

Deutsche Akkreditierungsstelle GmbH

Annex to the Accreditation Certificate D-IS-18678-01-00 according to DIN EN ISO/IEC 17020:2012

Valid from: 08.04.2019

Date of issue: 08.04.2019

Holder of certificate:

Blue Inspection Body GmbH
Hafenweg 18-20, 48155 Münster

for its inspection body Type A

“blue inspection body”

Inspections and declaration of conformity with general requirements due to expert assessment in the following field:

Inspections of excipient and active pharmaceutical ingredient manufacturers for pharmaceutical products and determination of the conformance with international GMP rules

This document is a translation. The definitive version is the original German annex to the accreditation certificate.

Abbreviations used: see last page

*The certificate together with its annex reflects the status at the time of the date of issue. The current status of the scope of accreditation can be found in the database of accredited bodies of Deutsche Akkreditierungsstelle GmbH.
<https://www.dakks.de/en/content/accredited-bodies-dakks>*

Field of Inspection: Inspections of excipient and active pharmaceutical ingredient manufacturers for pharmaceutical products and determination of the conformance with international GMP rules

Inspections of excipient and active pharmaceutical ingredient manufacturers for pharmaceutical products and determination of the conformance with international GMP rules, audits and on-site inspections, inspections of excipient and active pharmaceutical ingredients, inspection of the production documentation and of quality management

Inspection procedures of the Blue Inspection Body GmbH

SOP BLUE-H01 (Version 03, 15.01.2017)	Audit Preparation
SOP BLUE-H02 (Version 05, 01.10.2017)	Audit Procedures
SOP BLUE-H03 (Version 05, 15.01.2017)	Generation of the audit report
SOP BLUE-H04 (Version 03, 15.01.2017)	Assessment of audit reports
SOP BLUE-H05 (Version 02, 15.01.2017)	Assessment and Classification of Deficiencies and Non-conformities, Evaluation of the Quality System and Proposal of the Re-Audit Frequency during GMP-Audits.
SOP BLUE-H06 (Version 05, 15.01.2017)	Issuing and withdrawal of certificates
SOP BLUE-S07 (Version 05, 15.03.2017)	General Certification/Inspection Regulations

-Translation-

Annex to the accreditation certificate D-IS-18678-01-00

Abbreviations used:

DIN	Deutsches Institut für Normung e.V.
ISO	International Organization for Standardization
EN	European Norm (European Standard)
IEC	International Electrotechnical Commission
SOP H0x	In house method of the CAB
SOP S0x	In house method of the CAB

-Translation-