

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

218230Orig1s000

PRODUCT QUALITY REVIEW(S)



Title:	NDA Executive Summary		
Document ID:	OPQ-ALL-TEM-0013		
Effective Date:	31 May 2022	Revision:	00
Total Pages:	4		



Template Revision: 03

NDA Executive Summary

1. Application/Product Information

NDA Number.	218230
Applicant Name	GlaxoSmithKline LLC (GSK)
Drug Product Name	BLUJEPA (gepotidacin) tablets
Dosage Form.	Tablet
Proposed Strength(s)	750 mg
Route of Administration	Oral
Maximum Daily Dose	1500 mg
Rx/OTC Dispensed	Rx
Proposed Indication	Treatment of female adult and pediatric patients 12 years of age and older weighing at least 40 kilograms (kg) with uncomplicated urinary tract infections (uUTI) caused by the following susceptible microorganisms: <i>Escherichia coli</i> , <i>Klebsiella pneumoniae</i> , <i>Citrobacter freundii</i> complex, <i>Staphylococcus saprophyticus</i> , and <i>Enterococcus faecalis</i>
Drug Product Description	Gepotidacin is a novel, bactericidal, first-in-class, triazaacenaphthylene bacterial type II topoisomerase inhibitor indicated for the treatment of female adult and pediatric patients with uncomplicated urinary tract infections. The proposed drug product (gepotidacin tablet) has been developed under IND 111885 and was granted QIDP (Qualified Infectious Disease Product) designation during product development. The drug product, gepotidacin tablet, is formulated as an immediate-release tablet containing 750 mg of gepotidacin (as gepotidacin mesylate (b) (4)). Gepotidacin tablets are yellow, film-coated, capsule-shaped tablets, debossed with 'GS GU3' on one side and plain on the other side, to be packaged in a 20-count HDPE bottle (b) (4)
Co-packaged product information	N/A



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Device information:	N/A		
Storage Temperature/ Conditions	Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature]		
Review Team	Discipline	Primary	Secondary
	<i>Drug Substance</i>	Karina Zuck	Katherine Windsor
	<i>Drug Product</i>	Juliana Quarterman	Dorota Matecka
	<i>Labeling</i>	Juliana Quarterman	David Claffey
	<i>Manufacturing/ Microbiology</i>	Iwona Weidlich	Nathan Davis
	<i>Biopharmaceutics</i>	Alaadin Alayoubi	Elsbeth Chikhale
	<i>EA</i>	Xiaoqin Wu	James Laurenson
	<i>PQS Assessment for ECs (OQS)</i>	Eric Twum	Mary Manibusan
	<i>Other (specify):</i>		
	<i>Office of Biostatistics</i>	Tengfei Li Chao Wang	Meiyu Shen
	<i>RBPM</i>	Dahlia Walters	
<i>ATL</i>	Dorota Matecka		
Consults	Office of Biostatistics (<i>as indicated above</i>)		

2. Final Overall Recommendation - Approval



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3. Action Letter Information

a. Expiration Dating:

24 months when stored at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) [See USP Controlled Room Temperature]

b. Additional Comments for Action

4. Basis for Recommendation:

a. Summary of Rationale for Recommendation:

The NDA, as amended, has provided sufficient CMC information to assure the identity, strength, purity, and quality of the proposed drug substance (gepotidacin mesylate) and drug product, gepotidacin tablets. That includes information regarding the control strategy for the (b) (4) impurity (b) (4) which was identified in the drug substance and drug product during product development and discussed extensively with the FDA through a number of meetings (correspondences documented in DARRTS under IND 111885). The information regarding the (b) (4) impurity, including the proposed acceptance criterion in the drug substance and drug product specifications, was consulted with and found acceptable by the Pharmacology/Toxicology review team for this NDA. In addition, the FDA's Office of Biostatistics (OB) was consulted and provided a consult review of the kinetic model that was developed and included in the NDA by the Applicant to further assess the rate and extent of (b) (4) formation in gepotidacin tablets (for details refer to the Drug Product and OB reviews, below). The NDA also provides for a number of Established Conditions in the drug substance and drug product manufacturing processes, which were reviewed and found acceptable by the Drug Substance and OPMA teams (refer to the respective reviews below). In addition, the Product Quality System (PQS) Assessment for the Established Conditions was performed by the OQS team who found the PQS "acceptable for the Established Conditions in this NDA" (refer to the OQS review attached below). The overall stability information provided in the NDA was found supportive of the proposed 24 months expiry dating for the drug product to be stored under controlled room temperature conditions. Furthermore, all manufacturing and testing facilities listed in the NDA have been found acceptable and the Overall Manufacturing Inspection Recommendation of "Approve" was entered into Panorama by the Office of Pharmaceutical Manufacturing Assessment on January 23, 2025. Therefore, this application is recommended for approval by the OPQ team.

