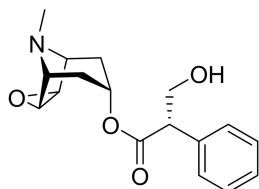




# Scopolamine



<b>Chemical formula:</b>	C <sub>17</sub> H <sub>21</sub> NO <sub>4</sub>
<b>IUPAC name:</b>	[(1R,2R,4S,5S)-9-methyl-3-oxa-9-azatricyclo[3.3.1.0 <sup>2,4</sup> ]nonan-7-yl] 3-hydroxy-2-phenylpropanoate
<b>CAS number:</b>	51-34-3
<b>Alternative Name(s):</b>	hyoscine
<b>Molecular weight:</b>	303.35

## Scopolamine

Scopolamine is a naturally occurring anticholinergic agent derived from plants in the nightshade family (*Solanaceae*). Its pharmacologic activity comes from its ability to block the neurotransmitter acetylcholine and is used to treat motion sickness and post-surgical nausea and vomiting.

Scopolamine is also derivatized to make other active pharmaceutical ingredients (APIs). It is also listed as an essential medicine by the World Health Organization<sup>1</sup>.

Scopolamine, like many plant-based drugs, goes back to early civilizations. The agricultural nature of pharmaceutical supply chains depend on many variables thereby resulting in significant challenges in inventory and quality control. In fact, there have been historical shortages of this essential medicine due to supply challenges lasting as long as 15 months<sup>3</sup>.

## Biosynthetic Scopolamine

Antheia is the first supplier of biosynthetic scopolamine. Antheia's proprietary scopolamine-producing yeast strains<sup>4</sup> are capable of yields sufficient to make industrial microbial fermentation an efficient, controlled, sustainable, and reliable alternative to existing agricultural extraction. The company's biomanufacturing platform reduces production lead time from years to weeks and adds more transparency, reliability, compliance, efficiency, and flexibility to pharmaceutical supply chains.

Additionally, because Antheia's scopolamine is produced biosynthetically, it is not vulnerable to global supply chain issues and can enable rapid-response production to meet sudden changes in demand. The quality, reproducibility, and security of the supply chain of APIs is greatly improved in the controlled environment of a fermentation vessel, compared to the year-to-year variation inherent in field-grown crops.

## Regulatory and Quality Standards

Antheia manufactures all KSMs and APIs under cGMP conditions and will have all appropriate regulatory filings related to our materials. In addition, appropriate regulatory submissions will be prepared and submitted to support our customers who use scopolamine and need to reference and access necessary process-related information.

Every product lot is thoroughly characterized and analyzed against approved specifications and comes with a certificate of analysis (CoA). KSMs and APIs produced via fermentation will perform at the same quality levels as those extracted from plants.

## Safety Data Sheet

A scopolamine SDS will be ready for request in late 2024.

# Antheia's Mission: Rapid response biomanufacturing for the future of KSM and API production

Antheia is a science and technology company developing next-generation plant-inspired medicines. Antheia was founded in 2015 to transform pharmaceutical supply chains and ensure equitable access to essential medicines.

Today, nearly half of KSMs and APIs for medicines are sourced from nature, including many common and essential drugs. The inherent complexity of these molecules does not lend itself to commercially viable chemical synthesis. As a result, the pharma industry is beholden to agriculture-based supply chains that have high latency and lack the flexibility to meet sudden changes in demand. These critical supply chains are also vulnerable to natural disasters, climate change, pests, and disease.

Modern healthcare requires greater consistency, predictability, and agility in pharmaceutical manufacturing to produce essential medicines.

Applying synthetic biology, Antheia has pioneered a new approach to reconstruct drug-producing, biosynthetic pathways in engineered brewer's yeast (*Saccharomyces cerevisiae*) to manufacture KSMs and APIs. This fermentation-based approach has many advantages over agriculture-based extraction, including:

- **More resilient and efficient pharmaceutical supply chains**

An agile, on-demand platform for improved transparency, greater process consistency, and better control across the supply chain.

- **Accelerated manufacturing cycles and reduced inventory**

APIs can be produced in weeks, rather than the years needed to grow, harvest, extract, and purify compounds from plants.

- **Domestic and localized manufacturing**

Fermentation allows localized production in the U.S. and other key regions to reduce lead times, improve supply chain transparency, and ease export/import requirements.

To discuss Antheia's products or technology, please reach out to

**info@antheia.bio**

or visit our website for more information:

**www.antheia.bio**

## References:

1. World Health Organization Model List of Essential Medicines, 22nd List, 2021. Geneva: World Health Organization; 2021. <https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02>
2. Kohnen-Johannsen KL, Kayser O. Tropane Alkaloids: Chemistry, Pharmacology, Biosynthesis and Production. *Molecules*. 2019;24(4):796. <https://www.mdpi.com/1420-3049/24/4/796>
3. U.S. Food and Drug Administration. FDA Drug Shortages: Scopolamine Transdermal System (FDA Drug Shortages database, accessed online 14 April 2020). [https://www.accessdata.fda.gov/scripts/drugshortages/dsp\\_ActiveIngredientDetails.cfm?AI=Scopolamine%20Transdermal%20System&st=r](https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Scopolamine%20Transdermal%20System&st=r)
4. Srinivasan P, Smolke C.D. Biosynthesis of medicinal tropane alkaloids in yeast. *Nature*. 2020. 585, 614–619 (2020). <https://doi.org/10.1038/s41586-020-2650-9>