CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

218772Orig1s000

PRODUCT QUALITY REVIEW(S)

NDA Executive Summary

1. Application/Product Information

NDA Number.	218772 Resubmission		
Applicant Name	Scienture, Inc.		
Drug Product Name	(b) (4) (losartan potassium)		
Dosage Form.	Suspension		
Proposed Strength(s)	10 mg/mL		
Route of Administration	Oral		
Maximum Daily Dose	100 mg		
Rx/OTC Dispensed	Rx		
Proposed Indication	• Treatment of hypertension, to lower blood pressure in adults and children greater than 6 years old. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy. There is evidence that this benefit does not apply to Black patients. • Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension.		
Drug Product Description	A white, translucent suspension with a peppermint odor supplied as 165 mL in a 6 ounce HDPE bottle with seal and child-resistant plastic cap.		
Co-packaged product information	N/A; no dosing device or other device component is co-packaged with or co-labeled for use with the drug product.		
Device information:	N/A		
Storage Temperature/ Conditions	20 °C to 25°C		
Review Team	**Discipline**	**Primary**	**Secondary**

	Drug Substance	See previous IQA dated August 8, 2025	See previous IQA dated August 8, 2025
	Drug Product/ Labeling	Ali Mohamadi	Theodore Carver
	Manufacturing	Upasana Sahu	Sateesh Kumar Sathigari
	Biopharmaceutics	N/A	
	Microbiology	See previous IQA dated August 8, 2025	
	Other (specify):	N/A	
	RBPM	Grafton Adams	
	ATL	Theodore Carver	
Consults	N/A		

2. Final Overall Recommendation - Approval

3. Action Letter Information

a. Expiration Dating:

A shelf life of 18 months is granted for the drug product when stored at 20°C to 25°C**.**

b. Additional Comments for Action None.

4. Basis for Recommendation:

a. Summary of Rationale for Recommendation:

1) Background

The Applicant, Scienture, Inc., has submitted New Drug Application (NDA) 218772 for marketing approval of Losartan Potassium Oral Suspension,

10 mg/mL, according to Section 505(b)(2) of the Federal, Food, Drug, and Cosmetic Act. NDA 218772 makes reference to the Listed Drug COZAAR® (losartan potassium) tablets, 100 mg, for which the applicant is Organon, LLC and which was approved under NDA 20386. This NDA seeks the same indications, doses, and dosing regimen as the RLD. A Complete Response was issued by FDA for this NDA on August 19, 2024 due to product quality deficiencies identified for the assays and stability studies submitted in the original NDA. The resubmitted NDA was reviewed by drug product and manufacturing review teams.

2) Review of response to product quality deficiencies.

The drug product is a white, translucent suspension with a peppermint odor that is filled into 6 oz. (b) (4) white high-density polyethylene (HDPE) bottles and packaged in cartons. (b) (4) . The original NDA review identified deficiencies in the information provided for the particle size and content assay methods and inadequate investigations of OOS and OOT results during stability studies, including a failure to adequately follow up on results of investigations documented in reports. The Applicant provided additional information in the resubmission that was deemed adequate to address the product quality deficiencies. In addition, the method for measuring particle size was verified by FDA. See drug product and manufacturing reviews and lifecycle comments below. The NDA remains adequate with respect to all other OPQ review disciplines.

3) Quality Labeling

The quality aspects of the product labeling were reviewed and found to be adequate after comments were communicated to the Applicant.

b. Is the overall recommendation in agreement with the individual discipline recommendations? Yes

Recommendation by Subdiscipline:

Drug Substance	**-**	**Adequate**
Drug Product	**-**	**Adequate**
Quality Labeling	**-**	**Adequate**
Manufacturing	**-**	**Adequate**
Biopharmaceutics	**-**	**N/A**
Microbiology	**-**	**Adequate**

Environmental Assessment: Categorical Exclusion - Adequate

QPA for EA(s): No

5. Life-Cycle Considerations

Established Conditions per ICH Q12: No
Comments: None

Comparability Protocols (PACMP): No
Comments: None.

Additional Lifecycle Comments:

Deficiencies identified in the review of the original NDA included failures to report changes to test methods and inadequate followup of results of investigations of out-of specification and and out-of trend results. We recommend a lifecycle approach to verifying testing methods validation and data reporting and a review of their change control practices at the next surveillance inspection for the drug product manufacturing facility, (b) (4)

Theodore Carver

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CHAPTER IV: LABELING

NDA Number	218772
Assessment Cycle Number	2
Drug Product Name	ARBLI (losartan potassium) oral suspension, for oral use

Assessment Recommendation: Adequate

Item	Assessment Conclusion	SDN # where labeling is adequate ("N/A" otherwise)
Prescribing Information Labeling	Adequate	**0027**
Instruction for Use (IFU)	N/A	
Container Labels	Adequate	**0027**
Carton Labeling	Adequate	**0027**

Brief Description of Outstanding Issues:

Submissions being reviewed:

Document Reviewed (eCTD #, SDN #)	Date Received	Information Provided
0027	10/01/2024	CC labels
0027	10/01/2024	PI label

1.0 PRESCRIBING INFORMATION[1]

Assessment of Product Quality Related Aspects of the Prescribing Information:

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Product Title in Highlights[2] [21 CFR 201.57(a)(2)]		

[1] Labeling Review Tool (LRT) (March 2022), including use of consistent terminology for dosage form and unit of measure for strength in the product title and DOSAGE FORMS AND STRENGTHS heading in Highlights, in the DOSAGE AND ADMINISTRATION, DOSAGE FORMS AND STRENGTHS, DESCRIPTION, and HOW SUPPLIED/STORAGE AND HANDLING sections (see page 2 of LRT)

