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

Certificate of suitability
No. R0-CEP 2021-481 - Rev 00

Name of the substance:
AMIODARONE HYDROCHLORIDE

Name of holder:
HAINAN POLY PHARMACEUTICAL COMPANY LIMITED
Guilinyang Economic Development Area
Meilan District
China-571 127 Haikou, Hainan Province

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 **AMIODARONE HYDROCHLORIDE** no. 803 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis acetone and water are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph with a limit of not more than 0.5%.

A risk management summary for elemental impurities has been provided. (Annex 2)

The re-test period of the substance is 24 months if stored in two laminated film bags (polyethylene terephthalate/aluminium/polyethylene) placed in a fiber 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.

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.

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

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 **9 March 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 of 1 page each.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 9 March 2023

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

HAINAN POLY PHARMACEUTICAL COMPANY LIMITED, as holder of the certificate of suitability

R0-CEP 2021-481 - Rev 00 for Amiodarone 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*):

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

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Annex 1: Site(s) of production for R0-CEP 2021-481 - Rev 00

Production of Amiodarone hydrochloride:
HAINAN POLY PHARMACEUTICAL COMPANY LIMITED
Guilinyang Economic Development Area
Meilan District
China-571 127 Haikou, Hainan Province

Risk Management Summary of Elemental Impurities in Amiodarone hydrochloride

Intended route of administration / Use of the substance: Parenteral				
Element	**Class**	**Intentionally added?**	**Considered in risk management?**	**Conclusion**
Cd	1	No	Yes	Absent
Pb	1	No	Yes	Absent
As	1	No	Yes	Absent
Hg	1	No	Yes	Absent
Co	2A	No	Yes	Absent
V	2A	No	Yes	Absent
Ni	2A	No	Yes	Absent
Tl	2B	No	No	N/A
Au	2B	No	No	N/A
Pd	2B	No	No	N/A
Ir	2B	No	No	N/A
Os	2B	No	No	N/A
Rh	2B	No	No	N/A
Ru	2B	No	No	N/A
Se	2B	No	No	N/A
Ag	2B	No	No	N/A
Pt	2B	No	No	N/A
Li	3	No	No	Absent
Sb	3	No	Yes	Absent
Ba	3	No	No	N/A
Mo	3	No	Yes	Absent
Cu	3	No	Yes	Absent
Sn	3	No	No	N/A
Cr	3	No	Yes	Absent

Note: Absent means less than 30% of ICH Q3D option 1 limit.