

Technical Data Sheet

PurifiDE[®] XG-12 Purified Siliceous Earth USP-NF (Bulk Pharmaceutical Excipient Filter Aid GMPs)

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All PROPERTIES SHOWN ARE TYPICAL VALUES – NOT TO BE USED FOR SPECIFICATIONS

Read appropriate Material Safety Data Sheet before using.

Contact EP Minerals for approval of product specifications.

PRODUCT

Description	Fresh water diatomaceous earth (siliceous earth), flux calcined, leached, and rinsed
PurifiDE XG-12 Purified Siliceous Earth USP-NF (<u>Bulk Pharmaceutical Excipient Filter Aid GMPs</u>)	Intended for use as a filter aid (component [†]) in the manufacturing of pharmaceuticals and components used in pharmaceuticals

[†]21 CFR Part 210.3

TYPICAL PHYSICAL PROPERTIES

Color	White or light gray
Appearance	Fine powder
Density, centrifuge wet, lbs./ft ³ (g/ml)	20.8 (0.33)
Permeability (Darcy)	1.1
150 mesh screen analysis (% retains, w/w)	5.0
Mean particle size (microns)	31.0
pH, 10 % in deionized water	6.4
Conductivity (μS/cm)	4.0
Specific gravity	2.2
Moisture (% w/w)	0.1
Loss on ignition (% w/w)	0.4
Acid soluble substances (% w/w)	0.07
Water soluble substances (% w/w)	0.04

TYPICAL ACID SOLUBLE ELEMENTAL IMPURITIES (mg/kg, ppm) DETECTED BY ICP-MS**

Aluminum	0.2
Antimony	< 0.025
Arsenic	< 0.025
Cadmium	< 0.025
Cobalt	< 0.025
Copper	0.15
Iron	4.0
Lead	0.035
Lithium	< 2.5
Mercury	< 0.003
Molybdenum	< 0.025
Nickel	0.08
Selenium	< 0.125
Tin	< 2.5
Vanadium	< 0.025

** 0.1 M HCl for 1 hr., at RT

TYPICAL BULK CHEMICAL COMPOSITION (%) ANALYZED BY XRF SPECTROSCOPY

SiO ₂	87.6
Al ₂ O ₃	3.5
Fe ₂ O ₃	1.8
Na ₂ O	2.8
CaO	0.4
TiO ₂	0.2
MgO	0.2
K ₂ O	0.1
Other oxides	1.0

Products meet the specifications of the USP40-NF35 Monograph on Purified Siliceous Earth
 Read appropriate Material Safety Data Sheet before using.