

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
200603

CHEMISTRY REVIEW(S)



NDA 200-603

**LATUDA (Lurasidone Hydrochloride) Tablets,
40 mg and 80 mg**

Sunovion Pharmaceuticals, Inc.

Division of Psychiatry Products, HFD 130

**Shastri Bhamidipati, Ph.D.
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment**

**Received Date: 30-DEC-2009
PDUFA Goal Date: 30-OCT-2010**

Table of Contents

Table of Contents	2
Chemistry Review Data Sheet.....	3
The Executive Summary	7
I. Recommendations	7
1. Recommendation and Conclusion on Approvability	7
B. Recommendation on Phase 4 (Post-Marketing) Commitments, Agreements, and/or Risk Management Steps, if Approvable.....	7
II. Summary of Chemistry Assessments.....	7
A. Description of the Drug Product(s) and Drug Substance(s).....	7
B. Description of How the Drug Product is Intended to be Used.....	9
C. Basis for Approvability or Not-Approval Recommendation.....	9
III. Administrative	9
A. Reviewer's Signature.....	9
B. Endorsement Block.....	9
C. CC Block.....	9
Chemistry Assessment	10
I. Review of Common Technical Document-Quality (Ctd-Q) Module 3.2: Body of Data	10
S DRUG SUBSTANCE [Lurasidone Hydrochloride,]	10
P DRUG PRODUCT [LURASIDONE TABLETS, 40, 80 & 120mg]	10
R REGIONAL INFORMATION	21
II. Review Of Common Technical Document-Quality (Ctd-Q) Module 1	21
A. Labeling & Package Insert.....	21
III. List Of Deficiencies To Be Communicated.....	22

Chemistry Review Data Sheet

Chemistry Review Data Sheet

1. NDA 200-603
2. REVIEW #: 2
3. REVIEW DATE:26-OCT-2010
4. REVIEWER: Shastri Bhamidipati, Ph.D.
5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
NDA 200-603 Original Submission	30-DEC-2009
NDA 200-603 Amendment (SD #6)	04-MAR-2010
NDA 200-603 Amendment (SD#17)	27-MAY-2010

6. SUBMISSION(S) BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
NDA 200-603 Amendment (SD#34)	17-SEPT-2010
NDA 200-603 Amendment (SD#37)	07-OCT-2010
NDA 200-603 Amendment (SD#40)	13-O8T-2010
NDA 200-603 Amendment (SD#43)	18-OCT-2010

7. NAME & ADDRESS OF APPLICANT:

Name:	Sunovion Pharmaceuticals Inc.
Address:	One Bridge Plaza, Suite 510 Fort Lee, NJ 07024
Representative:	Bridget Walton Director, Regulatory Affairs Sunovion Pharmaceuticals Inc.
Telephone:	(201) 228-8333

8. DRUG PRODUCT NAME/CODE/TYPE:



CHEMISTRY REVIEW



Chemistry Review Data Sheet

- a) Proprietary Name: LURASIDONE
- b) Non-Proprietary Name (USAN): Lurasidone Hydrochloride
- c) Code Name/# (ONDQA only): N/A
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: 1
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 21 CFR 314.50 , 505(b)(1)

10. PHARMACOL. CATEGORY: Psychiatry, Schizophrenia

11. DOSAGE FORM: Immediate Release Tablets

12. STRENGTH/POTENCY: 40 mg and 80 mg tablets

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 Names: (3*aR*,4*S*,7*R*,7*aS*)-2-{(1*R*,2*R*)-2-[4-(1,2-benzisothiazol-3-yl) piperazin-1-ylmethyl] cyclohexylmethyl}hexahydro-4,7-methano-2*H*isoindole-1,3-dione hydrochloride

Molecular Formula: C₂₈H₃₆ N₄O₂S. HCl

Molecular Weight: 492.68 Lurasidone free base
529.14 Lurasidone Hydrochloride salt

CAS: [367514-88-3]

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.