Nitrites Collaborative Meeting 2025

shared **knowledge** • shared **progress**



Day One:

Open 12:00 (all times are BST), Lunch Available

Intro 13:00

Supporting Nitrites in Excipients through Shared Knowledge with Lhasa and IPEC

Meeting welcome from Grace Kocks, Head of Toxicology at Lhasa Limited

Session 1 13:10 Nitrosamines and Nitrites in Excipients: Ph. Eur. Perspective and Ongoing Reflections

Anne Garnier, Scientific Program Manager at European Pharmacopoeia

Session 2 13:35

Advancing Trace Nitrite Analysis: The Role of Sonication and Insights from IC Method Implementation

Rebekka Spellerberg, Global Application Manager at MEGGLE GmbH & Co. KG

Session 3 14:00 From Excipients to Drug Products: Analytical Development and Control Strategies for Nitrosamine Risks

Jinjian Zheng, Sr. Principal Scientist at MSD

Session 4 14:25 From Method Selection to Risk Evaluation: A Perspective on Nitrite and Nitrosamine Control

Pauline van der Wijst-Janssen, Global Technical Lead at DFE Pharma GmbH

Break 15:00, Coffee & Refreshments

Session 5 15:15

Excipient Nitrite Testing Strategy

Rosanne Salisbury, Senior Manager at Pfizer

Session 6 (inc. Q&A) 15:40

News on IPEC Federation Nitrosamine Questionnaire for Excipients – Supporting Nitrosamine Risk Assessment for Drug Products

Ulrich Reichert, Head of CDMO and Bioprocess Materials at Merck KGaA

Session 7 16:25

Nitrite Testing in Excipients – Industry Best Practices

Sebastian Hickert, Senior Manager Analytical and Preparative LC at Merck KGaA

Session 8 16:50

From Origins to Outcomes: Trends, Challenges, and Collaboration in Excipients Nitrite Levels

Gemma Packer, Senior Scientist at Lhasa Limited

Close 17:15, Evening Dinner 18:00

Day Two:

Open 9:00 (all times are BST), Refreshments Available

Session 9 9:30

Nitrite Determination by Ion Chromatography: A Strategic Approach to Nitrosamine Risk Mitigation

Mrunal Jaywant, VP of R&D at USP

Session 10 9:55

Innovative Solutions for Nitrosamine Risk Control

Marianna Pierobon, Global Technical Product Management Pharma Solutions at BASF

Session 11 10:20

Statistical Visualization Options for a Data Pool with Nitrite Results for Customer Risk Assessment

Darek Lewin, Head of Quality at JRS Group

Break 10:45. Coffee & Refreshments

Panel & Open Floor 11:00

What is the Root Cause of Nitrite in Excipients?

Lhasa invites collaboration across analytical, regulatory, and manufacturing perspectives as well as opens the floor for both in-person and online audiences to provide insights, questions and expert remarks. Together, we aim to drive data sharing, collaboration and support on the topic of nitrite in excipient testing.

Supporting panel:

Sebastien Hickert, Senior Manager Analytical and Preparative LC at Merck KGaA Ulrich Reichert, Head of CDMO and Bioprocess Materials at Merck KGaA Kevin Moore, Harmonisation team for USP

Anne Garnier, Scientific Program Manager at European Pharmacopoeia Julien Patoor, Director Global Analytical Project Management Late Phase at Novartis

Close 12:10

Lhasa Closing Statement: Thank you to all the speakers, the attendees, and IPEC Europe

Grace Kocks, Head of Toxicology Science at Lhasa Limited

Depart 12:20

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A report summarising each presentation and concluding remarks from Lhasa Limited will be available shortly after the event.