

## **Beyond the Label: A Critical Translational Review of *Boswellia serrata* Preparations, Human Exposure, and Clinical Interpretability**

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### **Abstract**

**Objective:** To explain why *Boswellia serrata* preparations sharing the same botanical label remain analytically, pharmacokinetically, clinically, and regulatorily non-comparable, and to propose a translational framework for judging interpretability across studies.

**Methods:** This manuscript was designed as a critical translational review. A predefined literature search through March 10, 2026, was centered on PubMed/MEDLINE and supplemented by backward citation chaining, publisher-site verification, and official European regulatory sources. Evidence was synthesized with a best-fit framework spanning raw-material identity, extract definition, analyte panel, formulation platform, human exposure, pharmacodynamic or clinical linkage, and regulatory traceability.

**Results:** Comparability often fails early in the *Boswellia* chain. Studies differ substantially in resin sourcing, extraction, standardization, analyte selection, and dosage form, and these variables are frequently incompletely reported. Exposure is strongly formulation sensitive. A high-fat meal produced several-fold increases in boswellic-acid exposure, phospholipid systems improved solubility and flux, and a 2024 crossover trial reported 1,720-4,291% relative bioavailability for a micellar product versus a native dry extract, without proportional improvement in ex vivo anti-inflammatory readouts. Analytical studies also document marked between-product heterogeneity and recent adulteration work has identified undeclared acids

and highlighted the need to monitor pharmaceutical adulterants. Clinical efficacy signals are concentrated in osteoarthritis and are largely product-specific and frequently proprietary.

**Conclusions:** For *Boswellia serrata*, the clinically relevant unit is not the plant name alone but the traceable preparation-exposure-response chain. Future development should standardize extract reporting, analyte panels, formulation disclosure, human pharmacokinetic characterization, and independent replication.

**Keywords:** *Boswellia serrata*, boswellic acids, pharmacokinetics, bioavailability, formulation, adulteration, osteoarthritis, translational phytopharmacy

## Introduction

*Boswellia serrata* resin preparations continue to attract interest as phytopharmaceutical and nutraceutical interventions for chronic inflammatory disorders, especially osteoarthritis (Abdel-Tawab et al., 2011). Yet the field has long suffered from a recurring conceptual error: products are frequently discussed as if “*Boswellia serrata*” itself were the therapeutic unit. In practice, the biological and clinical behavior of a *Boswellia* product is determined by a much narrower and more fragile chain that begins with the raw resin and continues through extraction, standardization, analyte selection, formulation design, gastrointestinal processing, systemic exposure, target engagement, and finally clinical outcome. Once that chain is broken, the label ceases to be an adequate proxy for comparability.

This problem is no longer theoretical. Human pharmacokinetic studies show that food effects and formulation technology can change boswellic-acid exposure by several-fold, and newer micellar systems can increase relative bioavailability into the four-digit percentage range compared with native dry extracts (Schmiech et al., 2024; Sterk et al., 2004). At the same time, analytical studies reveal pronounced differences among marketed *Boswellia* preparations, while recent adulteration work has shown that nominal “total boswellic acid” values can be misleading when undeclared acids are present (Börner et al., 2021; Püski et al., 2024). The resulting translational question is therefore sharper than a simple efficacy question. The central issue is not merely whether *Boswellia* preparations can work, but which preparation defined how, under which exposure conditions, and with what degree of legitimate cross-study comparability.

That distinction matters scientifically and regulatorily. The European Medicines Agency granted orphan designation in 2002 for a *Boswellia serrata* resin extract intended for peritumoral oedema derived from brain tumours, but that designation was later withdrawn on the sponsor’s request (European Medicines Agency [EMA], 2007). This combination of clinical

promise, product heterogeneity, and regulatory discontinuity makes *Boswellia serrata* an instructive case for translational phytopharmacy.

The aim of this review is therefore threefold. First, it critically examines the translational weak points that make apparently similar *Boswellia serrata* preparations non-comparable. Second, it synthesizes the literature through a best-fit framework that links product definition to human exposure and clinical interpretability. Third, it proposes a Boswellia Translational Comparability Framework, presented here as a heuristic framework rather than a validated instrument, to guide future study design, clinical interpretation, and regulatory standard setting.

