

Original Article

From dissolution to dermal benefits: *In vitro*, *ex vivo*, and *in vivo* evaluation of mesoporosil[®] as a highly bioavailable silicium source

Nicolas Mannu¹, Tom Bourjac¹, Geert Van Gijsegem¹, Frederik Monsuur², Nicolas Rabasso³ , Ivan Coste-Maniere⁴

¹Department of Research and Development, Sil'Innov SRL, Courcelles, ²ConSilation, Hasselt, Belgium, ³Institut de Chimie Moléculaire et des Matériaux d'Orsay, Université Paris-Saclay, CNRS, Orsay, ⁴SKEMA Business School, Université Côte d'Azur, Valbonne, France.



***Corresponding author:**

Nicolas Mannu,
Department of Research and
Development, Sil'Innov SRL,
Courcelles, Belgium.

n.mannu@silinnov.eu

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ABSTRACT

Objectives: The objective of this study is to assess how effectively Mesoporosil[®], a next-generation mesoporous silica ingredient, dissolves, is absorbed in the intestine, and becomes bioavailable in the body, with the aim of improving silicium delivery for skin and connective tissue health.

Material and Methods: A comprehensive assessment was performed using *in vitro*, *ex vivo*, and *in vivo* models. Dissolution kinetics of Mesoporosil[®] were quantified in water and fasted state simulated intestinal fluid (FaSSIF) using inductively coupled plasma optical emission spectrometry and silicomolybdc acid spectrophotometry. *Ex vivo* intestinal transport was evaluated using Ussing chambers on isolated rat jejunum to determine the apparent permeability coefficient (Papp) and the corresponding absorbed fraction (AF). Pharmacokinetic profiling was conducted in Sprague–Dawley rats after oral administration of Mesoporosil[®] microcapsules, measuring key parameters including Cmax, Tmax, and area under the curve (AUC).

Results: Mesoporosil[®] exhibited rapid and extensive silicium release, achieving approximately 90% dissolution after 8 h in water, about 380-fold higher than standard mesoporous silica and up to 27-fold greater silicium liberation in FaSSIF compared with commercial silicium supplements. *Ex vivo* permeability testing showed a Papp of 3.35×10^{-5} cm/s, corresponding to an estimated AF of 96.7%, indicating highly efficient intestinal transfer. In the *in vivo* model, Mesoporosil[®] demonstrated fast systemic uptake with a Cmax of approximately 73 ng/mL, a Tmax of 1 h, and an AUC of roughly 274 ng•h/mL. These data confirm effective oral absorption and robust bioavailability of silicium delivered through Mesoporosil[®].

Conclusion: Across all experimental models, Mesoporosil[®] showed enhanced dissolution, absorption, and bioavailability compared with conventional silicium sources. These benefits are attributed to its optimized mesoporous structure, which promotes efficient hydrolytic conversion to orthosilicic acid, the bioactive and absorbable form of silicium. The demonstrated performance supports Mesoporosil[®] as a highly bioavailable silicium ingredient with strong potential to benefit skin and connective tissue health through improved silicium delivery.

Keywords: Dissolution, Mesoporosil[®], Plasma, Silicium, Skin

INTRODUCTION

Silicium, often referred to as silicon, is the third most abundant trace element in the human body, following iron and zinc.^[1] It should not be confused with silicone, a synthetic compound

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widely used in sealants, adhesives, implants, and cosmetic products such as moisturizers, primers, and scar treatments. To prevent any misunderstanding, this study will consistently use the term silicium.

Silicium plays a key role in activating hydroxylation enzymes, and promotes the synthesis of collagen and glycosaminoglycans, protecting collagen from free-radical damage, and preserving the skin's strength, elasticity, hydration, and antioxidant defenses.^[2] The most bioavailable form, orthosilicic acid (OSA), has been the subject of research for its skin-related benefits.^[3] Studies show that OSA stimulates fibroblasts, which are responsible for producing new Type I collagen and supporting wound healing. Silicium may also enhance the synthesis of glycosaminoglycans (e.g., hyaluronic acid) or influence how these molecules bind water, thus contributing to hydration of the dermal matrix. Through these supportive roles, supplementation may lead to improved dermal thickness, reduced appearance of fine lines, and better skin resilience. Clinical observations from supplements combining silicium with other agents report enhanced hydration, elasticity, and barrier function. A high concentration of silicium in hair enhances growth and reduces fragility, while in nails it contributes to durability and resistance. Nutritional supplements containing silicium are designed to raise serum silicon levels, though their effectiveness may be limited by inconsistent absorption in the digestive system.^[4,5]

With age, skin loses firmness, elasticity, and hydration, partly due to declining collagen and elastin turnover and matrix degradation. Some researchers propose that supplementation with bioavailable silicium may prevent and counteract this decline. A randomized, double-blind, placebo-controlled clinical trial in women with photodamaged skin showed that oral intake of OSA (10 mg Si/day for 20 weeks) led to improvements in skin surface roughness parameters and skin mechanical properties compared to placebo. In a separate open-label evaluation, use of OSA over 90 days was judged to improve skin texture, firmness, and hydration relative to baseline.

