CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

209139Orig1s000

PRODUCT QUALITY REVIEW(S)

NDA 209139; Prexxartan (Valsartan) Oral Solution
ATL Review and Final Risk Assessment

Recommendation: Approval

Drug Name/Dosage Form	Prexxartan (Valsartan) Oral Solution
Strength	4 mg/mL
Route of Administration	Oral Solution
Rx/OTC Dispensed	Rx
Applicant	Carmel Biosciences Inc.

Submissions (s) Reviewed	NDA 209139, and all the submitted CMC amendments

Quality Review Team

DISCIPLINE	REVIEWER	BRANCH/DIVISION
Drug Substance and Drug Product	Mariappan Chelliah	ONDP/DNDPI/NDPBI
Process	Hang Guo	OPQ/OPF/DPAI/PABI
Facility	Christina Capacci-Daniel & Wenzheng Zhang	OPF/DIA/IABI
Biopharmaceutics	Yang Zhao	ONDP/DB/BBI
Microbiology	Denise Miller	OPQ/OPF/DMA/MABII
Regulatory Business Process Manager	Grafton Adams & Dahlia Woody	OPRO DRBPMI/RBPMBI
Environmental Assessment (EA)	Mariappan Chelliah	ONDP/DNDPI/NDPBI
Laboratory (OTR)	N/A	
Application Technical Lead	Mohan Sapru	ONDP/DNDPI/NDPBI

1. RELATED/SUPPORTING DOCUMENTS:

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
Type II DMFs	# (b) (4)	The DMFs were reviewed in the context of this NDA submission

2. CONSULTS: N/A

Executive Summary

I. Recommendations

A. Recommendation and Conclusion on Approvability

From the chemistry, manufacturing, and controls (CMC) perspective, NDA 209139 Prexxartan (Valsartan) Oral Solution is recommended for approval.

B. Recommendation on Post-Marketing Commitments (PMCs), Agreements, and/or Risk Management Steps, if Applicable

Not applicable.

II. Summary of Quality Assessments

Valsartan, a non-peptide, orally active, angiotensin II receptor blocker, has been primarily used in treatment of hypertension, congestive heart failure, or post-myocardial infarction. Oral liquid dosage forms are often required by patients, especially in the pediatric and geriatric populations who are unable, or experience difficulty, swallowing tablets. Currently, a liquid dosage form for Valsartan is prepared by compounding the tablets into a suspension. This involves a potential product quality risk since the product may not be made consistently from one pharmacist to another. The applicant, Carmel Biosciences, has sought U.S. marketing approval for Prexxartan (Valsartan) Oral Solution 4 mg/mL under the provisions of Section 505(b)(2) of the Federal Food and Cosmetic Act. This submission relies on a) the FDA's previous finding of safety and effectiveness for the listed drug Diovan® (Valsartan) Tablets (320 mg; previously approved under NDA 021283), and b) Comparative Bioavailability Study of 80 mL of Valsartan Oral Solution 4 mg/mL (a total of 320 mg) of Carmel Biosciences, and Diovan Tablets 320 mg (containing valsartan 320 mg) distributed by Novartis Pharmaceuticals.

A. Drug Substance (Valsartan, USP) Quality Summary

Valsartan, an off-white to white hygroscopic powder is a chiral compound with absolute (S) chirality. The CMC information for the drug substance, manufactured in (b) (4) is cross-referenced to Type II DMFs i.e., DMF# (b) (4) Both these DMFs have been reviewed and found adequate (please refer to DMF (b) (4) Quality Review #4, dated 7/5/2016 by F. C. Sequeira, and DMF# (b) (4) Quality Review #4, dated 10/02/2017 by M. Chelliah for details). Specifically, the drug substance batches used in the three primary stability batches of the drug product have been manufactured using (b) (4). However, for the commercial batches, the applicant has proposed to use drug substance batches manufactured (b) (4). The drug substance batches from both processes have comparable impurity profile. The specification provided by the applicant for testing the incoming API is based on the drug substance specification provided under

DMF# (b) (4). The stability data support a retesting period of (b) (4) for the drug substance. Based on the review of DMF# (b) (4), the CMC details concerning structural characterization, manufacturing process, and control strategies, including release specification, and stability for the Valsartan drug substance are adequate.

