

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

Sample-code(s), 2014011114 Raamsdonksveer, 07-02-2014

**Manufacturer's batch certificate**

Description of the product **Dexamethason in DMSO**  
Pack size **Bottle of 100 ml**  
Product number **P2134**  
Recipe/filling number **R0695 U0047**  
Batch number **13 L 024**  
Manufacturing/output date **01-2014 / 01-2014**

Registration number **Zul.Nr.:6778053.00.00**  
Order number **4578**  
Batch size **4895 pcs**  
Expiry date **11-2016**

| Method         | Description                                 | Result                 | Unit   | Target                 | Lower limit | Higher limit | Lower warning | Higher warning |
|----------------|---|------------------------|--------|------------------------|-------------|--------------|---------------|----------------|
| <u>LAF002A</u> | <u>Relative density</u>                     | 1.105                  |        | 1.100                  | 1.080       | 1.120        |               |                |
| <u>LAF003A</u> | <u>Refractive index</u>                     | 1.469                  |        | 1.475                  | 1.450       | 1.500        |               |                |
| <u>LAF008A</u> | <u>Appearance</u>                           | reference suspension 1 |        | reference suspension 1 |             |              |               |                |
| <u>LAF011A</u> | <u>Colour</u>                               | colourless             |        | colourless             |             |              |               |                |
| <u>LAF011B</u> | <u>Colour with reference solutions</u>      |                        |        |                        |             |              |               |                |
|                | <u>Reference solution brown</u>             | >9                     |        | 9                      |             |              |               |                |
| <u>LAF025A</u> | <u>Homogeneity</u>                          | homogeneous            |        | homogeneous            |             |              |               |                |
| <u>LAV021B</u> | <u>Dexamethason and DMSO identification</u> |                        |        |                        |             |              |               |                |
|                | <u>Dexamethason</u>                         | 0.0513                 | mg/ml  | 0.050                  | 0.0485      | 0.0525       |               |                |
|                | <u>Identification Dexamethason</u>          | positive               |        | positive               |             |              |               |                |
|                | <u>Identification Dimethylsulfoxide</u>     | positive               |        | positive               |             |              |               |                |
| <u>LAV021E</u> | <u>Dexamethason impurities</u>              |                        |        |                        |             |              |               |                |
|                | <u>Hydrocortison</u>                        | < 0.05                 | %      |                        |             | 0.2          |               |                |
|                | <u>Methylprednisolon</u>                    | < 0.05                 | %      |                        |             | 0.2          |               |                |
|                | <u>Betamethason</u>                         | < 0.05                 | %      |                        |             | 0.3          |               |                |
|                | <u>Dexamethason acetate</u>                 | < 0.05                 | %      |                        |             | 0.2          |               |                |
|                | <u>sum related substances</u>               | < 0.05                 | %      |                        |             | 0.5          |               |                |
|                | <u>Unknown impurities single</u>            | 0.8                    | %      |                        |             | 2.0          |               |                |
|                | <u>sum unknown impurities</u>               | 0.8                    | %      |                        |             | 4.5          |               |                |
| <u>LAF004E</u> | <u>Extractable volume (ml)</u>              | 100.5                  | ml     | 101                    | 100         | 102.5        |               |                |
| <u>LAV509B</u> | <u>Microbial quality</u>                    |                        |        |                        |             |              |               |                |
|                | <u>Total viable aerobic microbial count</u> | 0                      | CFU/ml |                        |             | 100          | 0             |                |
|                | <u>Total combined yeast/mould count</u>     | 0                      | CFU/ml |                        |             | 10           | 0             |                |
|                | <u>S. aureus</u>                            | absent                 |        | absent                 |             |              |               |                |
|                | <u>Pseudomonas aeruginosa</u>               | absent                 |        | absent                 |             |              |               |                |

All mentioned limits are equal to or stricter than the limits mentioned in the available documentation. Additional items may be specified without actual impact on the product specifications. 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 181 J 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 and analysed at a qualified third party site, packaging and further quality control being performed at the below mentioned site in full compliance with the EU GMP requirements and with the specifications as agreed with the marketing authorization holder 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.

Initials qualified persons:

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a. deposited at the chamber  
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Produlab  
Pharma

QS geprüft  
10.04.2014 PL



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Manufacturer's batch certificate

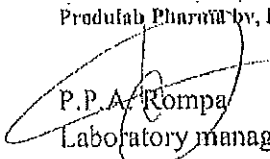
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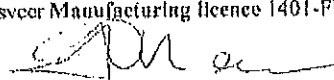
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|--------|--------------------------|--------|------|--------|----------------|-----------------|------------------|-------------------|
|--------|--------------------------|--------|------|--------|----------------|-----------------|------------------|-------------------|

Produlab Pharma b.v., Forellenweg 16, NL-4941 SJ Raamsdonksveer Manufacturing licence 1401-FLG

  
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10. FEB. 2014  