Most dietary supplements containing silicium are available in liquid form. However, liquid mineral supplements present several drawbacks, including the need for controlled storage temperatures, difficulties with accurate dosing, unpleasant taste or odor, and reduced portability. These limitations often make liquid formulations inconvenient for consistent use.

To overcome these challenges, significant research has focused on alternative delivery methods. In 2021, a novel and highly bioavailable form of mesoporous silica particles (MPS), marketed as Mesoporosil[®], was introduced to the European dietary supplement market. Compared with traditional MPS, this innovation shows a much faster

biodegradation rate and improved bioavailability, making it a more efficient carrier for OSA.

MPS is composed of amorphous silicon dioxide and stands out due to its unique structural features. It has pores ranging from 2 to 50 nm and a three-dimensional, periodic atomic arrangement with organized pores. This architecture creates a very high specific surface area, which substantially increases both its bioavailability and overall effectiveness as a dietary supplement.^[6-8]

The term “biodegradable” is used here to align with existing literature, although its application to inorganic materials is often inappropriate. However, the terms “biodegradable” or “biostabilized” are often used inappropriately in the literature to describe the degradation of inorganic materials such as mesoporous silicas. The International Union of Pure and Applied Chemistry (IUPAC) has, however, recommended an appropriate terminology concerning biorelated polymers and applications. Biodegradation was defined as the “degradation caused by an enzymatic process resulting from the action of cells.”

According to this convention, the term biodegradable is thus considered inappropriate for “*in vitro* activity of isolated enzymes,” which should be called “enzymatic degradation,” “*in vivo* degradation resulting solely from hydrolysis by the water,” which should be called “hydrolytic degradation,” and “cell-mediated chemical modification without main chain scission” which is a “bioalteration.” According to this definition, mesoporous silicas should not be described as biodegradable but rather as degradable materials.^[9]

In 2025, a study on the supplementation with Mesoporosil[®] highlighted its effectiveness in promoting skin health. The results demonstrate progressive and significant improvements in skin firmness, hydration, and elasticity, with high levels of overall satisfaction, excellent cutaneous compatibility, effectiveness, and safety of the Mesoporosil[®] treatment in women with aging skin.^[10]

Therefore, the goal of this study is to evaluate the solubility, absorbability, and bioavailability in plasma of the solid silicium source through a series of *in vitro*, *ex vivo*, and *in vivo* trials of Mesoporosil[®].

MATERIAL AND METHODS

Materials

Mesoporosil[®] is a biodegradable mesoporous silica-based material produced and supplied for this study by Eytelia. Standard mesoporous silica, used in this study, is defined as being micronized silica available on the market for food and pharma, with a pore size between 2 and 50 nm (IUPAC).

Three silicium-based products currently available on the global market were evaluated and compared to Mesoporosil[®] and renamed as follows:

- Nutricolin®
- Exsynutriment®
- SiliciuMax®

One rat Sprague–Dawley, male, weighing 166 g, corresponding to the strain typically used for Ussing experiment from Janvier Labs, was used. Ringer solution by Biogalenys, Carbogen supplied by Air Products.

For the pharmacokinetic (PK) study of silicium in the life phase, four male Sprague–Dawley rats (8 weeks old) were obtained from Janvier Labs. The animals were housed in the European standard type III cages under controlled environmental conditions. Aspen wood chips (Tapvei, Brogaarden, Denmark) were used as bedding, which was replaced once per week. Each cage was equipped with shelter, nesting material, and a wooden chewing stick to promote animal welfare.

The animal room was maintained at a temperature of 20–24°C and a relative humidity of 45–55%, both regulated by the ambient ventilation system. Air exchange occurred approximately 12 times/h. The lighting cycle was set to 12 h of light and 12 h of darkness. During the acclimatization and experimental periods, the animals were fed the SAFE-A30 rodent diet (Safe Diets, France). Analytical reports provided by the supplier were reviewed and approved prior to use. Tap water was supplied *ad libitum* via drinking bottles, which were replaced twice per week. Routine analyses of drinking water were conducted to verify the absence of contaminants. All animal handling was performed by trained personnel under the supervision of a veterinarian. Animal welfare was monitored daily, and records were maintained throughout the study. Discussions regarding animal health and welfare were conducted regularly, in consultation with the study director whenever possible.