[2] Draft guidance: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format* (January 2018)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Established name(s)[3]	Adequate	**Adequate per revision below:** **Revision: ARBLI (losartan potassium) oral suspension** Original: [redacted]
Route(s) of administration	Adequate	oral use
Controlled drug substance symbol (if applicable)	N/A	
Initial U.S. Approval [§201.57(a)(3)]	Adequate	Initial U.S. Approval: 1995
Dosage Forms and Strengths Heading in Highlights [§ 201.57(a)(8)]		
Dosage form(s)[4] and strength(s) in metric system[5]	Adequate	Oral Suspension: 10 mg/mL.
If the drug product contains an active ingredient that is a salt, clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (e.g., Tablets: 10 mg of drug-x hydrochloride).[6]	Adequate	The name and strength are expressed in terms of the salt for, "losartan potassium". This application is an exception to the Salt Policy because the proposed drug product is intended to be administered in the identical dose for the same indication as all other approved losartan products, therefore the name and strength should be consistent with other approved products to reduce the risk of medication errors. The previously approved products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."[7]	N/A	

[3] Established name = [Drug] [Route of Administration] [Dosage Form]. Do use not "USP" descriptor in the product title or within the Highlights (see page 3 of LRT).
[4] Draft guidance: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format* (January 2018); USP <1151>; USP Nomenclature Guideline
[5] Labeling Review Tool (March 2022, page 13), include limited packaging information; USP <7>
[6] Guidance: *Naming of Drug Products Containing Salt Drug Substances* (June 2015); MAPP 5021.1
[7] Guidance: *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation* (March 2013)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.[8]	N/A	

Assessment: *Adequate*

1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)[9]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents and/or soft food[10], storage conditions needed to maintain the stability of the reconstituted or diluted product).	N/A	In the section 16 of PI, the Applicant added: "Shake for 20 seconds prior to each use"
Important administration instructions supported by product quality information (e.g., do not crush or chew extended-release tablets, instructions for mixing with food).	N/A	

[8] Guidance: *Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use* (October 2018); USP <659>

[9] See § 201.57(c)(3); draft guidance: *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* (January 2023); Labeling Review Tool (March 2022, page 25)

[10] Draft Guidance: Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
For parenteral products: include statement: *"Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."*[11]	N/A	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.[12] Note the labeling requirement may be applicable to another section of the PI (e.g., Section 11).	N/A	This product is a new dosage form of losartan potassium, oral suspension, and it doesn't have a USP monograph.
For radioactive products, include radiation dosimetry for the patient and healthcare practitioner(s) who administer the drug	N/A	
For hazardous products, include the statement *"DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.*[x]*"* with x numerical citation to "OSHA Hazardous Drugs."	N/A	

Assessment: *Adequate*

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)[13]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	Adequate	Oral suspension
Strength(s) in metric system	Adequate	10 mg/mL

[11] §201.57(c)(3)(iv)
[12] USP General Notices 2.30 Legal Recognition
[13] See § 201.57(c)(4); Labeling Review Tool (March 2022, page 29)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance. Clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (e.g., Tablets: 10 mg of drug-x hydrochloride). No equivalency statement.	N/A	The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because the proposed drug product is intended to be administered in the identical dose for the same indication as all other approved losartan products, and therefore the name and strength should be consistent with the other approved products to reduce the risk of medication errors. The previously approved products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable.	Adequate	white, translucent suspension with a peppermint odor
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."	N/A	
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package type terms include pharmacy bulk package and imaging bulk package (see USP <659>).	N/A	

Assessment: *Adequate*

1.2.3 Section 11 (DESCRIPTION)[14]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DESCRIPTION section		
Proprietary and established name(s)[15] [§ 201.57(c)(12)(i)(A)].	Adequate	Losartan potassium
Dosage form(s) and route(s) of administration [§ 201.57(c)(12)(i)(B)].	Adequate	oral suspension
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per Salt Guidance and MAPP. For example: "TRADENAME contains 100 mg of drug-x (equivalent to 123.7 mg of drug-x hydrochloride)" [§ 201.57(c)(12)(i)(C)].	N/A	**Adequate per adding the equivalency statement below:** **Each mL contains 10 mg losartan potassium (equivalent to 9.2 mg losartan)**
List inactive ingredients (not required for oral use, except for colorant) by the USP/NF names in alphabetical order.[16] Avoid brand names. [§ 201.57(c)(12)(i)(C)].	Adequate	**Adequate per revision below** **Revision: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum.** (b) (4) [redacted]

[14] See § 201.57(c)(12); Labeling Review Tool (March 2022, page 56)

[15] Use of "USP" descriptor is not required to be included next to the established name throughout Prescribing Information (PI) labeling. If an applicant wants to use the "USP" descriptor next to the established name in the PI, recommend limiting its use to the product quality sections of the Full Prescribing Information (FPI) (i.e., DOSAGE FORMS AND STRENGTHS, DESCRIPTION, HOW SUPPLIED/STORAGE AND HANDLING) (see page 3 of LRT).

[16] Per § 201.100(b)(5)(i) and (ii), flavoring and colorants may be designated as such without naming their components except for FD&C Yellow No 5 and FD&C Yellow No 6, which must be listed per § 201.20. Per § 201.100(b)(5)(iii), trace amounts of harmless substances added solely for individual product identification need not be named. If an applicant wants to use the National Formulary (NF) descriptor next to excipients, recommend limiting its use to the product quality sections of the FPI (see page 3 of LRT). Do not list brand names, e.g., Opadry, Eudragit, Polistirex, etc.

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
		(b) (4) [redacted]
For parenteral injectable dosage forms, include the name and quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect. [§ 201.100(b)(5)(iii)].	N/A	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol at 60 °F. (15.56 °C) [§ 201.10(d)(2)].	N/A	
Sterility statement (if applicable) [§ 201.57(c)(12)(i)(D)].	N/A	
Pharmacological/Therapeutic class[17] [§ 201.57(c)(12)(i)(E)].	Adequate	angiotensin II receptor blocker
Chemical name[18], structural formula, molecular weight [§ 201.57(c)(12)(i)(F)].	Adequate	2-butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol monopotassium salt.
If radioactive, statement of important nuclear characteristics [§ 201.57(c)(12)(i)(G)].	N/A	
Other important chemical or physical properties (such as pKa or pH) [201.57(c)(12)(ii)].	N/A	
For oral prescription drug products, include gluten statement[19] (if applicable).	N/A	

[17] Listed before "indicated for" in INDICATIONS AND USAGE of Highlights section [§ 201.57(a)(6)]; can also search the term "FDA EPC Text Phrases" in FDA's Labeling Resources for Human Prescription Drugs for the most recent EPC list.

