



V.M.D nv/sa  
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## Certificate of analysis

P000330  
Alvebuton 100 mg/mL, 100 mL  
Batch number : 23050752  
Expiry date : 05/2024  
Manufacturing date : 19/05/2022

Control number : COA003471  
Quality order : Q0012798/Pass

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| Test                                                        | Requirements                                    | Results    |
|-------------------------------------------------------------|-------------------------------------------------|------------|
| Appearance                                                  | CF                                              | CF         |
|                                                             | Clear, yellowish to yellow liquid,<br>< or = J4 |            |
| Visible particles (2.9.20) :                                | CF                                              | CF         |
|                                                             | No visible particles                            |            |
| Filling volume :                                            | CF                                              | CF         |
|                                                             | 100 - 110 ml                                    |            |
| Density :                                                   | 1.030 - 1.040 .                                 | 1.035 .    |
| pH :                                                        | 7.8 - 8.6 .                                     | 8.4 .      |
| Refractive value :                                          | 1.3600 - 1.3700 .                               | 1.3627 .   |
| Identification of Menbutone (by UV spectro) :               | CF                                              | CF         |
|                                                             | Sp (R) = Sp (T)                                 |            |
| Identification of Menbutone (by HPLC) :                     | CF                                              | CF         |
|                                                             | Rt (R) = Rt (T)                                 |            |
| Identification of Chlorocresol (by HPLC) :                  | CF                                              | CF         |
|                                                             | Rt (R) = Rt (T)                                 |            |
| Identification of sodium metabisulfite (by potentiometry) : | CF                                              | CF         |
|                                                             | Positive                                        |            |
| Menbutone assay (by HPLC) :                                 | 95.0 - 105.0 mg/ml                              | 99.3 mg/ml |
| Chlorocresol assay (by HPLC) :                              | 1.9 - 2.1 mg/ml                                 | 2.0 mg/ml  |
| Assay of sodium metabisulfite (by potentiometry) :          | 1.8 - 2.1 mg/ml                                 | 1.8 mg/ml  |
| Impurity content i-Men-01 :                                 | 0.0 - 0.5 %                                     | 0.0 %      |
| Impurity content i-Men-02 :                                 | 0.0 - 0.5 %                                     | 0.0 %      |
| Impurity content i-Men-05 :                                 | 0.0 - 0.5 %                                     | 0.0 %      |
| Impurity content i-Men-06 :                                 | 0.0 - 0.5 %                                     | 0.0 %      |
| Unknown individual impurity content :                       | 0.0 - 0.5 %                                     | 0.2 %      |
| Degradation Product - Total (by HPLC) :                     | 0.0 - 1.0 %                                     | 0.2 %      |
| Sterility (bacterial and fungal)                            | CF                                              | CF         |
|                                                             | No proliferation                                |            |

Remarks :

Test results digitally approved by Bieke Sels, on 10/07/2023  
Batch disposition code RELEASED on : 10/07/2023  
Electronically signed by : Leo Aerden: Qualified Person



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|-----------------------------|------------|
| P000330                     |            |
| Alvebuton 100 mg/mL, 100 mL |            |
| Batch number :              | 23050752   |
| Expiry date :               | 05/2024    |
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|                  |               |
|------------------|---------------|
| Control number : | COA003471     |
| Quality order :  | QQ012798/Pass |

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