Animals were delivered 5 days before the start of the experimental procedures to allow for proper acclimatization and to permit the exclusion of any animals in poor condition or at the extremes of the body weight (BW) range. The supplier's Health Monitoring Report, provided with the shipment, was verified upon arrival to confirm the health status of the animals. During the acclimatization period, all rats were observed daily for signs of ill health. At the end of this period, any animals exhibiting poor condition were excluded from the study.

On arrival, the rats were unpacked, weighed, and randomly assigned to treatment groups. Following allocation, each animal was identified by ear punch as indicated in Table 1.

Measurement of degradation behavior

To date, the 2 available methods for silicium measurements are the silicomolybdic acid (SMA) spectrophotometric

method and inductively coupled plasma optical emission spectrometry (ICP-OES). Although SMA is time-consuming and non-environmentally friendly, it provides the full SiO₂ content. In comparison, ICP-OES is flexible, automated, and a fast measurement tool for the total Si content. Therefore, the latter is being used as a routine technique of measurement.

The degradation behavior of Mesoporosil® and a standard mesoporous silica was investigated in ultra-pure water (900 mL) at 37 ± 0.5°C under stirring at 75 rpm on a dissolution apparatus (Sotax AT Xtend) and characterized by ICP-OES (5110 VDV from Agilent) to assess the amount of degraded silica as a function of time. Both measurements have been performed with 100 mg of silicon dioxide (SiO₂), which has been introduced in the medium at t₀. The ICP-OES analyses have been compared to the SMA spectrophotometric method.^[11] For the last method, absorbance has been measured at 810 nm with a UV spectrophotometer from BMG LABTECH (SPECTO star Nano) to quantify the amount of silicium in solution.

The degradation behavior of Mesoporosil® was evaluated in comparison with commercially available silicium-based products currently present on the global market. The study was conducted using 900 mL of fasted state simulated intestinal fluid (FaSSIF) maintained at 37 ± 0.5°C under constant stirring at 75 rpm in a dissolution apparatus (Sotax AT Xtend). Samples were analyzed over time by Inductively Coupled Plasma – Optical Emission Spectroscopy (ICP-OES, 5110 VDV, Agilent Technologies) to quantify the amount of silicium released (degraded silica) as a function of time.

The FaSSIF medium was prepared following the Biorelevant® protocol using the FaSSIF powder mix (FFF02). Dissolution trials were initiated by introducing, at time zero (t₀), the daily dose prescribed by each manufacturer, as indicated in Table 2. This approach was selected to reflect real-world conditions of use and formulation performance, as the amount of elemental silicium is intrinsically linked to the

Table 1: Number of rats per group for the PK study.

Group no.	Rat no.
1	1
2	2, 3, 4

Table 2: Daily dose indicated by the manufacturer for each silicon-based ingredient evaluated.

Products	Supplier	Daily dose (mg)
Nutricolin®	GALENA	200
Exsynutriment®	BIOTEC	150
SiliciuMax®	FAGRON	150
Mesoporosil®	EYTELIA	50

presence and proportion of stabilizing agents required to maintain silicium in a bioavailable form. Since silicium cannot be isolated from its formulation matrix, comparisons based solely on equivalent elemental silicium content would not provide a meaningful assessment of dissolution efficiency. Evaluating dissolution at the daily dose level, therefore, allows a more relevant comparison of the effective silicium delivery achieved by each technology under practical usage conditions.

Transmembrane permeation assays through the jejunum rat intestine using Ussing chambers

The *in vitro* transintestinal absorption through rat jejunum has been investigated for over 2 h. Fluxes were measured from the mucosal (apical) to the serosal side (basolateral). The matrix used for the experiment in the Ussing chamber was a Ringer solution where 2 mmol/L of L-glutamine was added. Six Ussing chambers with a 1 cm² surface of exchange were used simultaneously.

Intestinal patches were placed between the two half-chambers as represented in Figure 1.^[12] In the Ussing chambers, the temperature was maintained at 37 ± 2°C during the entire experiment. A continuous perfusion of carbogen (CO₂) was observed during all the experiments in each chamber. The donor solution was placed on the donor side. A tablet containing Mesoporsosil[®] has been evaluated (Reference: OTH-3-029-A V6). This tablet of 346.28 mg contains 30 mg of SiO₂. Samples from donor and receptor sides were analyzed by ICP-OES (5110 VDV from Agilent) from t₀ to t = 120 min.