B. Drug Product (Prexxartan (Valsartan) Oral Solution) Quality Summary

Valsartan Oral Solution, 4 mg/mL is a liquid oral dosage intended for the treatment of hypertension, heart failure, and myocardial infarction. The inactive ingredients used for the formulation include poloxamer (NF), grape flavor (b) (4), sodium citrate dehydrate (USP), sucralose (NF), propylene glycol (USP), purified water (USP) (b) (4) potassium sorbate (NF), and methylparaben (NF). (b) (4) Except grape flavor, all the excipients are compendial grade. The CMC information for the grape flavor is provided under DMF (b) (4), which has been previously reviewed and found adequate. The maximum daily dose for Valsartan, USP is 320 mg/day (80 mL). All excipients used in Valsartan Oral Solution, 4 mg/mL fall within the IIG ranges, and hence are considered safe for use in this oral liquid dosage form. The proposed release specification for the drug product is acceptable. (b) (4) The batch data demonstrate that the drug product can be manufactured with consistent quality.

Manufacturing: Commercial manufacturing, processing, packaging, and labeling of Valsartan Oral Solution, 4 mg/mL will take place at (b) (4) facility. When required to package in unit doses, the packaged 16 oz bottled product will be shipped to a Contract Packager, who then packages the product in unit dose cups. The cGMP Certifications for the applicant (Carmel Biosciences, Inc.), drug product manufacturer (BioRamo, LLC), and unit dose packager (Unit Dose Solutions) have been provided. The overall manufacturing process is a straightforward process (b) (4)

Microbiological Aspects: The proposed formulation is a non-sterile liquid drug product that is administered orally. The applicant has provided adequate

information supporting the quality of the product from a microbiological perspective. Specifically, the USP <51> antimicrobial effectiveness testing (AET), involving two lots (b) (4) of the preservative concentration, respectively) are acceptable. The maintenance of the microbial quality over the shelf life of the product is supported by the antimicrobial preservative studies provided. The proposed product specifications regarding microbiological attributes is in compliance with USP <1111> for an oral drug product. Additionally, the specification includes the absence of B. cepacia, which is in line with current Agency expectations for an aqueous non-sterile product.

Control Strategies: Based on pharmaceutical development, the applicant first defined the quality target product profile (QTPP) based on the properties of the drug substance, characterization of the RLD product, and consideration of the RLD label and the intended patient population. Identification of critical quality attributes (CQAs) was based on the severity of harm to a patient (safety and efficacy) resulting from failure to meet that quality attribute of the drug product. For Valsartan Oral Solution, these primary CQAs included assay, degradation products, pH, and microbiological preservatives. Risk assessment was used throughout development to identify potentially high risk formulation and process variables in order to develop a control strategy based on applicant's improved product and process understanding throughout the development process. The product control strategies mainly consist of in-process controls, and release-, and stability testing. Product release specification involves testing the critical quality attributes of the product such as identification, API assay, impurity levels, pH (5.5-6.5; USP <791>), specific gravity (USP <841>), deliverable volume (USP <698>), assay of preservatives (b) (4) (based on USP <51> and 6 months stability results), and microbial enumeration testing (USP <1111>).

Container Closure System: Valsartan Oral Solution, 4 mg/mL is proposed to be packaged in 4 oz HDPE bottles, 16 oz HDPE bottles and 20 mL unit cups. The container/closure selected to package Valsartan Oral Solution, 4 mg/mL is designed to protect the product from moisture, light, and loss of drug product under ordinary conditions of handling, shipping, storage, and distribution. The protective characteristics of the container closure system include light resistance, moisture protection, and suitability for use, performance, and safety. The container closure system also serves to deliver requisite amount of the drug product. The containers meet the performance standard per USP <671>. Based on information provided, the commercial container closure system is adequate to protect the drug product during its proposed shelf-life. The revised carton label meets the labeling requirements.

