EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE

edqm
European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

VERDANT LIFE SCIENCES PVT., LIMITED
Mr Siva Rama Prasad Manne
Plot No. 55
Jawaharlal Nehru Pharma City (JNPC)
Parawada
India – 531 019 Visakhapatnam, Andhra Pradesh

CEP 2022-191-P01
Procedure owner: AMEL

Strasbourg, 31 August 2023

Re: CEP 2022-191 / Sertraline hydrochloride

Dear Mr Siva Rama Prasad Manne,

Please find enclosed the certificate granted following the treatment of your dossier.

If you find a mistake on the CEP, you should notify the EDQM within 3 months. After this period, any complaint may no longer be accepted.

You are reminded that in accordance with Resolution AP-CSP (07) 1, and as mentioned on the certificate, the submitted dossier must be updated after any change to its content, and this must be reported to EDQM.

For any question regarding the application, please contact us using the following e-mail address: CEP@edqm.eu

Yours faithfully,

Certification of Substances Department

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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Certification of Substances Department

Certificate of suitability
No. R0-CEP 2022-191 - Rev 00

Name of the substance:
SERTRALINE HYDROCHLORIDE

Name of holder:
VERDANT LIFE SCIENCES PVT., LIMITED
Plot No. 55
Jawaharlal Nehru Pharma City (JNPC)
Parawada
India-531 019 Visakhapatnam, Andhra Pradesh

Site(s) of production:
SEE ANNEX 1

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **SERTRALINE HYDROCHLORIDE** no. 1705 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

– Test for residual solvents by gas chromatography (Annex 2)

Methanol	not more than 3000 ppm
Isopropanol	not more than 5000 ppm
Ethyl acetate	not more than 5000 ppm

In the last steps of the synthesis water is used as solvent.

The following elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of the substance: Nickel.

The substance is packed in double polyethylene bags (outer black), placed in a polyethylene drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: https://www.edqm.eu

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **31 August 2023**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has two annexes, the first of 1 page and the second of 3 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 31 August 2023

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

VERDANT LIFE SCIENCES PVT., LIMITED, as holder of the certificate of suitability

R0-CEP 2022-191 - Rev 00 for Sertraline hydrochloride

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

Certification of Substances Department

Annex 1: Site(s) of production for R0-CEP 2022-191 - Rev 00

Production of intermediate(s):

SRI GAYATHRI DRUGS PRIVATE LIMITED
Survey No: 497, Behind Newland Laboratories
Bonthapally (Village), Gummadidala Mandal
India-502 313 Sangareddy, Telangana State

KEVY'S ORGANICS PRIVATE LIMITED
Plot No. 82 & 83, Phase-I Industrial Park
Dachepally Mandal
India-522 414 Guntur, Andhra Pradesh

Production of Sertraline hydrochloride:

VERDANT LIFE SCIENCES PVT., LIMITED
Plot No. 55
Jawaharlal Nehru Pharma City (JNPC)
Parawada
India-531 019 Visakhapatnam, Andhra Pradesh

	Residual solvents by GC	**Chromatographic conditions:** Chromatographic system : Gas chromatograph equipped with Auto Injector or equivalent. Column : DB-624 or equivalent to USP G43 (6% cyanopropylphenyl-94% imethyl polysiloxane) Column dimensions : 30m X 0.53mm ID; 3µm film thickness Oven temperature : Maintain initially at 60°C for 5 minutes, then increased to 140° at the rate of 8°C hold for 0 minutes then increased to 200°C at the rate of 30°C per minute and maintain at 200°C for 13 minutes. Injector temperature : 200°C Detector temperature : 250°C Carrier gas : Nitrogen Flow : 4.0mL/min Linear velocity : 20 cm/Sec Split : 10: 1 Hydrogen : 40mL/min Air : 400mL/min

Oven temperature	Rate	Temperature	Hold time	Total time
		60°C	5	5
	8°	140°C	0	15
	30°	200°C	13	30

	Residual solvents by GC	**Head Space conditions:** **Preparation of Blank:** Take 5mL of Dimethyl sulphoxide (DMSO) into a head space sampler vial and immediately place the septum and crimp the vial. **Standard preparation**: Transfer 76µL of Methanol, 127µL of IPA and 111µL of Ethyl Acetate and to a 10mL volumetric flask containing 5mL of Dimethyl sulfoxide and make up to the volume with same diluent. Transfer 1.0mL of above solution into a 100mL volumetric flask containing 50mL of Dimethyl sulfoxide and make up to the volume with same diluent. Transfer 5mL of this solution into a 20mL Head space vial and crimp the vial. **Preparation of Sample Solution:** Transfer about 100mg of accurately weighed sample into 20mL Head Space vial, add 5mL Dimethyl sulfoxide and crimp the vial.

Variables	Value	Variables	Value
Constant heat time	Off	Sample Equil. Time	15.00 min
G.C. Cycle time	40.00 min	Mixture	On
Valve oven temp.	115°C	Mixing time	20.00 min
Transfer line temp.	115°C	Pressurize	10 PSIG
Standby flow rate	50 mL/min	Pressurize time	2.00 min
Platen/Sample temp.	100°C	Loop fill pressure	5 PSIG
Platen temperature equilibrium time	1.0 min.	Loop fill time	2.00 min
Pressure equilibrium time	0.5 min.	Inject time	1.00 min

S.No.	Test parameter	Method of analysis
10	Residual solvents by GC	**System suitability:** % RSD of six standard replicate injections for all solvents is not more than 15% and the resolution between methanol and IPA should be not less than 2.0. **Procedure:** Inject 1mL of DMSO as blank in to the System two times and record the chromatograms. Program the data processor to inhibit the Integration of peaks due to blank. Inject each 1mL of standard solution for six replicate injections and calculate the resolution and %RSD for each solvent area response. After passing the system suitability parameters, inject two replicate injections of test sample. **Calculation:** $\frac{\text{Area of solvent in sample X volume of STD solution in µl X solvent density X 1 X 5 X } 10^6}{\text{Area of solvent in std. X 10 X 100 X Wt. of sample in mg}}$ = ppm