

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-594

Chemistry Review(s)



NDA 21-594

**Amiodarone Hydrochloride Injection
50 mg/mL, 3 mL and 18 mL (prefilled syringe)
Original NDA dated October 31, 2002 with
Amendment dated December 2, 2003**

International Medication Systems, Ltd.

**JV Advani
Cardio-Renal Drug Products (HFD-110)**



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Establishment Evaluation Report



Chemistry Review Data Sheet

1. NDA 21-594
2. REVIEW #: 3
3. REVIEW DATE: 01/21/04
4. REVIEWER: JV Advani
5. PREVIOUS DOCUMENTS: None

Previous Documents

NDA 21-594
NDA 21-594 (N00)BL
NDA 21-594 N000 (BC)
NDA 21-594 N000(BC)
NDA 21-594 N000(BC)

Document Date

10/31/02
01/09/03
03/12/03
07/21/03
08/21/03

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

NDA 21-594 N000 (BF)

Document Date

12/02/03



CHEMISTRY REVIEW



Chemistry Review Data Sheet

7. NAME & ADDRESS OF APPLICANT:

Name: International Medication System, Ltd.
Address: 1886 Santa Anita Avenue
South EI Monte, CA 91733
Representative: Mr. Stephen A. Campbell
Vice President, Regulatory Affairs
Telephone: 626-459-5253

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: None
- b) Non-Proprietary Name (USAN and INN): Amiodarone hydrochloride Injection
- c) Code Name/# (ONDC only):
- d) Chem. Type/Submission Priority (ONDC only):
 - Chem. Type: 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: N/A

PHARMACOL. CATEGORY: It is a class III anti-arrhythmic drug but possesses electrophysiologic characteristics of all four Vaughan Williams classes. It is indicated for initiation of treatment and prophylaxis of frequently recurring ventricular and hemodynamically unstable ventricular tachycardia in patients refractory to other therapy.

11. DOSAGE FORM: Injection

12. STRENGTH/POTENCY: 50 mg/mL, 3 mL and 18 mL (Prefilled Syringe)

13. ROUTE OF ADMINISTRATION: Intravenous

14. Rx/OTC DISPENSED: ☒ Rx ☐ OTC

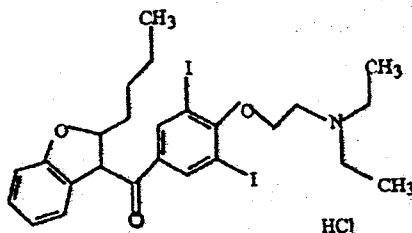
Chemistry Review Data Sheet

15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

____ SPOTS product – Form Completed

---X-----Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

*Structure of Amiodarone Hydrochloride**Structural Formula:***Molecular Formula:** $C_{25}H_{29}I_2NO_3 \cdot HCl$ **Molecular Weight:** 681.8 •**Chemical Name**

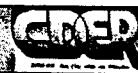
2-butyl-3-benofuranyl 4-(2-diethylaminoethoxy)-3,5-diiodophenylketone hydrochloride

(CAS) Registry Number

1 9774-82-4



CHEMISTRY REVIEW



Chemistry Review Data Sheet

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	COD E ¹	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
—	II	—	Drug Substance	3	Adequate	Updated review #7 dated 09/29/02 Dr. N. Samaan	
—	III	—		4	Adequate		
—	III	—	—	4	Adequate		
—	III	—	—	4	Adequate		

¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

* There is enough data in the application, there the DMF is not reviewed.

² Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION