



Presentation

2021

VISTIN

PHARMA

A photograph of a large industrial manufacturing facility, likely a pharmaceutical plant, showing stainless steel tanks, pipes, and machinery. The image is partially obscured by a white geometric shape that frames the text on the right.

A leading global dedicated supplier of Metformin

- **High Quality Premium manufacturer with ~10% global market share**
 - Dedicated & fully automated manufacturing site in Norway with 3500 MT Metformin API capacity
 - Ongoing expansion project doubling capacity to 7000MT during 2022
 - >60 years experience in Metformin manufacturing
 - Long term collaboration and sales to global multinational pharmaceutical companies
 - Certified by all significant international regulatory bodies
- **Products offered**
 - Metformin HCl (bulk API)
 - Metformin DC (directly compressible granules)
 - Metformin HCl with specific particle size distribution (PSD)
 - Metformin HCl with lubricants (Premix)
- **Unique offering**
 - High delivery performance (>98%), on time in full
 - Best free-flowing API on the market
 - Customized Particle Size Distribution
 - All shipments according to GDP (Good Distribution Practice)
 - Flexible customer solutions and excellent customer service
 - Strong focus on Environment, Social and Health (ESG)
 - API with no detectable content of nitrosamine
 - Low levels of residual DMA, impurity f

Product range & Capacities

Product	Pack & batch size	Annual capacity	Regulatory compliance
Metformin HCl Active Pharmaceutical Ingredient	Pack size: 25 kg carton (Big-bag available on request) Batch size: ~3100 kg	~3500 MT Additional capacity from 2022 +3500 MT	Ph.Eur. (CEP), USP, JP and BP US DMF - LoA to US DMF available on request
Metformin DC - Direct Compressible lubricated granules, 92,6%	Pack size: 25 kg carton (Big-bag available on request) Batch size: ~800 kg	~800 MT Additional capacity from 2022 +800 MT	US DMF - LoA to US DMF available on request

Regulatory Compliance

• Regulatory Status

- GMP Certificate for covering manufacturing of Metformin HCl (API) and Metformin DC (drug product intermediate)
- Certificate of Suitability to the European Pharmacopoeia (CEP)
- API in compliance with current Ph.Eur., USP and JP monographs
- US DMF filed for Metformin HCl and DC
- Other DMFs filed in Japan, Korea, Brazil, China and more
- Letter of Authorization to DMF available on request

• Latest authority inspections at Vistin Pharma

- Norwegian Medicines Agency (NoMA) 2018. (Audit closed)
- US Food and Drug Administration (FDA), 2019. 2 Form 483 observations. (Audit closed)
- PMDA “paper audit”, 2019. (Approved)
- Korean Food and Drug Administration (KFDA), 2012
- Brazilian Health Authorities (ANVISA), 2011

Business update Vistin Pharma

2019

- Successful installation of new fully automatic packaging line.
- High demand for Vistin's volume, sold out in 2019, 2020 and 2021

2020

- In April our board approved an investment to double our manufacturing capacity
- First step of our expansion project successfully implemented with a new duplicated reactor in week 41
- Finalization of our expansion project in Q2 2022 will double our capacity to ~7000 MT

Nitrosamines

- Based on risk assessment and current available data (approx. 230 batches tested in-house, and more than 700 batches tested by customers):
- No detectable content of NDMA present in our Metformin HCl
- No routine testing is required for controlling levels of Nitrosamines in Vistin Pharma API
- Vistin's Metformin HCl has low levels of residual DMA (impurity F) which is relevant factor for limiting NDMA formation in formulated drug products.

Covid-19

- No interruption in production due to raw material supply
- No employee affected
- Vistin is experiencing increased demand for European based supply of quality Metformin HCl

VISTIN

PHARMA

Thank you for your attention!