[18] Chemical names do not need to be capitalized unless it appears at the beginning of a sentence (see *Preferred IUPAC Names Provisional Recommendation*, September 2004; Chapter 1, par. 16 Name writing, p.80-90).

[19] Draft guidance: *Gluten in Drug Products and Associated Labeling Recommendations* (December 2017)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity").	N/A	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled. Note the labeling requirement may be applicable to another section of the PI (e.g., Section 2).	N/A	

Assessment: *Adequate*

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)[20]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s) [§ 201.57(c)(17)].	Adequate	oral suspension
Strength(s) in metric system. [§ 201.57(c)(17)(i)] If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance. Clearly state whether the strength is based on the active moiety. No equivalency statement.	Adequate	**Adequate per adding the equivalency statement below:** **Each mL contains 10 mg losartan potassium (equivalent to 9.2 mg losartan)**
Available units (e.g., bottles of 100 tablets) [§ 201.57(c)(17)(ii)].	Adequate	Adequate per DMEPA revision below: It is supplied as 165 mL high-density polyethylene (HDPE) bottle with a

[20] See § 201.57(c)(17); Labeling Review Tool (March 2022, page 70). Consider including proprietary name and established name.

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
		child-resistant cap and tamper-evident seal
Identification of dosage forms (e.g., shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable); Include NDC(s) [§ 201.57(c)(17)(iii)].	Adequate	white, translucent oral suspension
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."	N/A	
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package (see USP <659>).	N/A	
Special handling about the supplied product (e.g., protect from light, refrigerate). If there is a statement to "Dispense in original container," provide reason why (e.g., to protect from light or moisture, to maintain stability, etc.). For hazardous drugs, state "DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.[x]" with x numerical citation to "OSHA Hazardous Drugs." [§ 201.57(c)(17)(iv)]	Adequate	**Adequate per revision below:** **Once the bottle is opened, use it within 60 days.**
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature. (see USP <659>).	Adequate	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]. Keep container tightly closed. Protect from light.

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Latex: If product does not contain latex and manufacturing of product and container did not include use of natural rubber latex or synthetic derivatives of natural rubber latex, state: *"Not made with natural rubber latex. Avoid statements such as "latex-free."*[21]	N/A	
Include information about child-resistant packaging[22] (if chosen by manufacturer).	Adequate	high-density polyethylene (HDPE) bottle with a child-resistant cap and tamper-evident seal

Assessment: *Adequate*

1.2.5 Other Sections of Labeling

1.2.6 Manufacturing Information After Section 17 (for drug products)[23]

Item	Item in Proposed Labeling (choose "Adequate" or "Inadequate")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Manufacturing Information After Section 17		
Name and location of business (street address, city, state, and zip code) of the manufacturer, distributor, and/or packer.	Choose an item.	Adequate per revision below: Manufactured for: Scienture LLC Commack, NY 11725 Distributed by: Scienture LLC Commack, NY 11725

Assessment: *Adequate*

[21] Guidance: *Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex* (December 2014)
[22] Guidance: *Child-Resistant Packaging Statements in Drug Product Labeling* (August 2019)
[23] § 201.1(h)(5) and 201.1(i); Labeling Review Tool (March 2022, page 74)

2.0 PATIENT LABELING

None

3.0 CONTAINER AND CARTON LABELING[24]

3.1 Container Labels[25]

(b) (4)

[redacted]

3.2 Carton Labeling

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[24] Carton and Container Labeling Resources

[25] Per § 201.10(h)(2)(i)(1), if the drug container is too small to bear all labeling information required by section 502(e)(1)(A)(ii) and (B) of the FD&C Act, the container label should bear: proprietary name, established name, lot number, the name of the manufacturer, packer, or distributor of the drug.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
Proprietary name and established name[26], (font size and prominence) [§ 201.10(g)(2)].	Adequate	Yes	Arbli (losartan potassium) oral suspension
Strength(s) in metric system [§ 201.100(b)(4) & 201.100(d)].[27]	Adequate	Yes	10 mg/mL
Route(s) of administration, not required for oral use [§ 201.100(b)(3)].	Adequate	Yes	Oral suspension
If the active ingredient is a salt, include the equivalency statement per Salt Guidance and MAPP [§ 201.10(d)(1) & 201.100(b)(4), USP <1121>].	N/A	Choose an item.	**Adequate per adding the equivalency statement below:** **Each mL contains 10 mg losartan potassium (equivalent to 9.2 mg losartan)**
Net contents (e.g., tablet count, volume of liquid) [§ 201.51(a)].[28]	Adequate	Yes	165 mL
"Rx only" displayed on the principal display [§ 201.100(b)(1)].	Adequate	Yes	
NDC (requested, but not required for all labels or labeling) [§ 201.2 & 207.35].	Adequate	Yes	
Lot number and expiration date [§ 201.18 & 201.17].	Adequate	Yes	

[26] Established name = [Drug] [Route of Administration] [Dosage Form]

[27] Express as " XX mg per tablet" or "XX mg per capsule" for strength of professional samples of solid oral dosage form with small net quantities per container (e.g., 5 or less) or blister pack/carton. See Guidance: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)

[28] § 201.51(h): A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled "sample", "physician's sample", or a substantially similar statement and the contents of the package do not exceed 8 grams.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
Storage conditions. If applicable, include a space on the carton labeling for the user to write the beyond-use-date (BUD).	Adequate	Yes	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package, and these products require a "Not for direct infusion" statement. (See USP <659>).	N/A	Choose an item.	
Name of all inactive ingredients, in alphabetical order [§ 201.10(a)] [except for oral drug per § 201.100(b)(5) or limited space per § 201.10(i)(2)].	Adequate	Yes	**Adequate per adding the inactive ingredients below:** **Revision: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum** (b) (4) [redacted]

