

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**206439Orig1s000**

**CHEMISTRY REVIEW(S)**



## CHEMISTRY REVIEW



Chemistry Review Section

**NDA 206439**

**MDX-8704 (Memantine HCl ER/ donepezil HCl fixed  
dose combination capsules 28/10mg and 14/10mg)**

**Forest Laboratories Inc.**

**Pei-I Chu, Ph.D.**

**Office of New Drug Quality Assessment DPA1  
For Division of Neurology Products**

**Review of Chemistry, Manufacturing, and Controls**

## Chemistry Review Section

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# CHEMISTRY REVIEW



Chemistry Review Section

## Chemistry Review Data Sheet

1. NDA 206439
2. REVIEW # 1
3. REVIEW DATE: September 23, 2014
4. REVIEWER: Pei-I Chu, Ph.D.
5. PREVIOUS DOCUMENTS:

Previous Documents

Document Date

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) Reviewed

Document Date

Original

February 26, 2014

7. NAME & ADDRESS OF APPLICANT:

Name: Forest laboratories, Inc.  
Address: Harborside Financial Center, Plaza V,  
Suite 1900, Jersey City, USA, 07311  
Representative: Kathleen Waldron  
Telephone: 201-386-2115

8. DRUG PRODUCT NAME/CODE/TYPE: N/A

- a) Proprietary Name: Namzaric
- b) Non-Proprietary Name (USAN): MDX-8704 (memantine HCl extended release/donepezil HCl capsules)
- c) Code Name/# (ONDC only): N/A
- d) Chem. Type/Submission Priority (ONDC only):
  - Chem. Type: 1
  - Submission Priority:

## Chemistry Review Section

9. LEGAL BASIS FOR SUBMISSION: 505(b) (2)
10. PHARMACOL. CATEGORY: memantine: an orally active N-methyl-D-aspartate (NMDA) receptor antagonist, donepezil: an orally active reversible acetylcholinesterase inhibitor
11. DOSAGE FORM: Capsule
12. STRENGTH/POTENCY: 28mg memantine HCl ER/10mg donepezil HCl and 14mg memantine HCl ER/10mg donepezil HCl
13. ROUTE OF ADMINISTRATION: Oral
14. Rx/OTC DISPENSED:  Rx  OTC
15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

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

**Chemical Name: donepezil hydrochloride**

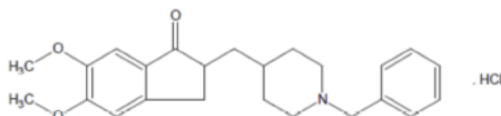
(±)-2,3-dihydro-5,6-dimethoxy-2-[[1-(phenylmethyl)-4-piperidinyl]methyl]-1H-inden-1-one hydrochloride

(±)-2-[(1-Benzyl-4-piperidyl)methyl]-5,6-dimethoxy-2,3-dihydroinden-1-one hydrochloride

*Molecular Formula:* C<sub>24</sub>H<sub>29</sub>NO<sub>3</sub>·HCl

*Molecular Weight:* 415.95 g/mol

Structural Formula



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