CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202107Orig1s000

CHEMISTRY REVIEW(S)

NDA 202-107

Korlym™ (Mifepristone) Tablets

Corcept Therapeutics

Xavier Ysern, PhD

ONDQA/ DNDQA III/ Branch VII

(Clinical Review Division: DMEP)

Table of Contents

Comment [Note1]:
All clinical reviews must contain the following sections organized as shown here Reviewers should feel free to organize subsections under these main headings as needed using standard outline conventions
To automatically have MSWord update the Table of Contents with the correct pagination, Click once anywhere in the Table of Contents (the Table of Contents should now be shaded) and then press either the F9 key or Alt+Shift+U

Chemistry Review Data Sheet

Chemistry Review Data Sheet

1. **NDA:** 202-107

2. **REVIEW #:** 2

3. **REVIEW DATE:** 17-Jan-2012

4. **REVIEWER:** Xavier Ysern

5. **PREVIOUS DOCUMENTS:**

Previous Documents	Document Date
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6. **SUBMISSION(S) BEING REVIEWED:**

Submission(s) Reviewed	Document Date
Original	15-Apr-2011
Amendment (Proprietary name)	19-Apr-2011
Amendment (Labeling/ Package Insert and Container-Carton)	25-Apr-2011

7. **NAME & ADDRESS OF APPLICANT**

Name: Corcept Therapeutics
Address: 149 Commonwealth Dr., Menlo Park, CA 94025
Representative: Luana Staiger
Telephone: 650 678 7230 (email: lstaiger@corcep.com)

8. **DRUG PRODUCT NAME/CODE/TYPE:**

a) Proprietary Name: Korlym™ (mifepristone) Tablets
b) Non-Proprietary Name (USAN): Mifepristone
c) Code Name/# --
d) Chem. Type/Submission Priority (ONDC only):
- Chem. Type: Type 5 – New Formulation
- Submission Priority:

(b) (4)

9. **LEGAL BASIS FOR SUBMISSION:** 505(b)(2)

10. **PHARMACOL. CATEGORY** Synthetic steroid, Progesterone receptor antagonist
[To reduce the effects of hypercortisolism in patients with endogenous Cushing's Syndrome.]

Comment [Note2]: Please Do Not Change the Order Only the items in bold will be in the template If there are categories that do not apply, these should not be deleted, but should be marked as "N/A" with an explanation as to why the review of the section is not applicable, if not obvious This Review Data Sheet is an integral part of the chemistry review and should always be part of the review documentation

Comment [Note3]: Add the review number for this review. All reviews for an A/NDA should be numbered sequentially even if the assigned reviewer is changed.

Comment [Note4]: The date when he review chemist completes the initial draft revie... [1]

Comment [Note5]: Name of review chemist. ... [2]

Comment [Note6]: This list should always include the original submission as well as a... [3]

Comment [Note7]: The type of submission should be indicated (specify whether it is ... [4]

Comment [Note8]: Include the exact address for the applicant. This may be an ... [5]

Comment [Note9]: a.Proprietary Name (If not appl... [6]

Comment [note10]: Type in the proprietary name(s) [a k a , trade name(s)] for the drug produc... [7]

Comment [note11]: Type in the Non-Proprietary name (i e , the USAN name) for the drug pro... [8]

Comment [note12]: For OGD only Type in the code name & Number for the drug product For... [9]

Comment [note13]: For ONDC use only Type in th... [10]

Comment [note14]: For ONDC use only Enter either S or P (for standard or priority) ... [11]

Comment [Note15]: The section should include: ... [12]

Comment [Note16]: Refer to FDA Form 356h or available references.

Chemistry Review Data Sheet

11. **DOSAGE FORM**: Tablet

12. **STRENGTH/POTENCY**: 300 mg

13. **ROUTE OF ADMINISTRATION**: Oral

14. **Rx/OTC DISPENSED**: Rx

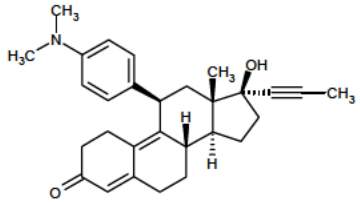
15. **SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM)** Not a SPOTS product

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

Mifepristone
Roussel Uclaf company name: RU486
Formula: $C_{29}H_{35}NO_7$

MW: 429.60 g/mol

CAS #: 84371-65-3



11β-[p-(Dimethylamino)phenyl]-17β-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one (IUPAC name)

17. **RELATED/SUPPORTING DOCUMENTS**

A. DMFs:

DMF #	Holder	Item Referenced	Code[1]	Status[2]	Review Completed	LOA da
(b) (4)			1	Adequate	29-Dec-2011	11-Mar-2
			4	Adequate		01-Mar-2
			4	Adequate		14-Feb-2
			4	Adequate		14-Mar-2
			4	Adequate		11-Mar-2
			4	Adequate		19-Mar-2
			1	Adequate	05-Jan-2012	03-Mar-2

[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")

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

Comment [Note17]: Refer to the CDER Data Standards Manual (General link for MAPP list: http://www.fda.gov/cder/mapp.htm), as needed or, for novel dosage forms, consult Nomenclature Standards Committee. For example, lyophilized powder for injection, tablets, or capsules.

Comment [Note18]: Strength should be defined clearly, (e.g., mg per ml, :g per tablet, or per dose). "Strength" is defined in 21 CFR §210.3(b)(16) as: : The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or The potency, that is, he therapeutic activity of the drug product as ... [13]

Comment [Note19]: Refer to the CDER Data Standards as needed, e.g., i.v., oral

Comment [Note20]:

Comment [Note21]: If applicable, fill out the form for special products and deliver to the team leader. The Spots Data Form can be retrieved by clicking or ... [14]

Comment [Note22]: Place the chemical structure on the first page, if possible, so as to maintain he sequence of items. If the structure is larger than a h ... [15]

Comment [Note23]: DMFs and Other Documents (e.g., INDs, NDAs, related drugs, texts and literature review ar icles which may aid the review of the NDA, bu ... [16]

Comment [note24]: 1 – DMF Reviewed. O her codes indicate why the DMF was not reviewed, as follows: 2 –Type 1 DMF 3 – Reviewed previously and ... [17]

Comment [note25]: Adequate, Inadequate, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

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