NIPPON **MUKI**

To customers
struggling with nitrosamine impurities in pharmaceuticals

Measurement Against Nitrosamine Formation

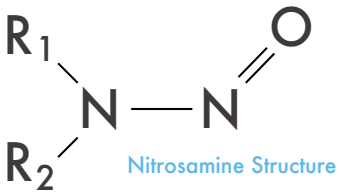
NOx Removal Gas-phase Filter System

■ It is widely known in the pharmaceutical manufacturing industry that amines and nitrogen oxides react to form nitrosamines. Nitrosamines are considered to increase health risks due to their potential carcinogenicity, leading to stricter regulations in pharmaceuticals.

Example of drugs

- Sultan
- Metformin
- Ranitidine
- Rifampicin
- Nizatidine
- NDSRIs : nitrosamine drug substance-related impurities

*antihypertensive drug, acid suppressant, oral antidiabetic drug, etc.

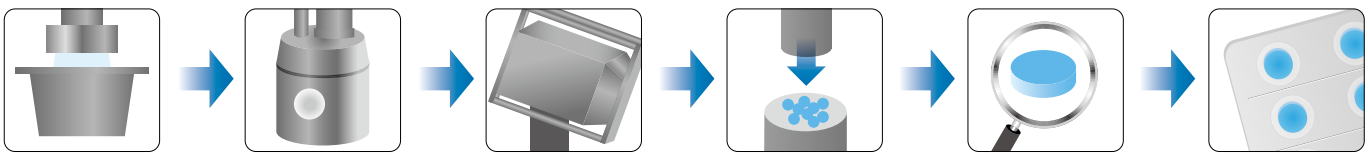


Nitrosamine Structure

Risk of Nitrosamine Contamination

■ There are multiple reasons why nitrosamines can be present in drugs;
It can be related to the drug's manufacturing process or its chemical structure or even the conditions in which they are stored or packaged.

API/Solid dosage form manufacturing process



① Weighing ② Granulation ③ Mixing ④ Tablet compression ⑤ Inspection ⑥ Packaging

■ The use of our gasphase filters for removing NOx in the manufacturing processes of pharmaceutical and API manufacturers has been validated, and their superior performance has been confirmed.

■ An article featuring our filter as a countermeasure against nitrosamine impurities has been published in GMP Platform. (Please access from the QR code on the right)

SCAN ME

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■ The FDA and EMA have issued notifications for pharmaceutical manufacturers to assess the risk of nitrosamine contamination.
Items found to contain nitrosamines exceeding the limit must be reported promptly.
If the limits are exceeded, it is recommended to take mitigation measures such as changing the manufacturing process.
Although the deadlines specified in the notifications have passed, this issue is not a one-time task
but a permanent challenge that requires ongoing management and risk mitigation.

➤FDA：By August 2025　➤EMA：By October 2023

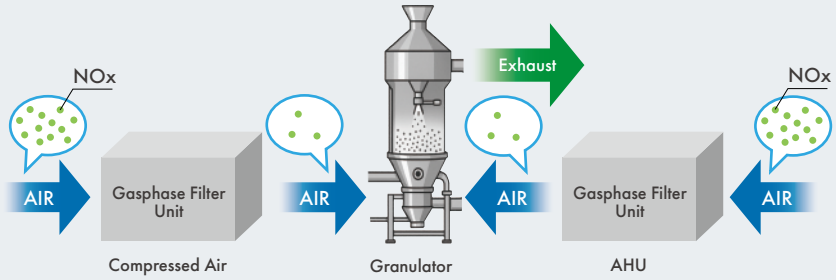
Target and Example of NOx removal system

API manufacturing

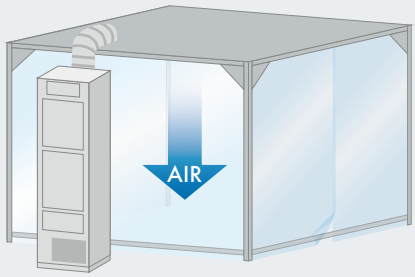
Pharmaceutical manufacturing

Equipment maker

NOx removal system example ①



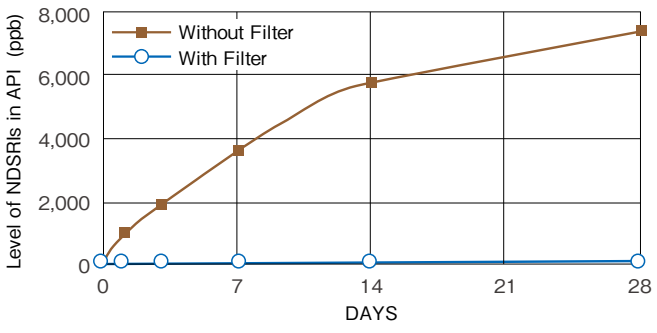
NOx removal system example ②
(Clean booth + Gasphase filter system)



Performance Evaluation of NOx Removal Filter System via Test Unit（Example）

■ Confirmed the change in the content of NDSRIs（nitrosamine impurities）in the active pharmaceutical ingredient with and without the NOx removal filter using a test machine.

<Customer A>



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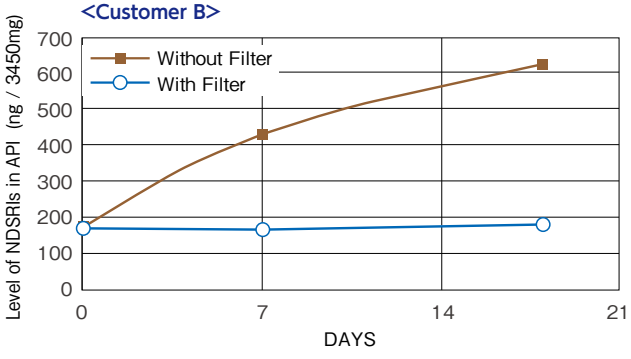

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2026.2.0000(OTM)NM1034-2