

Product line Secudur® Statements

Our product line Secudur® meets the requirements of the European Pharmacopoeia. The product quality is monitored within a quality management framework certified compliant with EN ISO 9001.

Residual Solvents Statement

We hereby confirm that, based on the knowledge of the manufacturing process and controlled handling and storage of our products, our product line Secudur® does not contain any solvents listed on the USP 467 (Residual Solvents List).

GMO / BSE / TSE Statement

We confirm that our product line Secudur® does neither contain, nor was manufactured with any animal products or any materials of animal or cell culture origin. We therefore confirm that this product is free of any Bovine Spongiform Encephalopathy (BSE), other Transmissible Spongiform Encephalopathie (TSE) and / or Genetically Modified Organism (GMO).

Melamin / Latex / Aflatoxine Kontamination:

We also confirm that our product line Secudur® does not contain Melamine, Latex and Aflatoxin or any related substances.

Allergens

Furthermore, we confirm that our product line Secudur® is free of allergens according to Regulation No. 1169/2011/EU.

ICH Q3D

Moreover, we confirm that our product line Secudur® follows the requirements of "ICH Q3D - Guideline for Elemental Impurities". Hereby we refer to the elaborations of the EIGA "ICH Q3D Risk Assessment Report - Elemental Impurities in Medicinal Gases" - Doc 216/20.

Nitrosamines

A risk assessment regarding the presence of nitrosamines was performed for our product line Secudur®. No risk of contamination with nitrosamines was identified for the respective products. Additionally we confirm that no nitrate, nitrite or ammonium compounds are present in the products of our product line Secudur®.

Münster, 7th December 2020



Dr. Tobias Revermann
QM-Specialist



Arne Kiewit
Quality Employee

+++ This declaration of conformity is valid until 31st December 2021. +++