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
			(b) (4) [redacted]
For parenteral injectable dosage forms, include quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect. [§ 201.100(b)(5)(iii)].	N/A	Choose an item.	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol at 60 °F. (15.56 °C) [§ 201.10(d)(2)].	N/A	Choose an item.	
Linear Bar code [§ 201.25(c)(2)].[29]	Adequate	Yes	
Adequate directions for use: "Recommended Dosage: See Prescribing Information" [§ 201.5 & 201.55].	Adequate	Yes	
Name of manufacturer/distributor /packer [§ 201.1(a), 201.1(h)(5)].	Adequate	Yes	
"Keep out of reach of children" statement, optional for Rx, required for OTC [§ 201.66(c)(5)(x)].	Adequate	Yes	
If there is a Medication Guide, must include a statement about dispensing a Medication Guide to each patient.	N/A	No	(b) (4) [redacted] (b) (4) [redacted]

[29] See § 201.25(b)(1)(i) for a list where bar code is not required, e.g., prescription drug samples, medical gases, radiopharmaceuticals, etc.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
No text on Ferrule and Cap overseal of a vial of injectable products unless a cautionary statement is required. (USP <7>).	N/A	Choose an item.	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.	N/A	Choose an item.	
When a drug product differs from the relevant USP standard of strength, quality, or purity, as determined by the application of the tests, procedures, and acceptance criteria set forth in the relevant compendium, its difference shall be plainly stated on its label.[30]	N/A	Choose an item.	
And others if space is available.	N/A	Choose an item.	

Assessment of Carton Labels and Container Labeling: *Adequate*

Adequate per revision below:

- **Once the bottle is opened, use it within 60 days.**
- **Each mL contains 10 mg losartan potassium (equivalent to 9.2 mg losartan)**
- **Correct order of inactive ingredients: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum**

[30] USP General Notices 3.20 Indicating Conformance

4. OUTSTANDING ISSUES AND RECOMMENDATIONS

None

Primary Labeling Assessor Name and Date:

Ali Mohamadi, Ph.D.; 2/10/2025

Secondary Assessor Name and Date (and Secondary Summary, as needed):

Ali Mohamadi

Digitally signed by Ali Mohamadi
Date: 2/10/2025 03:56:33PM
GUID: 508da6ea0002750ec7c6cb7cfc37f10e

Theodore Carver

Digitally signed by Theodore Carver
Date: 2/11/2025 09:12:52AM
GUID: 5d963967007fd4bc3c9fab2a6c3eaded

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THEODORE E CARVER
03/07/2025 02:17:06 PM

NDA Executive Summary

1. Application/Product Information

NDA Number.	218772		
Applicant Name	Scienture, Inc.		
Drug Product Name	(b) (4) (losartan potassium)		
Dosage Form.	Suspension		
Proposed Strength(s)	10 mg/mL		
Route of Administration	Oral		
Maximum Daily Dose	100 mg		
Rx/OTC Dispensed	Rx		
Proposed Indication	• Treatment of hypertension, to lower blood pressure in adults and children greater than 6 years old. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • Reduction of the risk of stroke in patients with hypertension and left ventricular hypertrophy. There is evidence that this benefit does not apply to Black patients. • Treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of hypertension.		
Drug Product Description	A white, translucent suspension with a peppermint odor supplied as 165 mL in a 6 ounce HDPE bottle with seal and child-resistant plastic cap.		
Co-packaged product information	N/A; no dosing device or other component is co-packaged with the drug product.		
Device information:	N/A		
Storage Temperature/ Conditions	20 °C to 25°C		
Review Team	**Discipline**	**Primary**	**Secondary**
	Drug Substance	Ben Zhang	Zhengfu Wang

	Drug Product/ Labeling	Ali Mohamadi	Theodore Carver
	Manufacturing	Upasana Sahu	Sateesh Kumar Sathigari
	Biopharmaceutics	N/A; see comments in Section 4 of this review.	
	Microbiology	Jianli Xue	Nandini Bhattacharya
	Other (specify):	N/A	
	RBPM	Grafton Adams	
	ATL	Theodore Carver	
Consults	N/A		

2. Final Overall Recommendation - Complete Response

3. Deficiencies

1. Your descriptions [redacted] (b) (4) are deficient with respect to information needed to provide assurance of the quality of the drug product. Specifically, we noted the following deficiencies:

[redacted] (b) (4)

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[redacted]

(b) (4)

4. Basis for Recommendation:

a. Summary of Rationale for Recommendation:

1) Background

The Applicant, Scienture, Inc., has submitted New Drug Application (NDA) 218772 for marketing approval of Losartan Potassium Oral Suspension, 10 mg/mL, according to Section 505(b)(2) of the Federal, Food, Drug, and Cosmetic Act. The NDA makes reference to the Listed Drug COZAAR® (losartan potassium) tablets, 100 mg, for which the applicant is Organon, LLC and which was approved under NDA 20386. This NDA seeks the same indications, doses, and dosing regimen as the RLD. See the proposed indications listed in the table above. Since the drug product is an oral suspension, all disciplines were initially assigned to review this NDA; however, during the review cycle it was determined that, since the

[redacted] (b) (4)

2) Drug Substance

Losartan Potassium is a [redacted] (b) (4) small molecule with no chiral centers. All chemistry, manufacturing, and controls (CMC) information is referenced to drug master file (DMF) [redacted] (b) (4) This DMF has been reviewed and found adequate to support the NDA. Refer to the review of DMF [redacted] (b) (4) for more information. The specifications for the drug substance included in the NDA were found to be adequate to support the quality of the drug substance. A retest date of [redacted] (b) (4) was assigned to the drug substance when stored at [redacted] (b) (4) in [redacted] (b) (4)

3) Drug Product

The drug product is a white, translucent suspension with a peppermint odor that is filled into 6 oz. [redacted] (b) (4) white high-density polyethylene (HDPE) bottles and packaged in cartons. The drug product bottle was originally proposed to be co-packaged with a dosing cup, however, in the current product configuration, this cup has been removed, because pediatric dosing will require use of an oral syringe. The Applicant provided information to support compatibility of the oral suspension with commercially marketed dosing cups and oral syringes that are representative of dosing device that are to be provided to patients by a pharmacist.

