

Product group: Lactose  
 Brand name: SuperTab® 14 SD  
 Article code: 743721  
 Product description: Lactose monohydrate  
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Manufacturing site: DMV-Fonterra Excipients GmbH & Co.KG, Nörten Hardenberg, Germany  
 Product name: SuperTab® 14SD  
 Conforms to USP - NF, Ph.Eur., JP Lactose monohydrate monograph, current at time of manufacture  
 Product description: A white or almost white, crystalline powder freely soluble in water, practically insoluble in ethanol  
 Residual solvents  
 (CPMP/ICH/283/95): No class 1,2,3 solvents are used during production  
 Identification: Complies with Pharmacopoeia when tested

## Specification

|  |  |
|--|--|
| Water (KF)   | 4.5 - 5.5 %                                |
| Loss on drying   | max. 1.0 %                                 |
| Specific optical rotation:<br>[α] <sup>20</sup> <sub>D</sub> , anhydrous basis | 54.4° to +55.9°                            |
| Residue on ignition/Sulphated ash  | max. 0.10 %                                |
| Proteins and Light Absorbing Impurities  |  |
| [A] 1%, 1 cm at 270 - 300 nm   | max. 0.07                                  |
| [A] 1%, 1 cm at 210 - 220 nm   | max. 0.25                                  |
| Appearance of solution (Ph.Eur.)   | Clear and not more coloured than ref. BY 7 |
| Clarity and Colour of Solution   | Clear and colourless or nearly colourless  |
| [A] 10%, 1 cm at 400 nm  | max. 0.04                                  |
| Acidity or Alkalinity (ml 0.1 N NaOH/6 g)                                      | max. 0.4                                   |
| Heavy metals   | max. 5 ppm                                 |


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|                               |            |                |
|-------------------------------|------------|----------------|
| Particle size distribution    | % < 45 µm  | max. 15        |
| (Air jet sieve)               | % < 100 µm | 30 - 60        |
|                               | % < 250 µm | min. 98        |
| Total aerobic microbial count |            | max. 100 cfu/g |
| Yeasts and Moulds             |            | max. 10 cfu/g  |
| E. coli                       |            | neg. in 10 g   |
| Salmonella                    |            | neg. in 100 g  |

**Storage:** Keep in original, unopened packing and away from strongly odorous materials.  
Temperature averaging between 5 and 25 °C, relative humidity of max. 70%

This document substitutes all previous versions issued for the brand names mentioned above.  
We trust this information, which is made up to the best of our knowledge, will be helpful to you.

**Name** : Rutger Drost  
**Job title** : Global Marketing, Innovation & Technology Director  
**Signature** : 

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