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



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Recommendation by Subdiscipline:

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

Environmental Assessment: Categorical Exclusion - Adequate

QPA for EA(s): Yes

5. Life-Cycle Considerations

Established Conditions per ICH Q12: Yes

Comments:

The proposed Established Conditions described in the document “Product Lifecycle Management (PLCM) and included in section 3.2.R.5 of the NDA were found acceptable. They include:

1. Drug Substance (manufacturing process) Established Conditions – *for details refer to the Lifecycle Management Considerations section of the Drug Substance review (attached below)*
2. Drug Product (manufacturing process) Established Conditions – *for details refer to the Manufacturing Review and Product Quality System Assessment for the Established Conditions (attached below)*

Comparability Protocols (PACMP): No

Comments: N/A

Additional Lifecycle Comments: N/A

136 Page(s) have been Withheld in Full as b4 (CCI/TS) immediately following this page



Title:	NDA IQA Template CHAPTER IV-LABELING		
Document ID:	OPQ-ALL-TEM-0045		
Effective Date:	18 Sep 2023	Revision:	00
Total Pages:	23		



Template Revision: 03

CHAPTER IV: LABELING

NDA Number	218230
Assessment Cycle Number	1
Drug Product Name	BLUJEPA (Gepotidacin) Tablets, 750 mg

Assessment Recommendation: Adequate pending revisions conveyed to the Applicant

Item	Assessment Conclusion	SDN # where labeling is adequate (“N/A” otherwise)
Prescribing Information Labeling	Adequate	Pending revisions conveyed to the Applicant
Patient Information	Adequate	Pending revisions conveyed to the Applicant
Instruction for Use (IFU)	N/A	N/A
Container Labels	Adequate	Pending revisions conveyed to the Applicant
Carton Labeling	N/A	N/A

Brief Description of Outstanding Issues:

1. The **Highlights Section**, was edited to include the drug substance name in the list of strengths
Tablets: 750 mg of **gepotidacin** (3)
2. In the **Highlights Section**, since this is an NME drug product, the approval date will be “2025” and will be added after approval of this drug product.
3. In **Section 3**, the drug product description was edited to include information about the side of that tablet which was not debossed.
Tablets are yellow, capsule shaped, and debossed with “GS GU3” on one side **and plain on the other side**
4. In **Section 11**, the Applicant requested a new established pharmacologic class (EPC) for this drug product and originally listed the drug substance as “a triazaacenaphthylene antibacterial that inhibits bacterial DNA gyrase and topoisomerase IV”. With input from Pharm/Tox and clinical divisions, the new

EPC of “**triazacacenaphthylene bacterial type II topoisomerase inhibitor**” was chosen. This section was edited to include this new EPC.

5. In **Section 11**, originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to **910.7 mg**.

6. In **Section 11**, originally, the Applicant listed (b) (4). This was edited (b) (4) and the inactive ingredients list was combined with the previous sentence. Additionally, the inactive ingredient list was edited to list them in alphabetical order:
Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, **polyethylene glycol**, polyvinyl alcohol, ~~polyethylene glycol~~, talc, titanium dioxide, and yellow iron oxide.

7. In **Section 16**, information that belonged in Section 11 of the PI was removed from this section entirely:

(b) (4)

8. In **Section 16**, the drug product description was edited to include information about the side of the tablet that is not debossed.
... yellow, film coated, capsule shaped tablets debossed with “GS GU3” on one side **and plain on the other side.** ✓

9. In **Section 16**, the storage temperature ranges were edited to exclude the use of dashes “-” and replace them with the word “to”.
Store at 20°C **to** 25°C (68°F **to** 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature]. ✓

10. In the **Medication Guide**, the storage temperature ranges were edited to exclude the use of dashes “-” and replace them with the word “to”.
Store at 20°C **to** 25°C (68°F **to** 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature]. ✓

11. The **Medication Guide**, was edited to (b) (4) put the inactive ingredients in alphabetical order:
(b) (4) **polyethylene glycol**, polyvinyl alcohol, ~~polyethylene glycol~~, talc, titanium dioxide and yellow iron oxide.