PK study of silicium in rats, in the life phase

PK study design and sample collection in rats

Mesoporosil[®] was incorporated into a microcapsule formulation and administered to the animals by oral gavage (per os, PO). Blood samples were collected at six time points within a 24-h period following administration. Plasma was subsequently prepared from the collected blood samples for the determination of silicium (Si) content.

Regarding the PK study of silicium in rats, in the life phase, 4 Sprague–Dawley male rats, 8 weeks of age, have been divided into 2 treatment groups as indicated in Table 3.

BWs were recorded before dosing. At time zero (t₀), the rats were dosed by oral gavage with the test article. Immediately following administration, 1 mL of drinking water was given to each rat by oral gavage to ensure complete delivery of the test material.

Blood samples were collected from all rats at the following time points: Pre-dose (0 h), and at 0.5-, 1-, 2-, 4-, and 6-h post-dose.

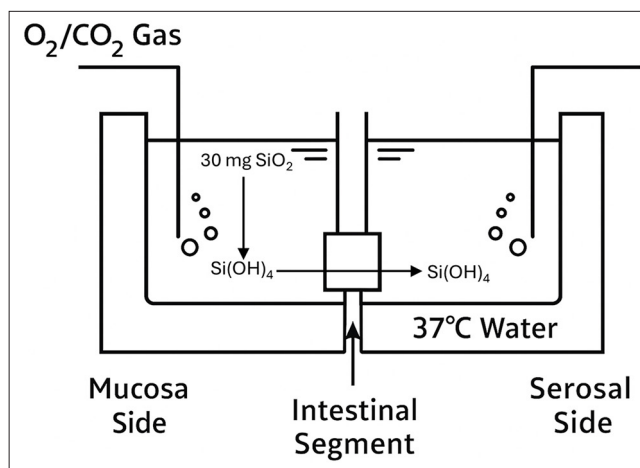


Figure 1: Schematic representation of a small piece of intestinal segment tissue mounted in the Ussing chamber.

Table 3: Product and formula administered to each group for the PK study.

Group No.	No. of rats	Test article	Formula
1	1	Blank	NA
2	3	Mesoporosil [®]	Microcapsule

At each timepoint, approximately 250 µL of blood was collected from the sublingual plexus. From each blood sample, around 100 µL of K₃ ethylene diamine tetra-acetic acid plasma was prepared. The plasma was divided into two aliquots of 50 µL each and stored at temperatures below -70°C pending bioanalysis.

PK analysis

The PK analysis was conducted on individual plasma concentration data for each animal within their respective dose groups. Non-compartmental analysis was performed using the Phoenix[®] WinNonlin[®] software (Model Type: Plasma (200–202); Dose Type: Extravascular).

Software used for PK analysis

The non-compartmental PK analysis was performed using the validated application Phoenix[®] WinNonlin[®], version 8.1 (Copyright © 1998–2018, Certara L.P., USA). Microsoft Office Standard, version 2019, was used for reporting, tabulation, and supplementary calculations.

Licence number for the conduct of animal experiments

The pharmacokinetic study was conducted according to the Swedish license number for the conduct of animal experiments. The study was reviewed by the local animal ethics committee. Permit number M140-16.

RESULTS

Dissolution tests of silica-based materials: comparison between SMA spectrophotometric method and ICP- OES analysis

Figure 2 shows the amount of silicium dissolved after 8 h in water for a standard mesoporous silica and Mesoporosil[®]. The measurements of the concentrations resulting from the samples analyzed by ICP-OES are compared to the SMA spectrophotometric method.

The results on each analytical method for Mesoporosil[®] show that approximately 90% of silica is dissolved in water

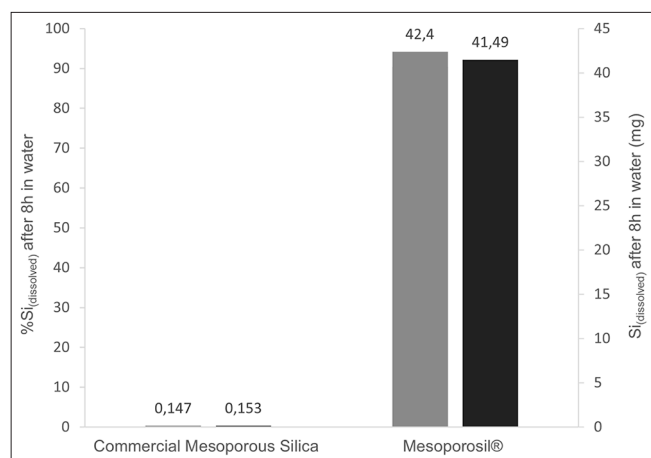


Figure 2: %Si (100% silicium dissolved relates to 46.7 mg of Si) in solution after 8 h in water for a standard mesoporous silica and Mesoporosil[®]. Comparison of analytical results of inductively coupled plasma optical emission spectrometry (■) and the silicomolybdic acid spectrophotometry method (■).