## Methods

### Review design

This manuscript was intentionally redesigned as a critical translational review. That choice follows two methodological realities. First, the principal objective is not to exhaustively map every Boswellia-related publication, but to explain why evidence generated with heterogeneous preparations cannot be naïvely collapsed into a single clinical proposition. Second, the product is conceptual as well as descriptive: the review seeks to derive a practicable framework for judging translational comparability across analytical, pharmacokinetic, clinical, and regulatory domains. This logic aligns closely with the critical-review tradition described by Grant and Booth (2009), in which analysis and conceptual advancement are central outcomes rather than secondary by-products.

Reporting quality was internally cross-checked against SANRA, a six-item tool developed for narrative and critical review articles, while the transparency of the search and selection process was strengthened through prespecified eligibility criteria and explicit synthesis domains (Baethge et al., 2019). No claim is made that this article is a PRISMA 2020 systematic review or a PRISMA-ScR scoping review. It is a critical review with a systematic search strategy and a best-fit framework synthesis.

### Search strategy and eligibility logic

A predefined search strategy was developed around the following core concepts: “*Boswellia serrata*”, “*Boswellia*”, “frankincense”, and “boswellic acid\*”, combined with terms related to pharmacokinetics, bioavailability, absorption, formulation, delivery, phospholipid, micellar, lipid particle, extract, standardization, quality, adulteration, analysis, osteoarthritis, brain oedema, and orphan designation. The search was centered on PubMed/MEDLINE from database inception through March 10, 2026. It was supplemented by backward citation tracking from key pharmacokinetic, analytical, and clinical papers; verification on publisher

pages when needed; and consultation of official European regulatory resources, particularly EMA and the European Commission orphan-register material. Because the purpose of the review was interpretability rather than pooled intervention efficacy, citation chaining was used deliberately to identify seminal translational studies that sit at the junction of chemistry, exposure, and clinical meaning.

Included evidence comprised five classes of records: (1) human pharmacokinetic studies of *Boswellia serrata* preparations; (2) formulation and biopharmaceutic studies with direct translational relevance to oral exposure; (3) analytical and quality-control studies addressing boswellic-acid composition, marker definition, or adulteration; (4) controlled clinical studies using defined *Boswellia serrata* products; and (5) official regulatory documents relevant to medicinal translation. Purely mechanistic in vitro papers without meaningful product definition, duplicated narrative summaries, and records on unrelated *Boswellia* species without clear relevance to *B. serrata* translational interpretation were not prioritized.

### **Critical appraisal and best-fit framework synthesis**

Formal generic risk-of-bias scoring was not applied across all included records because the evidence base is methodologically heterogeneous and the main review question is not a pooled effect estimate. Instead, each record was critically appraised for translational interpretability using seven prespecified features: botanical and raw-material definition, extract and standardization description, analyte panel and analytical method, dosage-form platform, human exposure characterization, pharmacodynamic or clinical linkage, and quality or regulatory traceability. These features formed the a priori scaffold for best-fit framework synthesis, consistent with the logic described by Dixon-Woods et al. (2011) and Carroll et al. (2013). As new recurrent patterns emerged, such as adulteration-driven distortion of marker claims and the separation between exposure gains and pharmacodynamic gains, the framework was iteratively refined.

### **Results and critical synthesis**

#### **1. Product identity is the first translational bottleneck**

The retrieved literature supports a simple but important conclusion: *Boswellia serrata* comparability often fails before clinical testing begins. Many records describe a “*Boswellia serrata* extract” without sufficiently specifying resin provenance, extraction solvent, drug-extract ratio, enrichment strategy, or the exact boswellic-acid panel used for standardization. This is not a minor reporting defect. In phytopharmaceutical translation, incomplete product definition creates ambiguity at every downstream step, because exposure data, biomarker changes, and clinical signals cannot be confidently assigned to a reproducible chemical entity.