12. In the **Container Label**, originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to **910.7 mg**.

Submissions being reviewed:

Document Reviewed (eCTD #, SDN #)	Date Received	Information Provided
eCTD 001, SDN 1	7/26/2024	Prescribing Information Labeling Patient Information Container Label
eCTD 017, SDN 16	10/21/2024	Container Label
eCTD 033, SDN 32	12/19/2024	Medication Guide

1.0 PRESCRIBING INFORMATION¹

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 Highlights² [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	BLUJEPA (gepotidacin) tablets
Route(s) of administration	Adequate	For oral use
Controlled drug substance symbol (if applicable)	N/A	
Initial U.S. Approval [§201.57(a)(3)]	Choose an item.	As this is an NME, the approval date will depend on the approval of the application.
Dosage Forms and Strengths Heading in Highlights [§ 201.57(a)(8)]		
Dosage form(s) ⁴ and strength(s) in metric system ⁵	Adequate	Tablets: 750 mg Changed to Tablets: 750 mg of gepotidacin
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	Changed to Tablets: 750 mg of gepotidacin
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state “functionally scored.” ⁷	N/A	No scoring

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	This is an oral tablet formulation

Assessment: *Adequate*

Highlights Section was edited to include the drug substance name in the list of strengths
Tablets: 750 mg of **gepotidacin** (3)

Since this is an NME drug product, the approval date will be “2025” and will be added after approval of this drug product.

1.2 FULL PRESCRIBING INFORMATION



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)

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	The PI states, “The recommended dose of BLUJEP is 1,500 mg taken orally, twice daily (approximately 12 hours apart) for 5 days.”
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	
For parenteral products: include statement: “ <i>Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.</i> ” 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	No USP monograph available
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 “ <i>DRUG X is a hazardous drug. Follow</i>	N/A	

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](#)

¹¹ §201.57(c)(3)(iv)

¹² USP General Notices 2.30 Legal Recognition

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)
<i>applicable special handling and disposal procedures.x</i> " with x numerical citation to "OSHA Hazardous Drugs."		

Assessment: Adequate

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)¹³

Each film coated tablet of BLUJEPA contains 750 mg of gepotidacin, (b) (4) Tablets are yellow, capsule shaped, and debossed with "GS GU3" on one side.

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	Tablets
Strength(s) in metric system	Adequate	750 mg
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.	Adequate	contains 750 mg of gepotidacin, (b) (4)
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	yellow, capsule shaped, and debossed with "GS GU3" on one side Edited to: Tablets are yellow, capsule shaped, and debossed with "GS GU3" on one side and plain on the other side
Assess if the tablet is scored. If product meets guidelines and	N/A	Not scored

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)
criteria for a scored tablet, state “functionally scored.”		
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*

The drug product description was edited to include information about the side of that tablet which was not debossed.

Tablets are yellow, capsule shaped, and debossed with “GS GU3” on one side **and plain on the other side**

1.2.3 Section 11 (DESCRIPTION)¹⁴



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

(b) (4)

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	BLUJEPA
Dosage form(s) and route(s) of administration [§ 201.57(c)(12)(i)(B)].	Adequate	Oral Tablet
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)].	Adequate	Originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to 910.7 mg .
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	Originally, the Applicant listed (b) (4) This was edited (b) (4) and the inactive ingredients list was combined with the previous sentence. Additionally, the inactive ingredient list was edited to list them in alphabetical order:

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)
		Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, ~~polyethylene glycol~~ , talc, titanium dioxide, and yellow iron oxide.
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	Pharmacologic class is still under discussion, once decided it will be added to the first sentence and will replace "a triazaacenaphthylene antibacterial that inhibits bacterial DNA gyrase and topoisomerase IV". Edited to: "triazacaenaphthylene bacterial type II topoisomerase inhibitor"
Chemical name ¹⁸ , structural formula, molecular weight [§ 201.57(c)(12)(i)(F)].	Adequate	Applicant has included the chemical name, structural formula and molecular weight of the drug substance.

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)
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	
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity").	Adequate	None of this is included
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	No USP monograph available

Assessment: Adequate

The Applicant requested a new established pharmacologic class (EPC) for this drug product and originally listed the drug substance as "a triazaacenaphthylene antibacterial that inhibits bacterial DNA gyrase and topoisomerase IV". With input from Pharm/Tox and clinical divisions, the new EPC of "triazacaenaphthylene bacterial type II topoisomerase inhibitor" was chosen. This section was edited to include this new EPC.

Originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to 910.7 mg.