after 8 h. Indeed, the silicium concentrations measured by ICP-OES were equivalent to those obtained by the SMA spectrophotometry method. Measurements on the standard mesoporous silica showed that Mesoporosil[®] was 380 times more soluble in water after 8h. Less than 0.5% of the standard mesoporous silica is dissolved under the same conditions after 8h.

Comparison of the degradation kinetic of Mesoporosil[®] with a standard mesoporous silica

Figure 3 (left) shows the degradation kinetic over 8 h for Mesoporosil[®] and a standard mesoporous silica (right). After 6 h, approximately 90% of Mesoporosil[®] is dissolved, and the maximum of dissolution is reached. For the standard mesoporous silica <0.3% is dissolved after the same period.

The degradation kinetic experiment of Mesoporosil[®] has been performed on 8 different batches to test the reproducibility of the results obtained. After 8 h, the %Si in solution is $87.1 \pm 0.8\%$ for all the samples of Mesoporosil[®] assessed.

Comparison of the degradation kinetic in FaSSiF of Mesoporosil[®] with other silicium technology present on the global market

Figure 4 shows the degradation kinetic over 8 h for Mesoporosil[®] and three silicium-based products. The percentage of silicium dissolved is relative to the daily dose introduced for each product. After 8 h, approximately 10% of the daily dose of Mesoporosil[®] was dissolved as silicium. The silicium-based products, available as powder, tested reach a maximum of approximately 2% for SiliciuMax[®] after 8 h and a minimum of 0.4% for the Nutricolin[®]. An amount

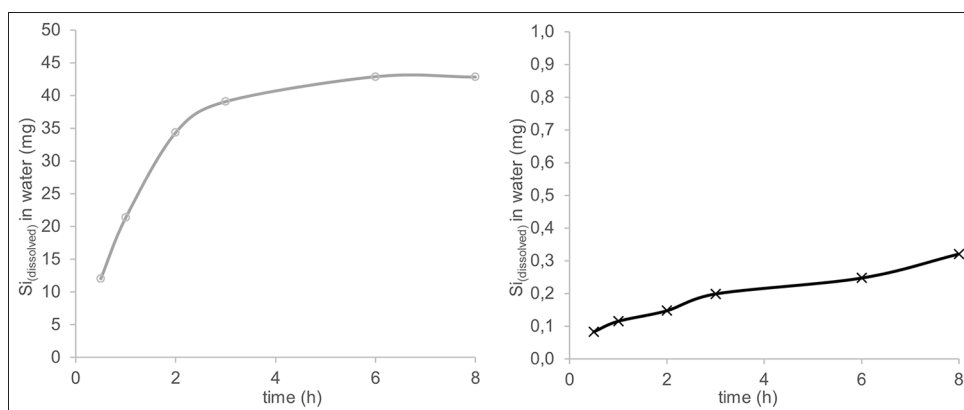


Figure 3: Degradation kinetic for 8 h of Mesoporosil[®] with a scale from 0 to 50 mg of silicium dissolved (left) and a standard mesoporous silica with a scale from 0 to 1.0 mg (right). The degradation behavior of Mesoporosil[®] and a standard mesoporous silica was investigated in ultra-pure water (900 mL) at $37 \pm 0.5^\circ\text{C}$ under stirring at 75 rpm and characterized by inductively coupled plasma optical emission spectrometry to assess the amount of degraded silica as a function of time. Both measurements were performed using 100 mg of silicon dioxide (SiO₂), introduced into the medium at t₀.

of approximately 1.5% of the daily dose is converted into silicium dissolved for the Exsynutriment®.

Table 4 summarizes the factors of increase (F) of the %Si dissolved after 8 h for Mesoporosil® related to the products of the competitors evaluated. F is determined as indicated in the expression (1).

$$F = \frac{\%Si_{Preblend\ Mesoporosil}}{\%Si_i} \quad (1)$$

%Si_i: Percentage of silicium dissolved after 8 h in FaSSIF at 37°C related to the daily dose of the products evaluated.