[redacted] (b) (4)

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[redacted]

(b) (4)

[redacted]

Facilities – The manufacturing facilities were all recommended for approval based on previous inspection history.

5) Biopharmaceutics
Because scientific bridging between the proposed and listed drug products was established using a comparative bioavailability/bioequivalence study, and the drug substance was determined to be fully dissolved in the drug product with no dissolution testing required, biopharmaceutics review was not required for this NDA.

6) Microbiology
After review of the Applicant's responses to information requests regarding supporting studies, the microbiology review determined that the tests and studies and other information provided in the NDA are adequate to support the microbiological quality of the drug product.

7) Quality Labeling
Final review of the quality aspects of the product labeling will be completed after the deficiencies have been addressed and the NDA is resubmitted for review.

b. Is the overall recommendation in agreement with the individual discipline recommendations? Yes

Recommendation by Subdiscipline:

Drug Substance	**-**	**Adequate**
Drug Product	**-**	**Inadequate**
Quality Labeling	**-**	**Adequate** – see comments in Section 4 above.
Manufacturing	**-**	**Adequate**
Biopharmaceutics	**-**	**N/A**
Microbiology	**-**	**Adequate**

Environmental Assessment: Categorical Exclusion - Adequate

[redacted]

QPA for EA(s): No

5. Life-Cycle Considerations

Established Conditions per ICH Q12: No
Comments: None

Comparability Protocols (PACMP): No
Comments: None.

Additional Lifecycle Comments:

None currently.

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CHAPTER IV: LABELING

NDA Number	218772
Assessment Cycle Number	1
Drug Product Name	Losartan Potassium

Assessment Recommendation: Adequate

Item	Assessment Conclusion	SDN # where labeling is adequate ("N/A" otherwise)
Prescribing Information Labeling	Adequate	**0001**
Patient Information	N/A	
Instruction for Use (IFU)	N/A	
Container Labels	Adequate	**0001**
Carton Labeling	Adequate	**0001**

Brief Description of Outstanding Issues:

Submissions being reviewed:

Document Reviewed (eCTD #, SDN #)	Date Received	Information Provided
0022	07/24/2024	CC labels
0007	01/16/2023	Medication guide
0022	07/24/2024	PI label

1.0 PRESCRIBING INFORMATION[1]

Assessment of Product Quality Related Aspects of the Prescribing Information:

[1] Labeling Review Tool (LRT) (March 2022), including use of consistent terminology for dosage form and unit of measure for strength in the product title and DOSAGE FORMS AND STRENGTHS heading in Highlights, in the DOSAGE AND ADMINISTRATION, DOSAGE FORMS AND STRENGTHS, DESCRIPTION, and HOW SUPPLIED/STORAGE AND HANDLING sections (see page 2 of LRT)

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Product Title in Highlights[2] [21 CFR 201.57(a)(2)]		
Established name(s)[3]	Adequate	(b) (4) [redacted]
Route(s) of administration	Adequate	oral use
Controlled drug substance symbol (if applicable)	N/A	
Initial U.S. Approval [§201.57(a)(3)]	Adequate	Initial U.S. Approval: 1995
Dosage Forms and Strengths Heading in Highlights [§ 201.57(a)(8)]		
Dosage form(s)[4] and strength(s) in metric system[5]	Adequate	Oral Suspension: 10 mg/mL.
If the drug product contains an active ingredient that is a salt, clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (e.g., Tablets: 10 mg of drug-x hydrochloride).[6]	Adequate	The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because the proposed drug product is intended to be administered in the identical dose for the same indication as all other approved losartan products, and therefore the name and strength should be consistent with the other approved products to reduce the risk of medication errors. The previously approved products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."[7]	N/A	

[2] Draft guidance: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format* (January 2018)
[3] Established name = [Drug] [Route of Administration] [Dosage Form]. Do use not "USP" descriptor in the product title or within the Highlights (see page 3 of LRT).
[4] Draft guidance: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format* (January 2018); USP <1151>; USP Nomenclature Guideline
[5] Labeling Review Tool (March 2022, page 13), include limited packaging information; USP <7>
[6] Guidance: *Naming of Drug Products Containing Salt Drug Substances* (June 2015); MAPP 5021.1
[7] Guidance: *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation* (March 2013)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package.[8]	N/A	

Assessment: *Adequate*

1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)[9]

(*copy of proposed text*)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents and/or soft food[10], storage conditions needed to maintain the stability of the reconstituted or diluted product).	N/A	Refer to section 16 for the shaking time
Important administration instructions supported by product quality information (e.g., do not	N/A	

[8] Guidance: *Selection of the Appropriate Package Type Terms and Recommendations for Labeling Injectable Medical Products Packaged in Multiple-Dose, Single-Dose, and Single-Patient-Use Containers for Human Use* (October 2018); USP <659>

[9] See § 201.57(c)(3); draft guidance: *Dosage and Administration Section of Labeling for Human Prescription Drug and Biological Products — Content and Format* (January 2023); Labeling Review Tool (March 2022, page 25)

[10] Draft Guidance: Use of Liquids and/or Soft Foods as Vehicles for Drug Administration: General Considerations for Selection and In Vitro Methods for Product Quality Assessments