Originally, the Applicant listed (b) (4). This was edited (b) (4) and the inactive ingredients list was combined with the previous sentence. Additionally, the inactive ingredient list was edited to list them in alphabetical order:
Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide, and yellow iron oxide.

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

Overall, this section was edited as such:

(b) (4)

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

(b) (4)

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)
HOW SUPPLIED/STORAGE AND HANDLING section		
Available dosage form(s) [§ 201.57(c)(17)].	Adequate	Tablets
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	750 mg
Available units (e.g., bottles of 100 tablets) [§ 201.57(c)(17)(ii)].	Adequate	Bottle of 20 tablets
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	BLUJEPA 750 mg tablets, are yellow, film coated, capsule shaped tablets debossed with “GS GU3” on one side Edited to include the additional descriptor “and plain on the other side.”
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state “functionally scored.”	N/A	Not scored
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)]	N/A	
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature. (see USP <659>).	Adequate	Store at 20°C-25°C (68°F-77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature]. Edited to add the word "to" instead of "-" for the temperature ranges.
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).	N/A	Applicant chose not to include this information into the label

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)

Assessment: Choose an item.

(Provide any revision, if applicable, e.g., different color font, strikethrough, etc.) **Any issues should be listed at the end in “OUTSTANDING ISSUES AND RECOMMENDATIONS”**

Information that belonged in Section 11 of the PI was removed from this section entirely:

(b) (4)

The drug product description was edited to include information about the side of the tablet that is not debossed.

... yellow, film coated, capsule shaped tablets debossed with “GS GU3” on one side and plain on the other side.”

The storage temperature ranges were edited to exclude the use of dashes “-” and replace them with the word “to”.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature].

Overall, this section was edited as such:

(b) (4)

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.	Manufactured for  GlaxoSmithKline Durham, NC 27701



Assessment: *Adequate*

2.0 PATIENT LABELING: Patient Labeling and Medication Guide

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	BLUJEPA (gepotidacin) tablets, for oral use
Special preparation instructions (if applicable).	N/A	
Storage and handling information (if applicable).	Adequate	Store BLUJEPA at 68-77°F (20-25°C) Edited to include the word "to" and replace "-"
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	No desiccant

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	Active ingredient: gepotidacin mesylate (b) (4)
Alphabetical listing of inactive ingredients (if applicable).	Adequate	Inactive ingredients: (b) (4) colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose (b) (4) polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide and yellow iron oxide. Edited to remove (b) (4) and put the inactive ingredients in alphabetical order: (b) (4) polyethylene glycol, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide and yellow iron oxide.
Name and location of business (street address, city, state, and zip code) of manufacturer, distributor, and/or packer.	Choose an item.	GlaxoSmithKline, Durham, NC 27701

Assessment: Adequate

The storage temperature ranges were edited to exclude the use of dashes "-" and replace them with the word "to".

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature].

Edited to remove (b) (4) and put the inactive ingredients in alphabetical order:

(b) (4) polyethylene glycol, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide and yellow iron oxide.

3.0 CONTAINER AND CARTON LABELING²⁵

²⁵ Carton and Container Labeling Resources

3.1 Container Labels²⁶



3.2 Carton Labeling

No carton label was provided by the Applicant.

Item	Item in Proposed Container Labeling (choose “Adequate”, “Inadequate”, or “N/A”)	Assessor’s Comments about Container Label (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	BLUJEP A (gepotidacin) tablets
Strength(s) in metric system [§ 201.100(b)(4) & 201.100(d)]. ²⁸	Adequate	750 mg
Route(s) of administration, not required for oral use [§ 201.100(b)(3)].	Adequate	Not required for oral use

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.

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

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 \(May 2022\)](#)

Item	Item in Proposed Container Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Container Label (If an item is Inadequate or different, provide more details, as appropriate)
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>].	Adequate	750 mg of gepotidacin (b) (4) Edited to show the correct salt equivalenc (b) (4) 750 mg of gepotidacin (equivalent to 910.7 mg of gepotidacin mesylate (b) (4)
Net contents (e.g., tablet count, volume of liquid) [§ 201.51(a)]. ²⁹	Adequate	20 tablets
"Rx only" displayed on the principal display [§ 201.100(b)(1)].	Adequate	Rx only
NDC (requested, but not required for all labels or labeling) [§ 201.2 & 207.35].	Adequate	NDC is shown
Lot number and expiration date [§ 201.18 & 201.17].	Adequate	Lot number and expiration date are present
Storage conditions. If applicable, include a space on the carton labeling for the user to write the beyond-use-date (BUD).	Adequate	Storage conditions are present
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	N/A	N/A

