

**CP Pharma GmbH**  
Ostlandring 13  
D-31303 Burgdorf  
Deutschland

Sample-code(s), 2013070147 Raamsdonksveer, 01-08-2013

**Manufacturer's batch certificate**

Description of the product **CP-Oxytocin**  
Pack size **Injection vial of 100 ml**  
Product number **P2638** Registration number **2293/3/07**  
Recipe/filling number **R0741 U0002** Order number **Mail Monika Arvai 2-4-2013**  
Batch number **13 G 026** Batch size **4848 pcs**  
Manufacturing/output date **07-2013 / 07-2013** Expiry date **06-2016**

| Method         | Description<br>Parameter   | Result             | Unit  | Target            | Lower<br>limit | Higher<br>limit | Lower<br>warning | Higher<br>warning |
|----------------|--|--------------------|-------|-------------------|----------------|-----------------|------------------|-------------------|
| <b>LAF001A</b> | <u>pH value</u>  | <b>3.54</b>        |       |                   | 3.0            | 4.0             |                  |                   |
| <b>LAF002A</b> | <u>Relative density</u>  | <b>0.996</b>       |       | 0.995             | 0.990          | 1.020           |                  |                   |
| <b>LAF003A</b> | <u>Refractive index</u>  | <b>1.33516</b>     |       |                   | 1.333          | 1.337           |                  |                   |
| <b>LAF008A</b> | <u>Appearance</u>  | <b>clear</b>       |       | clear             |                |                 |                  |                   |
| <b>LAF011A</b> | <u>Colour</u>  | <b>colourless</b>  |       | colourless        |                |                 |                  |                   |
| <b>LAF025A</b> | <u>Homogeneity</u>   | <b>homogeneous</b> |       | homogeneous       |                |                 |                  |                   |
| <b>LAV047B</b> | <u>Oxytocin acetate / Chlorobutanol</u><br><i>Oxytocin</i>       | <b>10.27</b>       | IU/ml | 10.0              | 9.50           | 10.50           |                  |                   |
|                | <i>Identification Oxytocin</i>                                   | <b>positive</b>    |       | positive          |                |                 |                  |                   |
|                | <i>Chlorobutanol</i>   | <b>2.828</b>       | mg/ml | informative value |                |                 |                  |                   |
|                | <i>Chlorobutanol hemihydrate</i>                                 | <b>2.971</b>       | mg/ml | 3.0               | 2.85           | 3.15            |                  |                   |
|                | <i>Identification Chlorobutanol hemihydrate</i>                  | <b>positive</b>    |       | positive          |                |                 |                  |                   |
| <b>LAV047C</b> | <u>Oxytocin acetate impurities</u><br><i>Impurity individual</i> | <b>0.62</b>        | %     | 1.5               |                | 1.5             |                  |                   |
|                | <i>Impurities total</i>  | <b>0.62</b>        | %     | 5.0               |                | 5.0             |                  |                   |
| <b>LAF004E</b> | <u>Extractable volume (ml)</u>                                   | <b>101.3</b>       | ml    |                   | 100            | 103             |                  |                   |
| <b>LAV502A</b> | <u>Sterility</u>   | <b>sterile</b>     |       | sterile           |                |                 |                  |                   |
| <b>LAV512A</b> | <u>Endotoxins</u>  | <b>2.5</b>         | IU/ml |                   |                | 5               |                  |                   |

All mentioned limits are equal to or more strict than the limits mentioned in the available documentation. LAV901A = component(s) not tested; result declared on the basis of the production amounts. LAV903A = component(s) not tested; result is declared amount according the composition.

Produlab Pharma retains samples till 1 year after the expiry date. Records of the analysis are retained for 7 years and are available on request.

We hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging and quality control, at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder/contract giver of the importing country. The batch processing, packaging, and analysis records were reviewed and found to be in compliance with GMP.

No deviations with a direct impact on the product quality are applicable for this product batch.

**Produlab Pharma bv**, Forellenweg 16, NL-4941 SJ Raamsdonksveer **Manufacturing licence 1401-BVEAK**

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