



Product Line Secudur®: Statements

All products of the Westfalen product line Secudur® meet 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 these products are free of any:

- BSE (Bovine Spongiform Encephalopathy)
- TSE (Transmissible Spongiform Encephalopathy)
- GMO (Genetically Modified Organism)

Contamination

We also confirm that the products of our product line Secudur® do not contain melamine, latex, fluorinated gasses, phthalates, aflatoxins or related substances.

Allergens

Furthermore, we confirm that the products our product line Secudur® are free of allergens according to Regulation No. 1169/2011/EU (annex II).

ICH Q3D

Moreover, we confirm that the products of our product line Secudur® follow 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 the products of 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® and no risk of contamination by using water or solvents in the process was identified. Equipment used for production of Secudur®-products is dedicated to the production of gasses without the risk of contamination during production or cleaning.

Münster, December 11th, 2023

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