



Partner with DSM

Discover co-innovation opportunities to develop risk-free formulations

We understand that meeting new regulatory requirements concerning nitrosamine formation in drug products can come with unique and complex challenges. As your purpose-led innovation partner in the pharmaceutical industry, we can offer potential solutions to address this pressing issue.

Whether it is supporting you with the reformulation of your existing drug product, or helping to bring new innovative therapies to market, we can assist you with your mitigation strategies to minimize the risk of nitrosamine formation in your formulation.

We have more than 70 years of experience in producing and securing the supply of vitamins for the pharmaceutical market. This, together with our unique innovation expertise and unparalleled ability to manage the market entry registration process, make us an ideal partner for purposeful advancements in the pharmaceutical space.

**This takes more than active
pharmaceutical ingredients.
It takes a partner.**



70 years
experience



Unique innovation
expertise



Ability to manage
market entry
registration process



DSM

BRIGHT SCIENCE. BRIGHTER LIVING.

Address nitrosamine risk mitigation with confidence

Blocking nitrosamine formation in drug products is a safe and effective way of mitigating the risk of impurities. This is possible with commonly used antioxidants – **ascorbic acid** (vitamin C) and **alpha-tocopherol** (vitamin E). When added to your formulation as excipients, ascorbic acid and alpha-tocopherol bring multiple benefits including:

- **Effective nitrosamine inhibition (>80%)¹**
- **Acts as a stabilizer in the finished drug product formulation**

¹ Nanda et al. Inhibition of N-nitrosamine formation in drug product: a model study. Journal of Pharmaceutical Sciences, 2021.






Using ascorbic acid and alpha-tocopherol excipients as nitrosamine formation inhibiting agents is an FDA recommended mitigation strategy proven to reduce the risk of nitrosamines in your formulation.

Advanced expert services to meet your unique formulation needs

DSM can consult on the reformulation of your existing drug product or future pharmaceutical developments. We offer superior formulation and technical expertise to help you mitigate the risk of nitrosamines in your oral, liquid or injectable formulations and ensure the safety of your finished drug product.

We can help you overcome critical formulation challenges in the pharmaceutical space. To learn more about our solutions for nitrosamine mitigation, connect with an expert today.

We offer an industry-leading portfolio of vitamin ingredients for use across the pharmaceutical industry. DSM's ascorbic acid and alpha-tocopherol are pharmaceutical grade excipients you can trust.

-  **Pharmaceutical grade quality**
-  **GMP-certified**
-  **Sustainable, secure supply**
-  **USP/EP/JP compliant**
-  **Supported by necessary documentation**
(including DMFs and CEPs)



The DSM difference

-  **Superior formulation expertise**
-  **Scientific services**
-  **Global reach**
-  **Regulatory insight**