

**Le Vet BV**  
Wilgenweg 7  
3421 TV Oudewater  
Nederland

## Manufacturer's batch certificate

Sample-code(s), 2021041131 Raamsdonksveer, 31-05-2021

Description of the product **Meloxoral 0.5 mg/ml**  
Pack size **PE bottle of 25 ml**  
Product N° PP / client **P4846 871797356937** Registration number **EU/2/10/111/004**  
Recipe/filling number **R0962 / 43 U0547** Order number **PO008962**  
Batch number **21D092** Batch size **681 pcs**  
Manufacturing/output date **04-2021 / 04-2021** Expiry date **03-2024**

| Method         | Description<br>Parameter                                  | Result                   | Unit  | Target                   | Lower<br>limit | Higher<br>limit | Lower<br>warning | Higher<br>warning |
|----------------|-----------------------------------------------------------|--------------------------|-------|--------------------------|----------------|-----------------|------------------|-------------------|
| <u>LAF001A</u> | <u>pH value</u>                                           | 4.46                     |       |                          | 4.2            | 4.6             |                  |                   |
| <u>LAF002B</u> | <u>Absolute density</u>                                   | 1.078                    | g/ml  | 1.077                    | 1.05           | 1.11            |                  |                   |
| <u>LAF005D</u> | <u>Uniformity of dosage (ml)</u>                          |                          |       |                          |                |                 |                  |                   |
|                | <i>Measured dosages</i>                                   | 20                       |       | informative value        |                |                 |                  |                   |
|                | <i>¼ 18 doses</i>                                         | conform                  |       | conform                  |                |                 |                  |                   |
|                | <i>» 2 doses</i>                                          | conform                  |       | conform                  |                |                 |                  |                   |
| <u>LAF006B</u> | <u>Viscosity (RotoVisco)</u>                              | 239                      | mPa·s | 240                      | 180            | 336             |                  |                   |
| <u>LAF007A</u> | <u>Resuspendability</u>                                   | resuspendability <60sec. |       | resuspendability <60sec. |                |                 |                  |                   |
| <u>LAF008A</u> | <u>Appearance</u>                                         | suspension               |       | suspension               |                |                 |                  |                   |
| <u>LAF011A</u> | <u>Colour</u>                                             | yellow-green             |       | yellow-green             |                |                 |                  |                   |
| <u>LAF014A</u> | <u>Particle size (volume)</u>                             |                          |       |                          |                |                 |                  |                   |
|                | 10%                                                       | 17.8                     | µm    | informative value        |                |                 |                  |                   |
|                | 20%                                                       | 28.8                     | µm    | informative value        |                |                 |                  |                   |
|                | 50%                                                       | 64.9                     | µm    | informative value        |                |                 |                  |                   |
|                | 80%                                                       | 137.3                    | µm    | informative value        |                |                 |                  |                   |
|                | 90%                                                       | 202.1                    | µm    | informative value        |                |                 |                  |                   |
|                | 100%                                                      | 1989.6                   | µm    | informative value        |                |                 |                  |                   |
| <u>LAF015B</u> | <u>Sedimentation (Turbiscan)</u>                          |                          |       |                          |                |                 |                  |                   |
|                | <i>sedimentation 1 hour</i>                               | 0                        | % v   |                          |                | 2.5             |                  |                   |
| <u>LAF025A</u> | <u>Homogeneity</u>                                        | homogeneous              |       | homogeneous              |                |                 |                  |                   |
| <u>LAF026A</u> | <u>Dissolution</u>                                        |                          |       |                          |                |                 |                  |                   |
|                | <i>Method used for ...</i>                                | LAV168J                  |       | informative value        |                |                 |                  |                   |
|                | <i>Dissolution percentage</i>                             | 92.5                     | %     |                          | 80             |                 |                  |                   |
|                | <i>Dissolution time</i>                                   | 45                       | min.  | 45                       |                |                 |                  |                   |
| <u>LAF029A</u> | <u>Odour</u>                                              | anise odour              |       | anise odour              |                |                 |                  |                   |
| <u>LAV168B</u> | <u>Meloxicam + impurities</u>                             |                          |       |                          |                |                 |                  |                   |
|                | <i>Impurity A</i>                                         | < 0.05                   | %     |                          |                | 0.5             |                  |                   |
|                | <i>Impurity B</i>                                         | < 0.05                   | %     |                          |                | 0.5             |                  |                   |
|                | <i>Impurity C</i>                                         | < 0.05                   | %     |                          |                | 0.5             |                  |                   |
|                | <i>Impurity individual unknown</i>                        | < 0.05                   | %     |                          |                | 0.3             |                  |                   |
|                | <i>Impurities total</i>                                   | < 0.05                   | %     |                          |                | 2.0             |                  |                   |
| <u>LAV168C</u> | <u>Meloxicam / Sodium benzoate</u>                        |                          |       |                          |                |                 |                  |                   |
|                | <i>Meloxicam</i>                                          | 0.498                    | mg/ml | 0.5                      | 0.475          | 0.525           |                  |                   |
|                | <i>Identification Meloxicam (RRT/UV scan to standard)</i> | positive                 |       | positive                 |                |                 |                  |                   |
|                | <i>Sodiumbenzoate</i>                                     | 1.739                    | mg/ml | 1.75                     | 1.575          | 1.925           |                  |                   |

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