

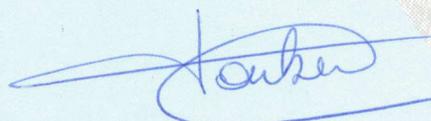
Certification of Substances Department

ATTESTATION OF REAL TIME REMOTE INSPECTION

Inspected site	DECCAN NUTRACEUTICALS PVT LTD (PART OF ALKALOIDS CORPORATION) Gat No. 1065, Golegaon Road Off Alandi Markal Road, Village Markal, Tal Khed India-412105 Pune , Maharashtra
Holder of the Certificate of Suitability	Alkaloids Corporation 8, Bentinck Street India-700 001 Kolkata
References of CEP dossier	CEP 2010-298 / Digoxin
Inspection dates	08/02/2021 to 12/02/2021
Scope of the inspection	Real time remote inspection carried out by EDQM. The inspection focused on the compliance with the information provided in the above-mentioned application for a certificate of suitability, as well as the implementation of a suitable Quality Management System based on the Good Manufacturing Practice as laid down in the EU Rules governing Medicinal Products in the European Union, Volume 4.
Conclusion	The company operates in accordance with the application submitted and the requirements of the Resolution AP-CSP (07) 1. This attestation is valid only in conjunction with a valid version of a CEP for the dossier mentioned above.

EDQM Inspection Reference number: INSP 2013-009 P02

Strasbourg, 4 June 2021



On behalf of the
Director of EDQM

