

## Certificate of Analysis

### Kaolin Pharma

Batch-No.: DE-23.03.22

Parameter	Method	Specification Ph.Eur. 01/2017:0503	Result
Appearance	Ph. Eur. 01/2017:0503 <sup>*1</sup>	fine, white or greyish-white, unctuous powder	complies
Solubility	Ph. Eur. 01/2017:0503 <sup>*1</sup>	practically insoluble in water and in organic solvents	complies
Identification A	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Identification B	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Identification C	Ph. Eur. 2.3.1 <sup>*1</sup>	complies	complies
Acidity or alkalinity	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Organic impurities	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Adsorption Power	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Swelling power	Ph. Eur. 01/2017:0503 <sup>*1</sup>	complies	complies
Substances soluble in dilute hydrochloric acid	Ph. Eur. 01/2017:0503 <sup>*1</sup>	≤ 1 %	< 1 %
Chlorides	Ph. Eur. 2.4.4 <sup>*1</sup>	≤ 250 ppm	< 250 ppm
Sulfates	Ph. Eur. 2.4.13 <sup>*1</sup>	≤ 0.1 %	< 0.1 %
Calcium	Ph. Eur. 2.4.3 <sup>*1</sup>	≤ 250 ppm	< 250 ppm
Heavy metals	Ph. Eur. 2.4.8 <sup>*1</sup>	≤ 25 ppm (Ph. Eur. 07/2010:0503)	< 25 ppm
TAMC <sup>*3</sup>	Ph. Eur. 2.6.12 <sup>*1</sup>	≤ 10 <sup>3</sup> CFU/g	< 100 CFU/g
TYMC <sup>*3</sup>	Ph. Eur. 2.6.12 <sup>*1</sup>	≤ 10 <sup>2</sup> CFU/g	< 100 CFU/g <sup>*2</sup>

<sup>\*1</sup> analysed in: Pharmaanalytik Münster

<sup>\*2</sup> Medium Typ: SAB

<sup>\*3</sup> The method is not validated

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