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 Container Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Container Label (If an item is Inadequate or different, provide more details, as appropriate)
require a "Not for direct infusion" statement. (See USP <659>).		
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	Due to space limitations, the Applicant has no included a list of inactive ingredients on the container label
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	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	N/A
Linear Bar code [§ 201.25(c)(2)]. ³⁰	Adequate	Barcode is present
Adequate directions for use: "Recommended Dosage: See Prescribing Information" [§ 201.5 & 201.55].	Adequate	"See prescribing information for dosage information."
Name of manufacturer/distributor /packer [§ 201.1(a), 201.1(h)(5)].	Adequate	MFD. for GSK Made in Belgium
"Keep out of reach of children" statement, optional for Rx, required for OTC [§ 201.66(c)(5)(x)].	Adequate	Present
If there is a Medication Guide, must include a statement about dispensing a	Adequate	There is a medication guide for this application. DMEPA has been consulted about

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 Container Labeling (choose "Adequate", "Inadequate", or "N/A")	Assessor's Comments about Container Label (If an item is Inadequate or different, provide more details, as appropriate)
Medication Guide to each patient.		this statement in the container label and it will be addressed.
No text on Ferrule and Cap overseal of a vial of injectable products unless a cautionary statement is required. (USP <7>).	N/A	N/A
If there is a USP monograph for the drug product and it contains a labeling requirement, ensure the labeling requirement is fulfilled.	N/A	No USP monograph available
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	N/A
And others if space is available.	N/A	N/A

Assessment of Carton Labels and Container Labeling: Adequate

Originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to 910.7 mg.

4. OUTSTANDING ISSUES AND RECOMMENDATIONS

Assessment: Adequate Pending revisions conveyed to the Applicant

13. The **Highlights Section**, was edited to include the drug substance name in the list of strengths

³¹ USP General Notices 3.20 Indicating Conformance

Tablets: 750 mg of **gepotidacin** (3)

14. In the **Highlights Section**, since this is an NME drug product, the approval date will be “2025” and will be added after approval of this drug product.
15. In **Section 3**, the drug product description was edited to include information about the side of that tablet which was not debossed.
Tablets are yellow, capsule shaped, and debossed with “GS GU3” on one side **and plain on the other side**
16. In **Section 11**, the Applicant requested a new established pharmacologic class (EPC) for this drug product and originally listed the drug substance as “a triazaacenaphthylene antibacterial that inhibits bacterial DNA gyrase and topoisomerase IV”. With input from Pharm/Tox and clinical divisions, the new EPC of “**triazacenaphthylene bacterial type II topoisomerase inhibitor**” was chosen. This section was edited to include this new EPC.
17. In **Section 11**, originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to **910.7 mg**.
18. In **Section 11**, originally, the Applicant listed (b) (4). This was edited to exclude (b) (4) the inactive ingredients list was combined with the previous sentence. Additionally, the inactive ingredient list was edited to list them in alphabetical order:
Inactive ingredients include colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, **polyethylene glycol**, polyvinyl alcohol, ~~polyethylene glycol~~, talc, titanium dioxide, and yellow iron oxide.
19. In **Section 16**, information that belonged in Section 11 of the PI was removed from this section entirely:
(b) (4)
20. In **Section 16**, the drug product description was edited to include information about the side of the tablet that is not debossed.
... yellow, film coated, capsule shaped tablets debossed with “GS GU3” on one side **and plain on the other side.**”
21. In **Section 16**, the storage temperature ranges were edited to exclude the use of dashes “-” and replace them with the word “to”.

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature].

22. In the **Medication Guide**, the storage temperature ranges were edited to exclude the use of dashes “-” and replace them with the word “to”.
Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F). [See USP Controlled Room Temperature].

23. The **Medication Guide**, was edited to remove (b) (4) and put the inactive ingredients in alphabetical order:
(b) (4) polyethylene glycol, polyvinyl alcohol, polyethylene glycol, talc, titanium dioxide and yellow iron oxide.

24. In the **Container Label**, originally, the Applicant used (b) (4) to calculate the salt equivalency, however they should not have included this in the calculations. The salt equivalency was therefore corrected to 910.7 mg.

Primary Labeling Assessor Name and Date:

Juliana Quarterman, PhD. 1/28/2025

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

David Claffey, PhD. 1/28/2025



Juliana
Quarterman

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David
Claffey

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