Expiration Date & Storage Conditions: The proposed product shelf-life of 24 months, when stored in commercial container closure system at 20°C - 25°C (68°F - 77°F),with excursions permitted at 15° - 30°C (59° - 86°F) is adequately supported by 24-month real time stability data.

C. Assessment of Manufacturing Facilities: The office of Process and Facilities has recommended overall approval for all the currently listed manufacturing facilities concerning this NDA. Both facility and process risks have been deemed low and the initially identified process risk has been mitigated.

III. Summary of Drug Product and Intended Use

Proprietary Name of the Drug Product	Prexxartan™
Non Proprietary Name of the Drug Product	Valsartan Oral Solution, 4 mg/mL
Active ingredient	Valsartan, USP
Proposed Indication(s) including Intended Patient Population	Valsartan Oral Solution, 4 mg/mL is a liquid oral dosage intended for the treatment of hypertension, heart failure, or myocardial infarction.
Route of Administration	Oral
Maximum Daily Dose/ Duration of Treatment	(b) (4)
Alternative Methods of Administration	N/A

Indication	Starting Dose	Dose Range
Adult Hypertension		
Pediatric Hypertension (6-16yrs)		
Heart Failure (6-16 yrs)	40 mg twice daily	40-160 mg twice daily
Post-Myocardial Infarction	20 mg twice daily	20-160 mg twice daily

D. Biopharmaceutics Considerations

1. BCS Designation: The applicant did not request an official BCS designation. Valsartan is low solubility drug.

2. Biowaivers/Biostudies: A biowaiver is not requested nor required for this NDA. The proposed drug product is an oral solution

3. IVIVC: N/A.

E. Any Special Product Quality Labeling Recommendations: N/A

F. Life Cycle Knowledge Information

Final Risk Assessment is listed below.

Final Risk Assessment-

NDA 209139 - Prexxartan (Valsartan) Oral Solution

Attribute/ CQA	Factors Impacting CQAs	Initial Risk Ranking	Risk Mitigation Approach	Final Risk Evaluation	Lifecycle Considerations / Comments
Assay, Stability	• Formulation • Container closure • Raw materials • Process parameters • Scale/equipment/site	Low (L)	The product CQAs such as identification, assay, and impurity levels are controlled by in-process controls and appropriate release specification using validated analytical methods. Product stability for a period of 24 months at controlled room temperature conditions has been demonstrated	Acceptable	Any changes in drug product pH specification or levels of antimicrobial preservatives or container closure configurations may need to be closely evaluated

Attribute/ CQA	Factors Impacting CQAs	Initial Risk Ranking	Risk Mitigation Approach	Final Risk Evaluation	Lifecycle Considerations / Comments
Physical Stability (solid state)	• Formulation • Raw materials • Process parameters • Scale/ equipment/ site	Low (L)	Valsartan USP is a previously approved API, and based on API manufacturing process and control strategy, there are no concerns due to polymorphic conversion	Acceptable	N/A
Physical Stability (phase separation)	• Formulation • Raw materials • Process parameters • Scale/ equipment/ site	Low (L)	Valsartan USP is a previously approved API, and based on API and product manufacturing processes and control strategies, including release specification and stability data, there are no product quality concerns due to listed potential failure modes	Acceptable	Any proposed changes to formulation, manufacturing or the control strategies will need to be evaluated for possible impact on product CQAs
Dosing Accuracy	• Formulation • Dosing device • Process parameters • Scale/equip ment/site	Low (L)	The deliverable volume (multiple-unit containers, and single-unit container; USP <698>), and uniformity of dosage units are controlled by product release specification	Acceptable	N/A
Palatability	• Formulation • Excipient change • Process parameters Scale/equip ment/site	Moder -ate (M)	(b) (4) have been used to enhance palatability of the drug product	Acceptable	N/A
Leachables	• Formulation • Container closure • Process parameters Scale/equip ment/site	Moder -ate (M)	The containers meet the performance standard per USP <671>. The 16 oz. and unit dose container closure systems have acceptable extractable and leachable performance	Acceptable	N/A