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
crush or chew extended-release tablets, instructions for mixing with food).		
For parenteral products: include statement: *"Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit."*[11]	N/A	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.[12] Note the labeling requirement may be applicable to another section of the PI (e.g., Section 11).	N/A	This product is a new dosage form of losartan potassium, oral suspension, and it doesn't have a USP monograph.
For radioactive products, include radiation dosimetry for the patient and healthcare practitioner(s) who administer the drug	N/A	
For hazardous products, include the statement *"DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.*[x]*"* with x numerical citation to "OSHA Hazardous Drugs."	N/A	

Assessment: *Adequate*

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)[13]

[11] §201.57(c)(3)(iv)
[12] USP General Notices 2.30 Legal Recognition
[13] See § 201.57(c)(4); Labeling Review Tool (March 2022, page 29)

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	Adequate	Oral suspension
Strength(s) in metric system	Adequate	10 mg/mL
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance. Clearly state whether the strength is based on the active moiety (e.g., Tablets: 10 mg of drug-x) or active ingredient (e.g., Tablets: 10 mg of drug-x hydrochloride). No equivalency statement.	N/A	The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because the proposed drug product is intended to be administered in the identical dose for the same indication as all other approved losartan products, and therefore the name and strength should be consistent with the other approved products to reduce the risk of medication errors. The previously approved products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable.	Adequate	white, translucent suspension with a peppermint odor
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."	N/A	
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package type terms include pharmacy bulk package and imaging bulk package (see USP <659>).	N/A	

Assessment: *Adequate*

1.2.3 Section 11 (DESCRIPTION)[14]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
DESCRIPTION section		
Proprietary and established name(s)[15] [§ 201.57(c)(12)(i)(A)].	Adequate	Losartan potassium
Dosage form(s) and route(s) of administration [§ 201.57(c)(12)(i)(B)].	Adequate	oral suspension
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per Salt Guidance and MAPP. For example: "TRADENAME contains 100 mg of drug-x (equivalent to 123.7 mg of drug-x hydrochloride)" [§ 201.57(c)(12)(i)(C)].	N/A	The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because all approved losartan products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt. Furthermore, the indication of NDA 218772 is the same as approved losartan products.
List inactive ingredients (not required for oral use, except for colorant) by the USP/NF names in alphabetical order.[16] Avoid brand names. [§ 201.57(c)(12)(i)(C)].	Adequate	Adequate per revision below Revision: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum

[14] See § 201.57(c)(12); Labeling Review Tool (March 2022, page 56)
[15] Use of "USP" descriptor is not required to be included next to the established name throughout Prescribing Information (PI) labeling. If an applicant wants to use the "USP" descriptor next to the established name in the PI, recommend limiting its use to the product quality sections of the Full Prescribing Information (FPI) (i.e., DOSAGE FORMS AND STRENGTHS, DESCRIPTION, HOW SUPPLIED/STORAGE AND HANDLING) (see page 3 of LRT).
[16] Per § 201.100(b)(5)(i) and (ii), flavoring and colorants may be designated as such without naming their components except for FD&C Yellow No 5 and FD&C Yellow No 6, which must be listed per § 201.20. Per § 201.100(b)(5)(iii), trace amounts of harmless substances added solely for individual product identification need not be named. If an applicant wants to use the National Formulary (NF) descriptor next to excipients, recommend limiting its use to the product quality sections of the FPI (see page 3 of LRT). Do not list brand names, e.g., Opadry, Eudragit, Polistirex, etc.

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
		(b) (4) [redacted]
For parenteral injectable dosage forms, include the name and quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect. [§ 201.100(b)(5)(iii)].	N/A	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol at 60 °F. (15.56 °C) [§ 201.10(d)(2)].	N/A	
Sterility statement (if applicable) [§ 201.57(c)(12)(i)(D)].	N/A	
Pharmacological/Therapeutic class[17] [§ 201.57(c)(12)(i)(E)].	Adequate	angiotensin II receptor blocker
Chemical name[18], structural formula, molecular weight [§ 201.57(c)(12)(i)(F)].	Adequate	2-butyl-4-chloro-1-[p-(o-1H-tetrazol-5-ylphenyl)benzyl]imidazole-5-methanol monopotassium salt.
If radioactive, statement of important nuclear characteristics [§ 201.57(c)(12)(i)(G)].	N/A	
Other important chemical or physical properties (such as pKa or pH) [201.57(c)(12)(ii)].	N/A	

[17] Listed before "indicated for" in INDICATIONS AND USAGE of Highlights section [§ 201.57(a)(6)]; can also search the term "FDA EPC Text Phrases" in FDA's Labeling Resources for Human Prescription Drugs for the most recent EPC list.

[18] Chemical names do not need to be capitalized unless it appears at the beginning of a sentence (see *Preferred IUPAC Names Provisional Recommendation*, September 2004; Chapter 1, par. 16 Name writing, p.80-90).

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
For oral prescription drug products, include gluten statement[19] (if applicable).	N/A	
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity").	N/A	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled. Note the labeling requirement may be applicable to another section of the PI (e.g., Section 2).	N/A	

Assessment: *Adequate*

1.2.4 Section 16 (HOW SUPPLIED/STORAGE AND HANDLING)[20]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s) [§ 201.57(c)(17)].	Adequate	oral suspension
Strength(s) in metric system. [§ 201.57(c)(17)(i)] If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance. Clearly state whether the strength is based on the active moiety. No equivalency statement.	Adequate	10 mg of losartan potassium per mL The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because all approved losartan products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.

[19] Draft guidance: *Gluten in Drug Products and Associated Labeling Recommendations* (December 2017)
[20] See § 201.57(c)(17); Labeling Review Tool (March 2022, page 70). Consider including proprietary name and established name.

