Landesamt für soziale Dienste Schleswig-Holstein

CERTIFICATE NUMBER: ***DE_SH_01_GMP_2017_0002***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with

The competent authority of confirms the following:
The manufacturer: ***Deccan Nutraceuticals PVT Ltd.***
Site address: ***Golegaon Road, Off Alandi Markal Road, Village Markal, Tal Khed Gat No. 1065, Pune, Maharashtra, 412105, India***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

Is an active substance manufacturer that has been inspected in accordance with Art. 111(1) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-06-24***, it is considered that it complies with:

- The principles of GMP for active substances [3] referred to in Article 47 of Directive 2001/83/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Clarifying remarks (for public users)

The inspection was performed by the EDQM in the framework of the CEP dossier for the manufacture of Digoxin. The inspection was accompanied by the German State Social Services Agency of Schleswig-Holstein. The holder of the Certificate of Suitability No. CEP 2010-298 is: Alkaloids Corporation 8, Bentinck Street 700 001 Calcutta India

2017-01-10

Name and signature of the authorised person of the Competent Authority of

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Confidential
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