Attribute/ CQA	Factors Impacting CQAs	Initial Risk Ranking	Risk Mitigation Approach	Final Risk Evaluation	Lifecycle Considerations / Comments
Microbial limits	• Formulation • Raw materials • Process parameters Scale/equipment/site	Low (L)	The proposed formulation is a non-sterile liquid drug product that is administered orally. The maintenance of the microbial quality over the shelf life of the product is supported by the antimicrobial preservative studies and product stability data	Acceptable	N/A

OVERALL ASSESSMENT AND SIGNATURES: EXECUTIVE SUMMARY

Application Technical Lead (ATL) Assessment and Signature:

From the chemistry, manufacturing, and controls (CMC) perspective, NDA 209139 Prexxartan (Valsartan) Oral Solution is recommended for approval.

Mohan Sapru, M.S., Ph.D.
Application Technical Lead (ATL)
CMC Lead for Cardiovascular and Renal Products (Acting)
ONDP/DNDPI/NDPBI

Mohan K. Sapru -S

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LABELING

R Regional Information

1.14 Labeling

Immediate Container Label

The latest container labels are provided in eCTD seq. 0012, dated 04-Aug-2017. The container label for 120 mL is shown below as a representative example for both 120 mL and 473 mL configurations.

Container label for 20 mL unit dose cups is shown below.

(b) (4)

[redacted]

Reviewer's Assessment: Adequate

During the review cycle, on the recommendation of the Agency, the Sponsor made the following revisions to the containers labels for the 120 mL and 473 mL configurations:

- Excipients were listed alphabetically.
- Storage condition was edited for clarity.

Additionally, for the 20 mL unit dose cup, the Sponsor replaced the following four lines that were present in the initial version of the container label:

(b) (4)

[redacted]

with:
'80 mg in 20 mL'

The revised container labels meet the labeling requirements.

Carton Labeling

Only the 120 mL configuration has carton, for which a revised labeling is provided under eCTD seq. 0016.

(b) (4)

Reviewer's Assessment: Adequate

The carton label meets the labeling requirements.

List of Deficiencies: None

Primary Reviewer: Mariappan Chelliah (see below for date)

Secondary Reviewer: Wendy Wilson-Lee (see below for date)

Mariappan Chelliah

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Wendy Wilson- Lee

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QUALITY ASSESSMENT

MICROBIOLOGY

Product Background: This is a liquid oral solution for the treatment of hypertension, heart failure, or myocardial infarction. The product has three proposed configurations, a 20 mL unit dose cup, a 120 mL bottle, and a 473 mL bottle.

NDA: 209-139/N000

Drug Product Name / Strength: Prexxartan (Valsartan Oral Solution, 4 mg/mL)

Route of Administration: Oral

Applicant Name: Carmel Biosciences, Inc.

Manufacturing Site: BioRamo, LLC Fort Lauderdale Florida

Method of Sterilization: NA, drug product is not sterile

Review Recommendation: Adequate

Review Summary: This is a non-sterile liquid drug product that is administered orally. The sponsor has provided adequate information supporting the quality of the product from a microbiological perspective. The maintenance of the microbial quality over the shelf life of the product is supported in the preservative studies provided. There were no deficiencies identified in the information provided.

List Submissions Being Reviewed:

Submit	Received	Review Request	Assigned to Reviewer
30 December 2016	30 December 2016	N/A	10 January 2017
06 April 2017	06 April 2017	N/A	NA
		N/A	
		N/A	

Highlight Key Outstanding Issues from Last Cycle: NA

Remarks: NA

Concise Description Outstanding Issues Remaining: NA

Supporting Documents: NA

List Number of Comparability Protocols (ANDA only): NA

S Drug Substance: NA

P.1 Description of the Composition of the Drug Product

- **Description of drug product –** This is a non-sterile oral solution. The product is a clear liquid with a grape odor. The product will be supplied in three configurations:
  - 20 mL unit dose cup
  - 120 mL fill in a 4 oz bottle
  - 473 mL fill in a 16 oz bottle

- **Drug product composition –** The composition is listed below in Table 1 (copied from Table 2 of submission section 3.2.P.1 Description of the Dosage Form):

