative stability |
| Oleic acid | One of the major monounsaturated fatty acids of the oil | Affects physicochemical properties of the lipophilic phase and may influence interactions of the topical system with the skin barrier |
| Tocopherols | Lipophilic components of the unsaponifiable fraction with antioxidant properties; content and profile depend on raw material and processing | Relevant to composition and oxidative stability; levels may change during production and refining |
| Phytosterols | Components of the unsaponifiable fraction | Characterize the unsaponifiable fraction and functional profile; levels depend on raw material and production technology |
| Acid and peroxide values | Indicators of hydrolytic changes and primary lipid oxidation, respectively | Used to assess quality and stability and suitability for subsequent pharmaceutical development |

Influence of production methods on composition and quality. The principal methods for obtaining corn germ oil are pressing, extraction with organic solvents and supercritical $CO_2$ extraction [3,9].

Marinho et al. studied supercritical $CO_2$ extraction at different temperatures and pressures. Oil yield depended on process parameters; cosolvents increased yield, whereas substantial changes in the fatty-acid profile were not observed. In that study, supercritical $CO_2$ extracts demonstrated higher antioxidant activity than samples obtained by Soxhlet extraction [3].

Espinosa-Pardo et al. compared approaches to recovering oil and protein fractions from corn germ and demonstrated that extraction yield and phenolic content depended on solvent polarity and pretreatment conditions [9].

A comparative assessment of the principal recovery approaches from the perspective of pharmaceutical development is presented in Table 2.

**Table 2. Comparison of corn germ oil production methods from the perspective of pharmaceutical development**

| Approach | Potential advantages | Limitations for pharmaceutical development |
|---|---|---|
| Cold / low-temperature pressing | No organic solvents; relatively mild processing; potential preservation of minor lipophilic compounds | Relatively low oil yield; composition variability; need to control oxidative stability and raw-material quality |
| Organic-solvent extraction | High lipid recovery; technologically established | Need to remove and control residual solvents; possible alteration of minor components during subsequent purification |
| Supercritical $CO_2$ extraction | No residual organic solvent when pure $CO_2$ is used; selectivity can be adjusted through process parameters | High equipment cost; yield and composition depend on pressure and temperature; process optimization and control required |
| Supercritical $CO_2$ extraction with cosolvent | Potentially higher yield and modified extraction selectivity | Appropriate cosolvent must be selected, removed and controlled for residual content |

Potential dermatological application. The main rationale is associated with the high linoleic-acid content. Linoleic acid is involved in epidermal lipid formation and skin-barrier maintenance, and deficiency may be associated with impaired barrier properties [6-8].

Reviews of dermal plant-oil use indicate that oils rich in linoleic acid may, under certain conditions, support a damaged skin barrier. The effect depends on composition, oxidation status, concentration, vehicle and skin condition; therefore, individual oils should be assessed in the context of the final formulation [4,7,8].

A systematic review by Herman and Herman indicates that some plant oils can affect skin permeability and may act as penetration-enhancing components in pharmaceutical systems [10]. However, direct studies of corn germ oil in finished dermatological medicinal products remain limited, so its use should be justified through formulation-specific experimental studies.

Quality by Design in topical semisolids. QbD-based development involves definition of the quality target product profile (QTPP), identification of critical quality attributes (CQA), critical material attributes (CMA) and critical process parameters (CPP), followed by risk assessment and, when appropriate, design-of-experiments studies [11-14].

For semisolid dosage forms, relevant attributes include the composition and properties of the lipophilic phase and excipients, pH, rheological characteristics, droplet size and distribution, homogeneity, physical and microbiological stability, and - for drug-containing products - in vitro release and, where necessary, skin penetration/permeation.

On the basis of the reviewed evidence, a preliminary QbD matrix was formulated to support subsequent experimental development of a dermatological semisolid containing corn germ oil.

**Table 3. QbD matrix for development of a dermatological semisolid dosage form containing corn germ oil**

| QbD element | Proposed parameters |
|---|---|
| QTPP - Quality Target Product Profile | Topical semisolid dosage form; defined organoleptic and rheological properties; ease of application; physical and microbiological stability throughout shelf life |
| CMA of corn germ oil | Fatty-acid profile; acid value; peroxide value; tocopherol content; moisture and impurities; viscosity |
| CMA of excipients | Type and concentration of emulsifier/co-emulsifier, structuring agent, antioxidant and preservative |
| CPP - Critical Process Parameters | Phase temperatures; order of addition; homogenization speed and duration; mixing time; cooling rate and conditions |
| CQA - Critical Quality Attributes | Appearance and homogeneity; pH; rheology; droplet size/distribution; physical stability; microbiological quality; for drug-containing dosage forms - in vitro release testing (IVRT) and, where appropriate, in vitro skin penetration/permeation (IVPT) |

## Discussion

The review indicates that the potential of corn germ oil for dermatological semisolid dosage forms reflects the combination of its fatty-acid composition, the unsaponifiable fraction and technological properties. At the same time, composition is variable and depends on raw material, production technology and refining; therefore, a standardized pharmaceutical raw-material specification is essential.

The production method is particularly important. Pressing and extraction with organic solvents are technologically accessible but differ in lipid recovery and in the effect of subsequent processing on minor components. Supercritical $CO_2$ extraction offers solvent-free recovery when pure $CO_2$ is used and provides opportunities to adjust selectivity, but requires specialized equipment and optimization of pressure, temperature and, where used, cosolvent conditions [3,9].

The dermatological potential is largely associated with linoleic acid. Its role in epidermal lipid formation and skin-barrier maintenance is supported by contemporary evidence; however, data from linoleic acid or other plant oils should not be interpreted as direct evidence of therapeutic efficacy for corn germ oil itself [6-8].

Plant oils may also alter skin permeability. Depending on the final dosage form this may be useful, neutral or undesirable. Therefore, potential penetration-enhancing properties must be evaluated in the context of the complete pharmaceutical system and, when a drug substance is present, by appropriate release and permeation studies [10].

Oxidative stability requires specific control. A high proportion of polyunsaturated fatty acids is relevant to dermatological use but simultaneously increases susceptibility to oxidation. Raw-material specifications, packaging, storage conditions and the possible use of antioxidants should therefore be justified during development.

QbD provides a practical framework for converting literature-derived characteristics into an experimental development programme. The preliminary matrix identifies material and process variables that should be assessed to establish a robust composition, manufacturing process and control strategy for a future semisolid dosage form.

## Conclusion

The reviewed evidence shows that corn germ oil may be considered a promising lipophilic component of dermatological semisolid dosage forms because of its fatty-acid composition and pharmaceutically relevant constituents of the unsaponifiable fraction.

Direct evidence for finished dermatological medicinal products containing corn germ oil is insufficient to support specific therapeutic indications. Data on linoleic acid and other plant oils provide a scientific rationale for further research rather than proof of efficacy of corn germ oil formulations.

The next step should be experimental pharmaceutical development including standardization of the oil, justification of formulation composition and manufacturing technology, assessment of physicochemical, rheological and microbiological

characteristics and stability, and - for drug-containing formulations - in vitro release and, where appropriate, skin permeation studies.

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