Determination of the increase factors shows that after 8 h in FaSSIF at 37°C, the amount of dissolved silicium in Mesoporosil® is approximately 27 times higher than in Nutricolin®, 6.46 times higher than in Exsynutriment® and 5.30 times higher than in SiliciuMax®.

Ex vivo transintestinal absorption of Mesoporosil® end product through rat jejunum during 2 h

The transintestinal absorption of Mesoporosil® end-product in tablet form is assessed by the fluxes of silicium from donor to receptor side. Fluxes are represented in Figure 5 for each repetition of a tablet containing Mesoporosil® (OTH-3-029-A V6).

The flux is calculated between 60 min and 120 min. This quantity of silica passed per unit of time and surface area is used to calculate the average apparent permeability ($P_{app} = \text{Flux} / \text{donor side Concentration}$), which is $3.35 \cdot 10^{-5} \pm 0.58 \cdot 10^{-5} \text{ cm/s}$. By comparing this P_{app} value to a correlation curve obtained under the same conditions with drugs having a known human Absorbed Fraction (AF%), the estimated AF value of Mesoporosil® end product (OTH-3-029-A V6) is $96.7 \pm 8.2\%$.

Silicium plasma concentration – Time profile following oral administration

Endogenous silicium is naturally present in plasma and various tissues, where it plays an essential role in connective tissue integrity, collagen synthesis, and bone metabolism. However, its physiological concentration declines progressively with

age, primarily due to reduced dietary intake and decreased intestinal absorption efficiency. As a result, older individuals generally display lower baseline plasma silicium levels, which may influence systemic bioavailability and the biological functions dependent on silicium.

In the present study, endogenous silicium levels in rats were evaluated and taken into account during the interpretation of the PK results. Although this evaluation was not part of the initial study design, it was undertaken following the observation of unexpected variability in baseline plasma silicium concentrations among the animals. Further investigation revealed a clear age-related difference between young rats (8 weeks old) and older rats (5 months old). The younger rats exhibited mean plasma silicium concentrations of $317 \pm 50 \text{ ng/mL}$, whereas the older animals showed markedly lower concentrations of $148 \pm 16 \text{ ng/mL}$. This age-associated variation is therefore reported as a supplementary

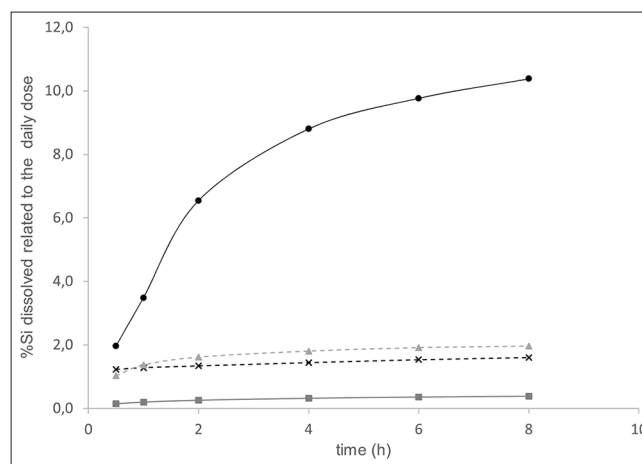


Figure 4: Degradation kinetic for 8 h of Mesoporosil® (●), SiliciuMax® (▲), Exsynutriment® (x) and Nutricolin® (■) in fasted state simulated intestinal fluid at 37°C. All the measurements have been performed by introducing in the medium at to the amount of the daily doses prescribed by the manufacturers and indicated in Table 1.

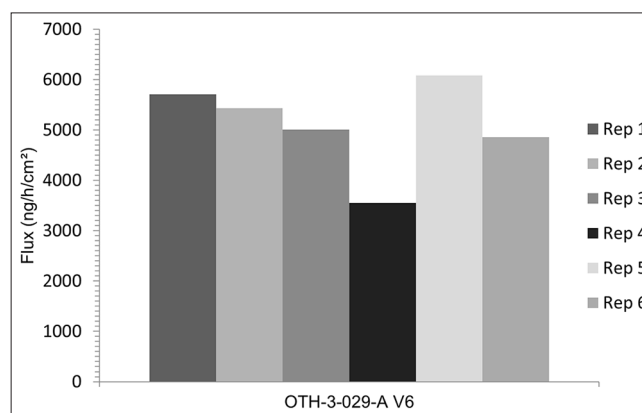


Figure 5: Flux values of each repetition of OTH-3-029-A V6.