Table 1: Composition of the Proposed Drug Product

Ingredient	Quality Standard	Function	% w/v	Weight (in kg) per 200 L
Valsartan[1]	USP	Active Ingredient	0.4	0.8
Potassium Sorbate	NF	(b) (4)		
Methylparaben	NF			
Grape Flavor (b) (4) (b) (4)	NA[2]			
Poloxamer (b) (4)	NF			
Sodium Citrate Dihydrate	USP			
Sucralose	NF			
Propylene Glycol	USP			
Purified Water	USP			
Total			100.00 %	(b) (4)

(b) (4)

- **Description of container closure system –** The oral solution will be packaged in 3 container sizes
  - 4 oz Boston round bottles with 24mm (b) (4) Closure with foam liner
  - 16 oz Rectangular White HDPE Bottle with 28/480 mm white closure with foam liner
  - Unit dose cups (small (b) (4) – 25 mL) with foil lid.

Reviewer's Assessment: ***Adequate***

P.2 Pharmaceutical Development

P.2.5 Microbiological Attributes

Antimicrobial Effectiveness Testing

Drug product to meet USP <51> Category III product requirements

Bacteria:

14 days: NLT (b) (4) log reduction from the initial calculated count

28 days: No increase from the 14 day count

Mold:

14 days: no increase from the initial calculated count

28 days: no increase from the initial calculated count

AET results were provided for two batches of drug product, the lowest level of preservative was (b) (4)% (acceptable lowest level is 84%). The provided AET study did not include a lot with the preservative at or below 84%; therefore does not support the effectiveness of the preservative below (b) (4)%.

Information request: USP <51> Antimicrobial Effectiveness Testing (AET) results for the three pilot batches is acknowledged. The lowest acceptable level for the preservative is 84%; however the lowest preservative level in the three pilot lots was (b) (4)%; therefore the AET information provided does not support the effectiveness of the preservative below (b) (4)%. Provide AET data for the formulation at or below the lowest acceptable preservative concentration. This may be a one-time study to demonstrate that the preservative is effective at or below the lowest acceptable preservative concentration.

Summary of Response: The requested AET bracketing study was provided in the response. During the formulation development, the AET was performed on two formulations, one with

100% and the other with 50% preservative (b) (4) The study was provided.

Review of Response: The study examined two lots, Lot RD090513-1 containing (b) (4) These levels are 100 and 50% of the preservative concentration (acceptable range (b) (4) %). The study followed USP <51> with one exception; the inoculation level for the yeast and mold were slightly under the 1.0 x 10^5 cfu/mL minimum inoculation requirement. *Candida albicans* ranged from (b) (4) mL and *Aspergillus niger* (b) (4) /mL. The other challenge organisms were within the required range between 1.0 x 10^5 and 1.0 x 10^6 cfu/mL. Based on the organism count of the growth suspension, the 0.2 uL inoculation volume in 20 mL of product should have resulted in a inoculation concentration of (b) (4) /mL; the actual count being just below the 1.0 x 10^5 cfu/mL limit was most likely due to microbial variation in the counting or due to the preservative reducing the initial count. This was not cited as a deficiency as the organism response to the preservative could still be assessed.

The acceptance criteria for a USP <51> Category III product is as follows:

Bacteria: NLT (b) (4) log reduction from the initial count at 14 days, and no increase from the 14 days' count at 28 days,

Yeast and Mold: No increase from the initial calculated count at 14 and 28 days

All organisms met the acceptance criteria. All the bacteria, yeast, and mold organisms demonstrated a reduction in counts that ranged from (b) (4) logs at the 14 day time-point.

Reviewer's Assessment: ***Adequate.*** The AET studies support the effectiveness of the preservative in the formulation within the proposed acceptable range of (b) (4) as well as the effectiveness of the formulation containing 50% of the labeled preservative content. The effectiveness of the preservative over the shelf life of the product is addressed in the stability program.

