



UPDATE

Registration no.:
DE_NI_01_Reg_2017_0001

Pharmaceutical Zinc Oxide API

**Pharmaceutical
Zinc Oxide API**

GMP Quality

**Conform with the
purity standards
defined in the
Ph. Eur., BP and
the USP**

Grillo Zinkoxid GmbH is one of the leading producers of zinc oxide in Europe and look back on more than 100 years of tradition at the site in Goslar, Germany. Grillo Zinkoxid GmbH is one of the first German manufacturers to produce ultra-pure zinc oxide that can be used both in human and veterinary medicine.

In cosmetics, zinc oxide nourishes skin, act as a UV absorber to protect skin against intensive sun exposure and supports wound healing.

Pharma 4 GMP, Pharma 6 GMP and Pharma 8 GMP are pharmaceutical, ultra-pure zinc oxides made from metallic super high grade (SHG) zinc in accordance with part II of the EU GMP guidelines. They conform – and in some cases exceed – with the purity standards defined in the applicable pharmacopoeias (Ph. Eur., BP and USP).

Grillo Zinkoxid GmbH has taken the following steps to obtain GMP certification:

- Mitigation risk assessment for all of process steps (Production, Laboratory, Dispatch)
- Qualification of the Plants, Systems and Equipments
- Validation remediation plan with time table

Grillo Zinkoxid GmbH is registered at the Pharmaceutical Supervising Authority under the following number [DE_NI_01_Reg_2017_0001](#) . The certification and the final GMP-Certificate will be expected in the 4th quarter 2018.

GMP	Zinc Oxide pharma 4 GMP	Zinc Oxide pharma 6 GMP	Zinc Oxide pharma 8 GMP
Compliant to EP and USP specification	yes	yes	yes
Max lead (Pb) specification	20 ppm	20 ppm	20 ppm
Specific surface area range (m ² /g)	BET 3-5	BET 5-7	BET 7-9



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