This ambiguity is intensified by analyte selection. Historically, KBA and AKBA received disproportionate attention because of their anti-inflammatory reputation, but translational work has shown that other boswellic acids may contribute materially to disposition and tissue exposure. In rat-brain work, all six major boswellic acids were detectable eight hours after oral administration of a *Boswellia serrata* extract, and the concentrations were not dominated by the classic “headline analytes” alone. In the same study, the four boswellic acids lacking the 11-keto group showed moderate permeability under physiologically adapted conditions, whereas  $\alpha$ - and  $\beta$ -boswellic acid were more intensely metabolized in microsomal systems (Gerbeth et al., 2013). These data argue against narrow marker logic and in favor of broader analyte panels when product comparability is assessed.

Analytical quality-control studies strengthen the same point from a different direction. Börner et al. (2021) found considerable differences among three commonly used frankincense-based remedies both in boswellic-acid content and in anti-inflammatory performance across multiple bioassays. More strikingly, Püski et al. (2024) analyzed 14 commercial *Boswellia serrata* extracts used in food supplements and reported that only two products met expected KBA and AKBA criteria, while 10 contained 6-11% citric acid, a non-characteristic constituent capable of distorting total-acid assessments. The problem did not end there. A 2025 analytical study developed CE-MS/MS specifically to screen Boswellia supplements for nonsteroidal anti-inflammatory drugs as potential adulterants and, while it found no NSAID adulteration in the tested products, it again detected undeclared compounds such as citric acid and ascorbic acid and highlighted marked quantitative variation in boswellic-acid profiles (Kosolapov et al., 2025). Taken together, these studies make clear that nominal extract labels and simple summary marker claims do not guarantee compositional authenticity or translational equivalence.

## 2. Formulation architecture determines exposure

Formulation is the next major bottleneck. Boswellic acids are highly lipophilic and intrinsically difficult to absorb. In a translational formulation study, a phospholipid/pluronic F127 system increased boswellic-acid solubility by up to 54-fold compared with a non-formulated extract and produced the highest mass net flux in permeability testing (Hüsch et al., 2012). Human data mirror this principle. Sterk et al. (2004) showed that administering a *Boswellia serrata* dry extract with a standardized high-fat meal yielded several-fold increases in AUC and C<sub>max</sub> for multiple boswellic acids, while  $\alpha$ -boswellic acid and acetyl- $\alpha$ -boswellic acid became detectable only in the fed state. Food, in other words, is not a nuisance variable in Boswellia research. It is an exposure modifier that can function like a surrogate formulation variable.

Newer delivery systems magnify that effect. In a 2024 crossover trial involving 20 healthy volunteers, a micellar *Boswellia serrata* product significantly increased C<sub>max</sub> and AUC<sub>0-48</sub> and shortened T<sub>max</sub> for all measured boswellic and lupeolic acids compared with a native dry extract, translating into relative bioavailability gains of 1,720-4,291% and the greatest increase for AKBA (Schmiech et al., 2024). Yet this impressive pharmacokinetic shift was not matched by a superior ex vivo anti-inflammatory profile. Both products reduced TNF- $\alpha$  release, and the native preparation even showed stronger inhibition of some readouts. This is one of the most important translational findings in the modern *Boswellia* literature. Exposure enhancement is real, but exposure enhancement alone is not sufficient surrogate for clinical or pharmacodynamic superiority.

Other human pharmacokinetic studies help refine this picture rather than overturn it. Kulkarni et al. (2021) reported measurable AKBA and KBA exposure after solid-lipid *Boswellia* particles in healthy volunteers, with T<sub>max</sub> values of 1.5 and 2.3 hours, respectively, and quantifiable elimination half-lives. Liu et al. (2020) examined *Boswellia* constituents administered alone and in a multi-ingredient osteoarthritis supplement combination and found no significant pharmacokinetic interaction across the measured constituents. These studies are valuable because they show that *Boswellia* exposure is not static, but they also reveal how product-specific the data remain. Cross-study inference is only as strong as the comparability of the preparations being compared.