P.5 Control of Drug Product

P. 5.1 Specification

The proposed specifications are as follows:

Total Aerobic Microbial Count: NMT (b) (4)

Total Yeast and Mold Count: NMT (b) (4)

Absence of *Escherichia coli* and *Burkholderia cepacia*

Reviewer's Assessment: ***Adequate.*** The proposed specifications are within recommendations of USP <1111> for an oral drug product. Additionally, the specifications include the absence of *B. cepacia* which is in line with current Agency expectations for an aqueous non-sterile product.

P.5.2 Analytical Procedures

The TAMC, TYMC and the Absence of Specified Organisms are tested following USP <61> and <62>.

Reviewer's Assessment: ***Adequate.***

P.5.3 Validation of Analytical Procedures

Microbial Limits (USP <61> and <62>)

The method suitability of the microbial limits testing was not provided and was requested.

Information Request:

The method suitability for the microbial quality tests were not found in the submission. Provide a summary of the method suitability studies per USP <61> and <62>.

Summary of Response: The sponsor provided the requested method suitability report.

Review of Response: Data was provided for the verification of the inoculum recovery and the enumeration testing for all the USP indicator organisms for three lots of product. The method suitability report provided supports the ability of the method to detect micro-organisms in the presence for the product when tested following USP <61> and <62>.

Reviewer's Assessment: ***Adequate.*** The method suitability was performed per USP <61> and <62> and supports the routine release testing for microbial quality.

P.8 Stability

Proposed shelf life is 24 month at room temperature.

P. 8.1 Stability Summary and Conclusion

Three lots were placed on stability, Lot R&D Oct13-2, Lot R&D Dec 13-1 and Lot R&D Dec 13-2. Each lot included the three packaging configurations, a unit dose packaging, a 4 oz bottle, and a 16 oz bottle.

Long Term Storage: 25 ± 2°C/40 ± 5% RH for 24 months
Testing for AET at initial and at 24 months
Testing for Microbial Limits at initial, 12 months, and 24 months

Intermediate Storage: 30 ± 2°C/65 ± 5% RH for 12 months
Testing for AET at 12 months

Accelerated Storage: 40± 2°C/NMT 25% RH for 6 months
Testing for AET at 6 months
Testing for Microbial Limits at initial and 6 months

Note: The absence of *B. cepacia* was included in the microbial limits testing.

Reviewer's Assessment: ***Adequate***

P. 8.2 Post-Approval Stability Protocol and Stability Commitment

The on-going stability study on the exhibit batches will be continued. Post approval, the first three commercial batches will be added to the stability program under the long term storage conditions. Thereafter, a minimum of one lot per year will be added if manufactured and placed on long term stability. Results will be reported in the annual reports. Any failing results will undergo a detailed investigation and failure to meet the established specifications will be reported to the Agency.

Reviewer's Assessment: ***Adequate***

P.8.3 Stability Data

Accelerated: Stability testing completed through the 12 month protocol for all three lots/packaging configuration. All testing for microbial quality meet the acceptance criteria.

Intermediate: Stability testing completed through the 12 month protocol for all three lots/packaging configuration. All testing for microbial quality meet the acceptance criteria.

Long term: Stability testing completed through the 24 month protocol for all three lots/packaging configuration. All testing for microbial quality meet the acceptance criteria.

Reviewer's Assessment: ***Adequate***.

A Appendices: NA

R Regional Information

Executed Batch Records

Executed batch records were submitted for the three exhibit lots, Lot# R&D Oct13-2, Lot# R&D Dec13-1 and Lot #R&D Dec 13-2.

Reviewer's Assessment: ***Adequate***

Comparability Protocols: NA

Reviewer's Assessment: NA

2. REVIEW OF COMMON TECHNICAL DOCUMENT – QUALITY (CTD-Q) MODULE 1

2.A. Package Insert: NA

Reviewer's Assessment: ***Adequate***. There are no quality microbiology concerns to address in the package insert.

Post-Approval Commitments: NA

List of Deficiencies: None

Primary Microbiology Reviewer Name and Date: Denise A. Miller, 05 June 2017

Secondary Reviewer Name and Date: Neal J. Sweeney, Ph.D. 22 June 2017

Neal Sweeney

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