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Certificate of analysis

P000330
Alvebuton 100 mg/mL, 100 mL
Batch number : 23051481
Expiry date : 05/2024
Manufacturing date : 19/05/2022

Control number : COA003753
Quality order : QO013687/Pass

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Test	Requirements	Results
Appearance	CF Clear, yellowish to yellow liquid, < or = J4	CF
Visible particles (2.9.20) :	CF No visible particles	CF
Filling volume :	CF 100 - 110 ml	CF
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 Sp (R) = Sp (T)	CF
Identification of Menbutone (by HPLC) :	CF Rt (R) = Rt (T)	CF
Identification of Chlorocresol (by HPLC) :	CF Rt (R) = Rt (T)	CF
Identification of sodium metabisulfite (by potentiometry) :	CF Positive	CF
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 No proliferation	CF

Remarks :
Test results digitally approved by Jo Wouters, on 13/09/2023
Batch disposition code RELEASED on : 14/09/2023
Electronically signed by : Leo Aerden: Qualified Person



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