

V.M.D nv/sa
Hoge Mauw 900
2370 Arendonk
Tel : 32 (0)14 67 20 51
Web : <http://www.inovet.eu/>
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Certificate of analysis

P000330
Alvebuton 100 mg/mL, 100 mL
Batch number : 22050030
Expiry date : 03/2023
Manufacturing date : 23/03/2021

Control number : COA000274
Quality order : Q0001541/Pass

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Test	Requirements	Results
Appearance	CF	CF
	Clear, yellowish to yellow liquid, < or = J4	
Visible particles (2.9.20) :	CF	CF
	No visible particles	
Filling volume :	CF	CF
	100 - 110 ml	
Density :	1.030 - 1.040 .	1.030 .
pH :	7.8 - 8.6 .	8.3 .
Refractive value :	1.3600 - 1.3700 .	1.3600 .
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	98.6 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 %	0.1 %
Degradation Product - Total (by HPLC) :	0.0 - 1.0 %	0.1 %
Sterility (bacterial and fungal)	CF	CF
	No proliferation	

Remarks :

Test results digitally approved by Bieke Sels, on 12/05/2022
Batch disposition code RELEASED on : 12/05/2022
Electronically signed by : Leo Aerden: Qualified Person



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Tel : 32 (0)14 67 20 51
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Authorization number : V 0371/79

Name of product and if applicable, destination country :	Alvebuton 100 mg/mL, 100 mL (ROU)
Strength / Potency (per mL or per g) :	Menbuton 100 mg/mL
Dosage form :	Solution for injection
Package size and type :	Vial
Batch number :	22050030
Manufacturing date :	23/03/2021
Expiry date :	03/2023
Reference of analysis :	COA000274
Comments/remarks :	
Certification statement :	I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries.
Batch disposition code :	RELEASED
Name and position / title of person who validated the batch disposition code :	Electronically signed by Leo Aerden: Qualified Person
Date of signature :	12/05/2022