

## Technical Data Sheet

### PurifiDE® XG-3 Purified Siliceous Earth USP-NF (Bulk Pharmaceutical Excipient Filter Aid GMPs)

UNCONTROLLED COPY FOR INFORMATION PURPOSES ONLY

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-3 Purified Siliceous Earth USP-NF ( <u>Bulk Pharmaceutical Excipient Filter Aid GMPs</u> ) | Intended for use as a filter aid (component <sup>†</sup> ) in the manufacturing of pharmaceuticals and components used in pharmaceuticals |

<sup>†</sup>21 CFR Part 210.3

#### TYPICAL PHYSICAL PROPERTIES

|  |             |
|--|-------------|
| Color  | Pink        |
| Appearance   | Fine powder |
| Density, centrifuge wet, lbs./ft <sup>3</sup> (g/ml) | 21.2 (0.34) |
| Permeability (Darcy)                                 | 0.28        |
| 150 mesh screen analysis (% retains, w/w)            | 5.0         |
| Mean particle size (microns)                         | 25.1        |
| pH, 10 % in deionized water                          | 4.3         |
| Conductivity (μS/cm)                                 | 7.8         |
| Specific gravity                                     | 2.2         |
| Moisture (% w/w)                                     | 0.2         |
| Loss on ignition (% w/w)                             | 0.6         |
| Acid soluble substances (% w/w)                      | 0.06        |
| Water soluble substances (% w/w)                     | 0.05        |

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     | 0.125   |
| Iron       | 5.75    |
| Lead       | 0.025   |
| Lithium    | < 2.5   |
| Mercury    | < 0.003 |
| Molybdenum | < 0.025 |
| Nickel     | 0.03    |
| Selenium   | < 0.125 |
| Tin        | < 2.5   |
| Vanadium   | 0.065   |

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

TYPICAL BULK CHEMICAL COMPOSITION (%) ANALYZED BY XRF SPECTROSCOPY

|                                |      |
|--------------------------------|------|
| SiO <sub>2</sub>               | 88.7 |
| Al <sub>2</sub> O <sub>3</sub> | 4.3  |
| Fe <sub>2</sub> O <sub>3</sub> | 2.2  |
| Na <sub>2</sub> O              | 1.6  |
| CaO                            | 0.4  |
| TiO <sub>2</sub>               | 0.3  |
| MgO                            | 0.2  |
| K <sub>2</sub> 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.

