



# Standard Compliance Certificate



This is to certify that



#### **BIOGRUND GmbH**

Neukirchner Straße 5 65510 Hünstetten Germany

with the organizational units/sites as listed in the annex has implemented and maintains a

EXCIPACT™: 2017 Certification Standard for Pharmaceutical Excipient Suppliers:

### **Good Manufacturing Practice Good Distribution Practice**

The certificate is only valid in conjunction with a valid ISO 9001 certificate

This assessment also meets the requirements of NSF/IPEC/ANSI 363-2016 Good Manufacturing Practice for Pharmaceutical Excipients

Scope:

Manufacture of Ready-to-use-Excipient Preparations for Solid Dosage Forms (for product groups 1-7 see annex)

Certificate registration no. 296948 EXCI
Valid from 2019-06-26
Valid until 2022-06-25

Date of certification 2019-06-26

EXCO

**DQS GmbH** 



Markus Bleher Managing Director





## Annex to Standard Compliance Certificate Registration No. 296948 EXCI

#### **BIOGRUND GmbH**

Neukirchner Straße 5 65510 Hünstetten Germany

Location	Scope of Products
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 1: Ready-to-use film coating agents (AquaPolish® brand group, BonuLac®, NutraPolish®) as excipients for the production of solid dosage forms.
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 2: Ready-to-use tabletting agents (CompactCel® brand group, RetardCel®, BonuTab®) as excipients for the production of solid dosage forms.
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 3: Ready-to-use coloring agents (TopMill® brand group, BonuTone®, BonuPrint®).
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 4: Ready-to-use sugar coating agents (IsuPolish® brand group).
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 5: Ready-to-use polishing agents (BonuWax® brand group).
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 6: Ready-to-use film coating agents (Eudragit® E PO ReadyMix brand group) as excipients for the production of solid dosage forms.
BIOGRUND GmbH Neukirchner Str. 5 65510 Hünstetten	Scope 7: Re-packaging and Re-labelling of pharmaceutical Excipients (BonuCel® brand group) under GMP conditions

