

Kollidon® Holistic contribution to nitrosamine control strategy

Over 80 years ago, BASF was the originator of Kollidon® (PVPs) building unique know-how for production of povidones, copovidones and crospovidones. This expertise in production and control processes ensures top-tier quality with no known risks of nitrite presence in all Kollidon® grades.

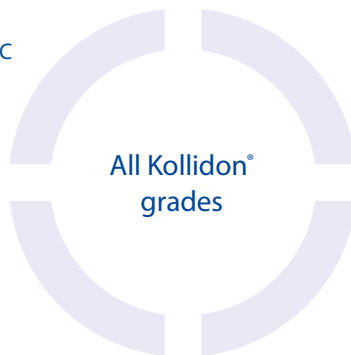
Validating nitrite test methods for all PVP matrixes with a scientific driven approach, BASF has continuously enhanced their sensitivity. To date, no nitrites have been detected in the BASF Kollidon® portfolio (*), providing you with reassurance.

Additionally, BASF launched a new cutting-edge ZoomLab® module that equips formulators with a powerful risk assessment app, allowing them to proactively evaluate the risks of nitrosamine formation using ZoomLab®'s excipient database and integrated with the drug product manufacturing conditions.

With this comprehensive, science-backed approach, BASF delivers unique solutions for nitrosamine risk management:

Proven Risk Assessment following IPEC questionnaire [1] and systematic evaluation, confirming no nitrite risk in Kollidon® production processes.

Customers can continue to use all our Kollidon® grades with no nitrite risks.



Reliable lot-to-lot consistency with no findings of nitrites (*) and average results reported in Risk Assessment statements.

No additional costly reformulation by relying on Kollidon®'s consistent quality.

(*) based on the LOQ / LOD of respective nitrite test methods

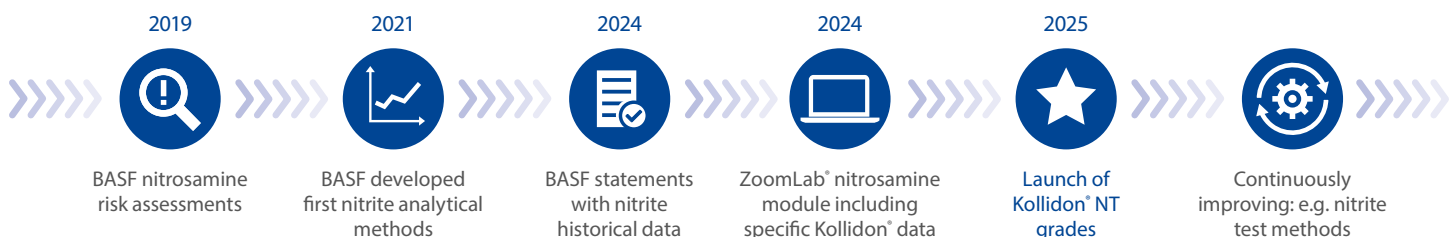
Kollidon® NT grades: Expanding excellence in nitrosamine risk control

In 2025, BASF takes the nitrosamine risk control a step further with the introduction of Kollidon® Nitrite Tested (NT) grades, an advanced service designed to support customers' nitrosamine control strategies with enhanced nitrite testing and documentation.

Kollidon® 30 NT Origin Germany
Kollidon® CL NT
Kollidon® VA 64 NT

- ✓ Nitrite tests on respective product specification & results on CoA for all delivered batches.
- ✓ No change in BASF's respective manufacturing processes.
- ✓ Enhanced quality assurance, but no need for qualification of Kollidon® NT grades
- ✓ Service covers our main Kollidon® grades in diverse applications.

We listen to our customers and are continuously improving our services



Kollidon® products meet the highest quality standards, with no nitrites detected so far. (*)

Ion Chromatography: Povidone and Copovidone

Kollidon® 30, 12 PF & 17 PF
LOQ = 0.1 ppm

Kollidon® 25, 90 Evo, VA 64 & VA 64 Fine
LOQ = 2 ppm

Liquid Chromatography: Crospovidone

Kollidon® CL grades
LOQ = 0.05 ppm

Available on RegXcellence®:
Nitrosamines Risk Assessments
with average results for all Kollidon®
products

Fully validated nitrite test methods
shared with customers on request to
help confidently measure nitrites

(*) based on the LOQ / LOD of respective nitrite test methods

Published data have demonstrated that BASF's Kollidon® excipients have the best performance regarding nitrite [2] and these are seen as best-in-class by our customers.

ZoomLab® – Your Drug Product Development Platform assists you in evaluating the nitrosamine risk in your drug products:

ZoomLab® helps you formulate faster, saving you time and money. Our advanced algorithms and machine-learning models will guide you through the formulation process. Our apps Degradation Products of Active Ingredients and Nitrosamine Risk Assessment and Mitigation help determining the risk of nitrosamine formation. Choose from a broad database of ingredients to identify strategies for improving your formulations and manufacturing processes to reduce nitrosamine impurities.

What we provide



Nitrosamine risk
assessments for all
Kollidon® grades



Validated analytical
methods



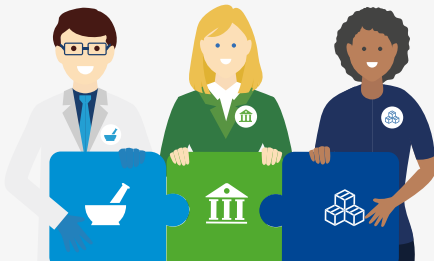
Nitrite-tested grades

Kollidon® CL NT
ART 50866347
Kollidon® 30 NT Origin Germany
ART 50866306
Kollidon® VA 64 NT
ART 50866307



ZoomLab®: algorithm-
based guidance on
formulation strategies
for nitrosamine reduction

- 1 <https://www.ipeceurope.org/articles/questionnaire-for-excipient-nitrosamines-risk-evaluation.html>
- 2 Golob, et al. Journal of Pharmaceutical Sciences, 2023 112 (5), 1277–1286. DOI: 10.1016/j.xphs.2023.03.007



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