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
		Furthermore, the indication of NDA 218772 is the same as approved losartan products.
Available units (e.g., bottles of 100 tablets) [§ 201.57(c)(17)(ii)].	Adequate	Adequate per DMEPA revision below: It is supplied as 165 mL high-density polyethylene (HDPE) bottle with a child-resistant cap and tamper-evident seal
Identification of dosage forms (e.g., shape, color, coating, scoring, imprinting, and color and clarity of the solution, when applicable); Include NDC(s) [§ 201.57(c)(17)(iii)].	Adequate	white, translucent oral suspension
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored."	N/A	
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package (see USP <659>).	N/A	

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Special handling about the supplied product (e.g., protect from light, refrigerate). If there is a statement to "Dispense in original container," provide reason why (e.g., to protect from light or moisture, to maintain stability, etc.). For hazardous drugs, state "DRUG X is a hazardous drug. Follow applicable special handling and disposal procedures.[x]" with x numerical citation to "OSHA Hazardous Drugs." [§ 201.57(c)(17)(iv)]	Adequate	Keep container tightly closed. Protect from light.
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature. (see USP <659>).	Adequate	Adequate per DMEPA revision below: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
Latex: If product does not contain latex and manufacturing of product and container did not include use of natural rubber latex or synthetic derivatives of natural rubber latex, state: *"Not made with natural rubber latex. Avoid statements such as "latex-free."*[21]	N/A	
Include information about child-resistant packaging[22] (if chosen by manufacturer).	Adequate	high-density polyethylene (HDPE) bottle with a child-resistant cap and tamper-evident seal

Assessment: *Adequate*

[21] Guidance: *Recommendations for Labeling Medical Products to Inform Users that the Product or Product Container is not Made with Natural Rubber Latex* (December 2014)
[22] Guidance: *Child-Resistant Packaging Statements in Drug Product Labeling* (August 2019)

1.2.5 Other Sections of Labeling

1.2.6 Manufacturing Information After Section 17 (for drug products)[23]

Item	Item in Proposed Labeling (choose "Adequate" or "Inadequate")	Assessor's Comments (If an item is Inadequate, provide more details on the issues, as appropriate)
Manufacturing Information After Section 17		
Name and location of business (street address, city, state, and zip code) of the manufacturer, distributor, and/or packer.	Choose an item.	Adequate per revision below: Manufactured for: Scienture Inc. Hauppauge, NY 11788 Distributed by: Scienture Inc. Hauppauge, NY 11788

Assessment: *Adequate*

2.0 PATIENT LABELING

Assessment of Product Quality Related Aspects of Patient Labeling (e.g., Medication Guides, Instructions for Use, Patient Information):

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Labeling (If an item is Inadequate, provide more details on the issues, as appropriate)
Established name[24]	Adequate	TRADENAME (losartan potassium oral suspension)
Special preparation instructions (if applicable).	Adequate	Adequate per revision below: Shake for 20 seconds prior to each use.
Storage and handling information (if applicable).	Adequate	Store TRADENAME oral suspension at 59°F to 86°F (15°C to 30°C).
If the product contains a desiccant, ensure the desiccant has a warning (e.g., "Do not eat.") and the size and shape of the desiccant differ from the dosage form.	N/A	

[23] § 201.1(h)(5) and 201.1(i); Labeling Review Tool (March 2022, page 74)
[24] Established name = [Drug] [Route of Administration] [Dosage Form]

Item	Item in Proposed Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Labeling (If an item is Inadequate, provide more details on the issues, as appropriate)
Active ingredient(s) (if applicable).	Adequate	losartan potassium
Alphabetical listing of inactive ingredients (if applicable).	Adequate	Adequate per revision below: Revision: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum (b) (4) [redacted]
Name and location of business (street address, city, state, and zip code) of manufacturer, distributor, and/or packer.	Adequate	Manufactured for: Scienture Inc. Hauppauge, NY 11788 Distributed by: Scienture Inc. Hauppauge, NY 11788

Assessment: *Adequate*

3.0 CONTAINER AND CARTON LABELING[25]

3.1 Container Labels[26]

3.2 Carton Labeling

[25] Carton and Container Labeling Resources

[26] Per § 201.10(h)(2)(i)(1), if the drug container is too small to bear all labeling information required by section 502(e)(1)(A)(ii) and (B) of the FD&C Act, the container label should bear: proprietary name, established name, lot number, the name of the manufacturer, packer, or distributor of the drug.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
Proprietary name and established name[27], (font size and prominence) [§ 201.10(g)(2)].	Adequate	Yes	Tradename (losartan potassium) oral suspension

[27] Established name = [Drug] [Route of Administration] [Dosage Form]

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
Strength(s) in metric system [§ 201.100(b)(4) & 201.100(d)].[28]	Adequate	Yes	10 mg/mL
Route(s) of administration, not required for oral use [§ 201.100(b)(3)].	Adequate	Yes	Oral suspension
If the active ingredient is a salt, include the equivalency statement per Salt Guidance and MAPP [§ 201.10(d)(1) & 201.100(b)(4), USP <1121>].	N/A	Choose an item.	The name and strength are expressed in terms of "losartan potassium salt". This application is an exception to the Salt Policy because the proposed drug product is intended to be administered in the identical dose for the same indication as all other approved losartan products, and therefore the name and strength should be consistent with the other approved products to reduce the risk of medication errors. The previously approved products (a) have the same active ingredient, losartan potassium and (b) their names and strengths are expressed in terms of potassium salt.
Net contents (e.g., tablet count, volume of liquid) [§ 201.51(a)].[29]	Adequate	Yes	165 mL
"Rx only" displayed on the principal display [§ 201.100(b)(1)].	Adequate	Yes	

[28] Express as " XX mg per tablet" or "XX mg per capsule" for strength of professional samples of solid oral dosage form with small net quantities per container (e.g., 5 or less) or blister pack/carton. See Guidance: *Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors* (May 2022)

