

## Technical Data Sheet

### Zano® M

Zano® M is manufactured and tested in compliance with GMP Part II / ICH Q7 requirements. Testing is done using EP/USP analytical methods or validated in-house analytical methods and is compliant to below mentioned specifications.

#### **General characters (EP) for Zano® M**

*Appearance:* soft, white or faintly yellowish-white, amorphous powder, free from gritty particles.

*Solubility:* practically insoluble in water and in ethanol (96 per cent). It dissolves in dilute mineral acids.

#### **Zinc oxide EP/USP product specifications for Zano® M**

|  | Specification  | Method  |
|--|----------------|---------|
| Identification A, B                          | PASS           | EP/USP  |
| Zinc Oxide                                   | 99,0 – 100,5 % | EP/USP  |
| Lead   | ≤0,0010 %      | ICP-AES |
| Cadmium                                      | ≤0,0005 %      | ICP-AES |
| Iron   | ≤0,0010 %      | ICP-AES |
| Arsenic                                      | ≤0,0005 %      | ICP-AES |
| Thallium                                     | ≤0,0005 %      | ICP-AES |
| Iron and other heavy metals                  | PASS           | USP     |
| Alkalinity                                   | PASS           | EP/USP  |
| Loss on Ignition                             | ≤1,0 %         | EP/USP  |
| Carbonates and color of solution             | PASS           | USP     |
| Carbonates and substances insoluble in acids | PASS           | EP      |

#### **Additional specifications for Zano® M**

|  | Specification                | Method |
|--|------------------------------|--------|
| Specific surface area (after production) | 8,0 – 10,5 m <sup>2</sup> /g | BET    |

Packaging: 12.5 – 20 kg bags in cardboard box