Table 4: Factors of increase (F) of the %Si dissolved of Mesoporosil® related to the products of the competitors evaluated on the global market.

Products Evaluated	F (after 8 h)
Mesoporosil®	1
Nutricolin®	27.14
Exsynutriment®	6.46
SiliciuMax®	5.30

and exploratory observation, providing contextual insight into endogenous silicium levels and supporting a more accurate interpretation of the PK data.

These findings clearly demonstrate that plasma silicium concentrations decrease with age, consistent with the physiological trend observed in other species, and underline the importance of accounting for endogenous silicium when assessing the absorption and bioavailability of silicium-containing formulations.

Figure 6 presents the plasma concentration–time profile of silicium (ng/mL, corrected for endogenous silicium) over a 6-h period following oral administration of Mesoporousil[®], alongside a blank control.

The blank shows a flat baseline (0 ng/mL) across all time points, confirming the absence of exogenous silicium in untreated conditions. In contrast, the Mesoporousil[®] group displays a distinct rise in plasma silicium concentration, reaching a peak at approximately 1-h post-dose ($C_{\max} = 73$ ng/mL). Thereafter, silicium levels decline progressively, approaching baseline by 6 h post-administration.

The observed concentration–time profile for Mesoporousil[®] indicates rapid absorption of silicium from the gastrointestinal tract, with maximum systemic exposure achieved within the 1st h following administration. The subsequent decline toward baseline suggests that silicium is efficiently cleared or distributed within a relatively short timeframe.

Compared with the blank, Mesoporousil[®] clearly results in a measurable and transient increase in plasma silicium levels, confirming its bioavailability and systemic absorption capacity.

The calculated exposure (area under the curve [AUC] ≈ 274 ng•h/mL) further supports the conclusion

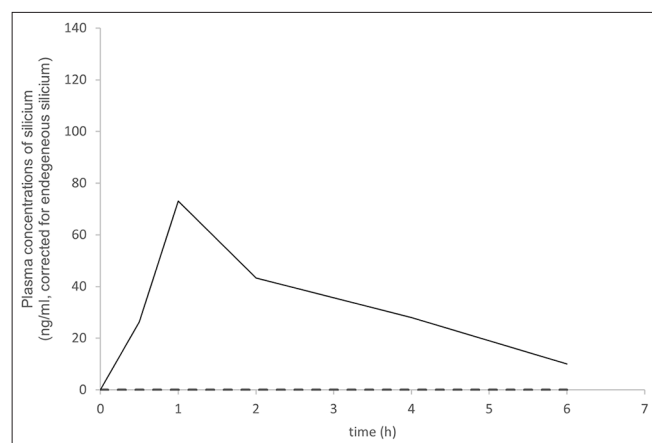


Figure 6: Plasma concentration–time profile of silicium (ng/mL, corrected for endogenous silicium) over a 6-h period following oral administration of Mesoporousil[®] (-) alongside a blank control (- -).

that Mesoporousil[®] enables significant, though short-lived, silicium absorption, returning to baseline concentrations by 6 h.

DISCUSSION

This investigation provides strong evidence that Mesoporousil[®] represents a significant advancement in the delivery and bioavailability of silicium for human supplementation. The comparative dissolution studies clearly established that Mesoporousil[®] exhibits an exceptionally rapid and complete degradation profile. Approximately 90% of the silicium content was solubilized within 8 h, as measured by both ICP-OES and the SMA spectrophotometric method, confirming the high reproducibility and reliability of the degradation kinetics. This represents a 380-fold increase in solubility compared to that of standard mesoporous silica under identical conditions, underscoring the role of Mesoporousil's unique pore architecture and optimized surface chemistry in facilitating water penetration and hydrolytic conversion into bioavailable OSA. When examined under simulated intestinal conditions (FaSSIF medium), Mesoporousil[®] continued to outperform other silicium-based formulations. The material achieved dissolution levels up to 27 times greater than Nutricolin[®], 6.5 times higher than Exsynutrient[®], and 5.3 times higher than SiliciuMax[®], despite being tested at substantially lower nominal doses. These results collectively confirm that Mesoporousil[®] possesses an intrinsic structural advantage that accelerates degradation into OSA, the only absorbable form of silicium, without the need for stabilizers or organic carriers.