[29] § 201.51(h): A drug shall be exempt from compliance with the net quantity declaration required by this section if it is an ointment labeled "sample", "physician's sample", or a substantially similar statement and the contents of the package do not exceed 8 grams.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
NDC (requested, but not required for all labels or labeling) [§ 201.2 & 207.35].	Adequate	Yes	
Lot number and expiration date [§ 201.18 & 201.17].	Adequate	Yes	
Storage conditions. If applicable, include a space on the carton labeling for the user to write the beyond-use-date (BUD).	Adequate	Yes	Adequate per revision below: Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature].
For injectable drug products for parenteral administration, use appropriate package type term (e.g., single-dose, multiple-dose, single-patient-use). Other package terms include pharmacy bulk package and imaging bulk package, and these products require a "Not for direct infusion" statement. (See USP <659>).	N/A	Choose an item.	
Name of all inactive ingredients, in alphabetical order [§ 201.10(a)] [except for oral drug per § 201.100(b)(5) or limited space per § 201.10(i)(2)].	Adequate	Yes	Adequate per adding the inactive ingredients below: Revision: hypromellose, methyl paraben, natural peppermint flavor, polyethylene glycol, povidone, propyl paraben, propylene glycol, purified water, simethicone, sodium phosphates, sucralose, and xanthan gum (b) (4) [redacted]

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
			(b) (4) [redacted]
For parenteral injectable dosage forms, include quantities of all inactive ingredients. For ingredients added to adjust the pH or make isotonic, include the name and statement of effect. [§ 201.100(b)(5)(iii)].	N/A	Choose an item.	
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol at 60 °F. (15.56 °C) [§ 201.10(d)(2)].	N/A	Choose an item.	
Linear Bar code [§ 201.25(c)(2)].[30]	Adequate	Yes	
Adequate directions for use: "Recommended Dosage: See Prescribing Information" [§ 201.5 & 201.55].	Adequate	Yes	
Name of manufacturer/distributor /packer [§ 201.1(a), 201.1(h)(5)].	Adequate	Yes	
"Keep out of reach of children" statement, optional for Rx, required for OTC [§ 201.66(c)(5)(x)].	Adequate	Yes	
If there is a Medication Guide, must include a statement about dispensing	N/A	No	(b) (4) [redacted]

[30] See § 201.25(b)(1)(i) for a list where bar code is not required, e.g., prescription drug samples, medical gases, radiopharmaceuticals, etc.

Item	Item in Proposed Carton Labeling (choose "Adequate", "Inadequate", or "N/A")	Is item in Container Labels same as that of Carton Labeling?	Assessor's Comments about Container Labels and Carton Labeling (If an item is Inadequate or different, provide more details, as appropriate)
a Medication Guide to each patient.			(b) (4) [redacted]
No text on Ferrule and Cap overseal of a vial of injectable products unless a cautionary statement is required. (USP <7>).	N/A	Choose an item.	
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.	N/A	Choose an item.	
When a drug product differs from the relevant USP standard of strength, quality, or purity, as determined by the application of the tests, procedures, and acceptance criteria set forth in the relevant compendium, its difference shall be plainly stated on its label.[31]	N/A	Choose an item.	
And others if space is available.	N/A	Choose an item.	

Assessment of Carton Labels and Container Labeling: *Adequate*

4. OUTSTANDING ISSUES AND RECOMMENDATIONS

None

[31] USP General Notices 3.20 Indicating Conformance

Primary Labeling Assessor Name and Date:

Ali Mohamadi, Ph.D.; 7/05/2024

Secondary Assessor Name and Date (and Secondary Summary, as needed):

Ali Mohamadi

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Date: 8/08/2024 08:45:52PM
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Theodore Carver

Digitally signed by Theodore Carver
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CHAPTER VII: MICROBIOLOGY

IQA NDA Assessment Guide Reference

Product Information	
NDA Number	218772
Assessment Cycle Number	MR01
Drug Product Name/ Strength	Losartan Potassium Oral Suspension, 10 mg/mL
Route of Administration	Oral suspension
Applicant Name	Scienture Inc.
Therapeutic Classification/ OND Division	CDER/OND/OCHEN/DCN
Manufacturing Site	(b) (4)
Method of Sterilization	N/A; the drug product is non-sterile

Assessment Recommendation: **Adequate**

Assessment Summary:

List Submissions being assessed (table):

Document(s) Assessed	Date Received
Original submission	10/19/2023
Quality information	1/16/2024
Quality information	2/22/2024
Quality information	4/19/2024

Highlight Key Issues from Last Cycle and Their Resolution: N/A

Remarks: None

Concise Description of Outstanding Issues: None

Supporting Documents: N/A

P.1 DESCRIPTION OF THE COMPOSITION OF THE DRUG PRODUCT

- **Description of drug product –** White translucent suspension with peppermint odor

- **Drug product composition –**

Sr. #	Ingredients	Proposed formulation- Losartan Potassium Oral Suspension, 10 mg/mL		Component function
		Qty per mL	(b) (4)	
1	Losartan Potassium, (b) (4)	10 mg		Active Pharmaceutical Ingredient
2	Polyethylene Glycol (b) (4)			(b) (4)
3	Propylene Glycol, (b) (4)			
4	Methylparaben, (b) (4)			
5	Propylparaben, (b) (4)			
6	Sodium Phosphate, (b) (4)			
	(b) (4)			
8	Hypromellose (b) (4) (b) (4)			
9	Povidone (b) (4) (b) (4)			
10	Xanthan Gum, (b) (4) (b) (4)			
11	Sucralose, (b) (4)			
12	Simethicone (b) (4) (b) (4)			
13	Natural Peppermint flavor (b) (4)			
14	Purified Water, (b) (4)			

Q.S - Quantity sufficient

- **Description of container closure system –** 6 oz (b) (4) Round (b) (4) White HDPE bottles and polypropylene (b) (4) cap with (b) (4)

Exhibit batches: S0083, S0084 and S0085, (b) (4)

Proposed commercial batch: (b) (4)

Assessment: *Adequate*

The sponsor provided an adequate description of the drug product's composition and container closure system.

P.2 PHARMACEUTICAL DEVELOPMENT

(b) (4)

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Jianli Xue

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Nandini Bhattacharya

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Date: 6/12/2024 10:11:33AM
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Theodore Carver

Digitally signed by Theodore Carver
Date: 8/08/2024 09:04:42PM
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/s/

THEODORE E CARVER
08/08/2024 09:13:02 PM