



## Certificate of Analysis

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|                   |                                                                                             |                                                       |
|-------------------|---------------------------------------------------------------------------------------------|-------------------------------------------------------|
| INSULIN GLULISINE | <b>Material:</b> 526885<br><b>GMID:</b> 567775<br><b>Date of manufacturing:</b> 18.Feb.2019 | <b>Batch:</b> C168<br><b>Expiry date:</b> 16.Feb.2022 |
|-------------------|---------------------------------------------------------------------------------------------|-------------------------------------------------------|

| Test item<br>Result                                                            | Specification                                                                  |
|--------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Appearance<br>fine powder, white                                               | fine powder, white to nearly white                                             |
| Identification / insulin glulisine (HPLC)<br>corresponds to reference standard | tR (sample) =<br>tR (reference) $\pm$ 5 per cent                               |
| Identification (peptide mapping)<br>corresponds to reference standard          | rel. tR digestion (sample) =<br>rel. tR digestion (reference) $\pm$ 2 per cent |
| 21A-Desamido-insulin glulisine (HPLC)<br>0.2 per cent                          | $\leq$ 1.0 per cent                                                            |
| Any other single related impurity (HPLC)<br>0.2 per cent                       | $\leq$ 0.5 per cent                                                            |
| Total related impurities (HPLC)<br>1.1 per cent                                | $\leq$ 2.0 per cent                                                            |
| High molecular weight proteins (HPSEC)<br>0.2 per cent                         | $\leq$ 1.0 per cent                                                            |
| Water content (Karl-Fischer)<br>2.8 per cent                                   | $\leq$ 10.0 per cent                                                           |
| E.coli proteins<br>< 9 ppm                                                     | $\leq$ 10 ppm                                                                  |



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| Test item<br>Result                                      | Specification                                                                                  |
|----------------------------------------------------------|------------------------------------------------------------------------------------------------|
| Total aerobic microbial count<br>< 10 cfu/g              | <= 300 cfu/g                                                                                   |
| Total yeasts and moulds count<br>< 10 <sup>2</sup> cfu/g | <= 10 <sup>2</sup> cfu/g                                                                       |
| Bacterial endotoxins<br>corresponds                      | < 10 USP-EU of endotoxins/mg                                                                   |
| Assay / insulin glulisine (HPLC)<br>98.8 per cent        | 95.0 – 105.0 per cent, calculated with<br>reference to the water and solvent free<br>substance |

**COMPLIES** to the requirements.

Data on stability and shelf-life only apply under appropriate conditions of storage.

batch technically released and electronically signed by

Thorsten Borosch

18.Apr.2019 11:51

Release authorized by Product Responsible Manager respectively Qualified Person

Dr. Thorsten Borosch

09. Mai 2019

Dr. T. Borosch