Ex vivo intestinal permeation assays using Ussing chambers further substantiated these findings by demonstrating a high rate of silicium flux across the jejunal barrier, with an average apparent permeability (P_{app}) of $3.35 \times 10^{-5} \pm 0.58 \times 10^{-5}$ cm/s, corresponding to an AF% of $96.7 \pm 8.2\%$. Such permeability values are consistent with those of highly bioavailable low-molecular-weight compounds, confirming that silicium derived from Mesoporousil[®] is rapidly and efficiently transferred from the intestinal lumen into systemic circulation. The AF is derived indirectly from an *ex vivo* animal model and is therefore intended to provide a qualitative indication of high intestinal permeability rather than a direct quantitative prediction of human absorption. Within these acknowledged limitations, the Ussing chamber results support a favorable absorption profile and contribute to a convergent body of evidence when interpreted alongside the *in vitro* dissolution and *in vivo* PK data.

This *in vitro/ex vivo* evidence was corroborated by the *in vivo* PK study, where a single oral dose of Mesoporousil[®] in rats produced a pronounced silicium plasma peak ($C_{\max} \approx 73$ ng/mL) within 1-h post-administration ($T_{\max} = 1$ h). Silicium concentrations

declined steadily thereafter, returning to baseline within 6 h, demonstrating both rapid absorption and efficient systemic clearance. The AUC (AUC \approx 274 ng•h/mL) confirmed significant transient exposure, indicating effective bioavailability and metabolic utilization.

The *in vivo* PK evaluation was conducted with a limited number of animals, which does not allow robust statistical power or definitive quantitative conclusions. Consequently, these PK results should be interpreted as indicative trends rather than confirmatory evidence. Nevertheless, the observed coherence between *in vitro*, *ex vivo*, and *in vivo* data supports the biological relevance of the findings and provides a rationale for future studies employing larger, adequately powered experimental designs to confirm and extend these observations.

Beyond physicochemical performance, these results hold clear physiological and dermatological implications. Silicium, once absorbed as OSA, plays a central role in collagen type I synthesis, elastin cross-linking, and glycosaminoglycan (notably hyaluronic acid) metabolism within the dermal matrix. Its presence enhances the activity of prolyl and lysyl hydroxylases, enzymes essential for stabilizing collagen's triple-helix structure, while simultaneously mitigating oxidative degradation of extracellular matrix proteins. This biochemical activity translates into visible improvements in dermal density, hydration, and elasticity parameters that tend to decline with chronological and photo-induced aging.^[4,13] Clinical evidence corroborates this mechanistic link: in an 84-day, prospective clinical trial involving women aged 40–66, oral supplementation with one tablet of Mesoporosil[®] delivering 14 mg Si/day produced statistically significant improvements in skin firmness, elasticity, hydration, and reduction in wrinkle depth, with participants reporting higher perceived radiance and comfort. No adverse effects or intolerance were recorded, highlighting the excellent safety and cutaneous compatibility of the formulation.^[9] In this context, previously published clinical findings are referenced to provide biological relevance, while recognizing that the present study did not directly assess clinical skin outcomes.

Together, these *in vitro*, *ex vivo*, and *in vivo* results confirm that Mesoporosil[®] exhibits an unparalleled combination of fast solubility, high intestinal absorption, and systemic bioavailability, far exceeding that of mesoporous silica and other silicium-based supplements. Importantly, the physiological implications of this enhanced bioavailability extend to bone,^[14] skin health, and connective tissue function.

CONCLUSION

Mesoporosil[®] is an advanced silica-based degradable material designed to optimize the solubility, intestinal absorption, and systemic bioavailability of silicium. After 6 h, the amount of silicium dissolved from Mesoporosil[®] was 380 times

greater than that released from standard mesoporous silica, confirming a remarkably enhanced dissolution rate.

The PK evaluation performed in Sprague–Dawley rats confirmed that Mesoporosil[®] silicium is rapidly absorbed following oral administration. Plasma silicium concentrations rose sharply to a peak ($C_{\max} \approx$ 73 ng/mL) within 1-h post-dose ($T_{\max} =$ 1 h), indicating prompt gastrointestinal uptake, followed by a gradual decline to baseline by 6 h, demonstrating efficient systemic clearance. The total systemic exposure (AUC \approx 274 ng•h/mL) confirmed significant transient bioavailability and metabolic utilization of silicium. These findings establish a direct translational link between Mesoporosil's superior dissolution characteristics and its effective systemic distribution *in vivo*.

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Ethical approval: The research/study was approved by the Institutional Review Board at Lund/Malmö local animal welfare ethics committee, number M140-16, dated July 13, 2021.

Declaration of patient consent: Patient's consent not required as there are no patients in this study.

Financial support and sponsorship: Nil.

Conflict of interest: There is no conflict of interest.

Use of artificial intelligence (AI)-assisted technology for manuscript preparation: The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript, and no images were manipulated using AI.

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