### **3. Clinical efficacy signals exist, but they are product-specific**

Clinical efficacy signals are strongest in osteoarthritis, but they too are heavily preparation-dependent. Early randomized data showed that *Boswellia serrata* extract reduced knee pain, improved flexion, and increased walking distance in osteoarthritis compared with placebo (Kimmatkar et al., 2003). Subsequent proprietary products enriched for AKBA or marketed as enhanced-bioavailability preparations reported faster and larger symptom reductions. For example, 5-Loxin produced significant improvements in pain and function as early as day 7 in the higher-dose group (Sengupta et al., 2008). Aflapin/AprèsFlex, standardized to 20% AKBA, showed significant improvement by day 5 and reductions in MMP-3, TNF $\alpha$ , hsCRP, COMP, and C2C over 30 days (Karlupudi et al., 2023). Boswellin Super, standardized to 30% AKBA, also demonstrated improvements in pain and function, including day-5 changes in some symptom components, over 90 days (Majeed et al., 2024). A later 180-day placebo-controlled study of SN13108F reported not only symptomatic improvement but also MRI-based gains in cartilage morphology and reductions in biomarker panels (Kumar et al., 2025).

These trials are encouraging, but they do not justify an undifferentiated claim that “*Boswellia* works” across all preparations. Most positive clinical studies are product-specific, are concentrated in musculoskeletal outcomes, and frequently arise from proprietary

development programs. In the 2008 5-Loxin trial, the lead affiliation was the Laila Impex R&D Center. In the 2024 Boswellin Super trial, multiple authors were employed by Sami-Sabinsa Group Limited or Sabinsa Corporation, and that employment relationship was declared in the conflict-of-interest statement. A 2025 spondylitis trial of a full-spectrum *Boswellia* extract and a *Boswellia*-curcumin co-delivery system likewise included authors from the product developer Akay Natural Ingredients (Sengupta et al., 2008; Majeed et al., 2024; Mamatha et al., 2025). None of this invalidates the results. It does, however, increase the importance of independent replication and of distinguishing product efficacy from class efficacy.

#### 4. Regulatory translation remains discontinuous

Regulatory translation remains incomplete. The EMA documents that *Boswellia serrata* resin extract received orphan designation in 2002 for peritumoral oedema derived from brain tumours and that the designation was withdrawn in 2006 at the sponsor's request (EMA, 2007). The historical significance of that episode is twofold. It demonstrates that *Boswellia* once reached a level of medicinal seriousness beyond the food-supplement market, but it also shows how little durable regulatory consolidation followed. In practical terms, the evidence landscape still resembles a cluster of product lines more than a coherent phytopharmaceutical class.

#### Proposed *Boswellia* Translational Comparability Framework

To make that landscape more interpretable, the present review proposes a *Boswellia* Translational Comparability Framework (BTCF), adapted from the earlier working BTCI scaffold but explicitly used here as a qualitative-analytic framework rather than a validated scoring tool. The framework has seven domains: (1) raw-material identity, including species, plant part, and provenance; (2) extract definition, including solvent system, DER, enrichment, and standardization target; (3) analyte architecture, including which boswellic acids and related triterpenes are measured; (4) formulation platform, including whether the preparation is native, phospholipid-based, micellar, lipid-particle-based, or another delivery system; (5) human exposure evidence, including C<sub>max</sub>, AUC, T<sub>max</sub>, half-life, and food effects; (6) pharmacodynamic or clinical linkage, including biomarkers and patient-centered outcomes; and (7) quality-regulatory traceability, including authenticity testing, adulteration control, official status, and conflict transparency.

A study becomes more clinically interpretable when these domains cohere. A trial that shows symptom relief but provides weak extract definition, limited analyte measurement, no exposure data, and minimal authenticity control may still be clinically interesting, but it remains hard to generalize. Conversely, a formulation study with rich pharmacokinetic information but no pharmacodynamic or clinical bridge remains translationally incomplete. The central value of

the framework is therefore not numerical ranking. Its value lies in forcing investigators and readers to ask the right question: comparable with what, and on which part of the resin-to-response chain?

**Table 1. Core domains of the Boswellia Translational Comparability Framework.**

| <b>Domain</b>                              | <b>What should be reported</b>                                                                  | <b>Why it matters for comparability</b>                                                 |
|--------------------------------------------|-------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| <b>Raw material identity</b>               | Species, plant part, provenance, harvest or sourcing, voucher or traceability                   | Without a defined starting material, downstream chemistry cannot be assumed equivalent. |
| <b>Extract definition</b>                  | Solvent system, DER, fractionation or enrichment, standardization target                        | Extraction design determines which triterpenes reach the final preparation.             |
| <b>Analyte architecture</b>                | Measured boswellic acids and related triterpenes, assay platform, calibration approach          | Single-marker logic can miss relevant constituents and conceal nonequivalence.          |
| <b>Formulation platform</b>                | Native extract, phospholipid complex, micellar system, lipid particle, co-delivery design       | Delivery technology strongly alters dissolution, permeability, and exposure.            |
| <b>Human exposure</b>                      | C <sub>max</sub> , AUC, T <sub>max</sub> , half-life, fed/fasted conditions, dose normalization | Clinical interpretation is weak when systemic exposure is unknown.                      |
| <b>PD or clinical linkage</b>              | Biomarkers, ex vivo readouts, symptom scales, imaging, safety                                   | Exposure gains are not automatically equivalent to therapeutic gains.                   |
| <b>Quality and regulatory traceability</b> | Authenticity testing, adulteration screening, official status, funding/conflict transparency    | Commercial and regulatory context materially affects generalizability.                  |

*BTCF is proposed as a heuristic framework for interpretive rigor. It is not presented here as a validated scoring instrument.*

**Table 2. Selected studies linking Boswellia formulation to disposition and translational interpretability.**

| Study                         | Preparation and design                                                               | Main translational finding                                                                                                                           |
|-------------------------------|--------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sterk et al. (2004)</b>    | BSE-018 dry extract; randomized open-label fed/fasted crossover in healthy men       | High-fat meal caused several-fold AUC/Cmax increases; alphaBA and acetyl-alphaBA detectable only in fed state.                                       |
| <b>Hüsch et al. (2012)</b>    | Phospholipid/co-surfactant formulation study                                         | Extract/phospholipid/pluronic F127 system increased boswellic-acid solubility up to 54-fold and improved mass net flux.                              |
| <b>Gerbeth et al. (2013)</b>  | Physiologically adapted permeability and rat-brain availability study                | All six major boswellic acids were detectable in rat brain; non-11-keto acids showed relevant permeability.                                          |
| <b>Liu et al. (2020)</b>      | Open-label, four-period crossover in 16 healthy volunteers                           | No significant PK interaction when Boswellia constituents were administered in a multi-ingredient OA supplement combination.                         |
| <b>Kulkarni et al. (2021)</b> | Solid-lipid Boswellia particles in 10 healthy volunteers                             | AKBA Tmax 1.5 h and KBA Tmax 2.3 h with quantifiable exposure and half-life estimates.                                                               |
| <b>Schmiech et al. (2024)</b> | Single-dose crossover trial in 20 healthy volunteers; micellar vs native dry extract | Micellar product increased relative bioavailability to 1,720-4,291% but did not show proportional superiority in ex vivo anti-inflammatory readouts. |

**Table 3. Selected controlled clinical studies illustrating product-specific efficacy claims.**

| Study                          | Preparation                      | Population and duration                          | Interpretive comment                                                                                                |
|--------------------------------|----------------------------------|--------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|
| <b>Kimmatkar et al. (2003)</b> | <i>Boswellia serrata</i> extract | Knee OA; randomized crossover; 8 weeks per phase | Early placebo-controlled efficacy signal, but product definition is limited by current standards.                   |
| <b>Sengupta et al. (2008)</b>  | 5-Loxin (30% AKBA)               | Knee OA; randomized placebo-controlled; 90 days  | Symptom improvements, including day-7 signal at higher dose; proprietary product with developer-linked affiliation. |
| <b>Karlapudi</b>               | Aflapin/Après                    | Knee OA;                                         | Day-5 symptomatic                                                                                                   |

|                              |                                                                                 |                                                                                             |                                                                                                |
|------------------------------|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------|
| <b>et al. (2023)</b>         | Flex (20% AKBA)                                                                 | randomized placebo-controlled; 30 days                                                      | improvement with biomarker reductions; preparation-specific claim rather than class claim.     |
| <b>Majeed et al. (2024)</b>  | Boswellin Super (30% AKBA)                                                      | Knee OA; randomized three-arm placebo-controlled; 90 days                                   | Positive symptomatic trial; several authors employed by the commercial developer.              |
| <b>Kumar et al. (2025)</b>   | SN13108F / Aflapin                                                              | Mild to moderate knee OA; randomized placebo-controlled; 180 days                           | Adds MRI-based cartilage outcomes, but still evaluates a proprietary standardized preparation. |
| <b>Mamatha et al. (2025)</b> | Bioavailability-enhanced full-spectrum Boswellia extract, with/without curcumin | Moderate spondylitis/spondylosis symptoms; randomized three-arm placebo-controlled; 28 days | Suggests expansion beyond OA, yet again around a developer-specific delivery platform.         |

## Discussion

Three overarching conclusions follow from this synthesis. First, *Boswellia serrata* research should move away from plant-name essentialism. The repeated use of the botanical name as if it conferred pharmacological uniformity is no longer tenable in light of modern analytical and human pharmacokinetic evidence. Second, the field should stop treating bioavailability enhancement as a self-justifying endpoint. Exposure matters, but the 2024 micellar trial demonstrates that a major increase in plasma concentration does not automatically produce superior pharmacodynamic performance. Third, clinical interpretation must become conflict-sensitive and product-specific. Positive osteoarthritis trials are real and important, but they support the efficacy of defined preparations under defined conditions, not an interchangeable Boswellia category.

These points have practical consequences for future study design. At a minimum, clinical papers should report resin identity, extraction process, standardization logic, full analyte panel, dosage form, meal conditions, and analytical method for constituent measurement. Human studies intended to support medicinal claims should ideally include at least a sentinel pharmacokinetic sub-study or a robust exposure rationale anchored in a prior PK publication on the same preparation. Analytical authentication should not be limited to headline marker

percentages. Orthogonal methods that can detect undeclared acids or pharmaceuticals are becoming increasingly relevant as the commercial market expands. Finally, promising proprietary products should be replicated by independent groups if they are to support broader therapeutic claims.

This review also has limitations. It is not a PRISMA-formatted systematic review and does not provide pooled effect sizes. The search strategy was transparent and predefined, but it was intentionally organized around translational interpretability rather than exhaustive meta-analytic completeness. The evidence base itself is heterogeneous, and several important clinical records involve proprietary formulations, which constrains generalizability. These limitations are acceptable for a critical translational review, but they should be kept in mind when the conclusions are applied to guideline or formulary decisions.

## **Conclusion**

*Boswellia serrata* remains a promising but methodologically fragmented field. The strongest contemporary evidence does not support a simple yes-or-no verdict on “*Boswellia* efficacy.” It supports a more precise conclusion: defined *Boswellia* preparations can generate favorable clinical and anti-inflammatory signals, but these signals are inseparable from extract chemistry, formulation architecture, exposure behavior, quality control, and regulatory traceability. The path forward is therefore not more undifferentiated *Boswellia* trials. It is better-defined *Boswellia* science.

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## **Conflicts of interest**

The author declares no conflicts of interest.

## **Ethics statement**

This article is a literature-based critical review and did not involve human participants, animals, or identifiable personal data. Formal ethics approval was therefore not required.

## **Author contributions**

Phil Kading: conceptualization, literature search, evidence selection, synthesis, framework development, writing of the original draft, and revision of the manuscript.

## **Data availability**

No new primary dataset was generated for this work. All evidence discussed is contained in the cited literature and regulatory sources.

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