

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208712Orig1s000

PRODUCT QUALITY REVIEW(S)

Recommendation: APPROVAL

NDA 208712

Review # 1

Drug Name/Dosage Form	Pacritinib/ Oral capsules
Strength	100 mg
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	CTI Bio Pharma Corp

SUBMISSIONS REVIEWED	DOCUMENT DATE
Original	12/21/20
Quality Amendment	3/30/2021, 7/16/2021, 7/26/2021, 8/17/21, 8/20/21, 8/25/21, 9/7/21

Quality Review Team

DISCIPLINE	PRIMARY REVIEWER	SECONDARY REVIEWER
Drug Substance	Joseph Leginus	Suong Tran
Drug Product	Dhanalakshmi Kasi	Mohan Sapru
Process/ Facility	Nancy Waites	Dan Obrzut
Biopharmaceutics	Joan Zhao	Poonam Delvadia
Regulatory Business Process Manager	Grafton Adams	
Application Technical Lead	Dhanalakshmi Kasi	

Quality Review Data Sheet

1. RELATED/SUPPORTING DOCUMENTS

A. DMFs: None

B. Other Documents: None

2. CONSULTS

N/A

Executive Summary

I. Recommendations and Conclusion on Approvability

The final OPQ recommendation is for Approval.

II. Summary of Quality Assessments

A. Product Overview

Pacritinib from CTI Biopharma is a new molecular entity and it was granted orphan drug status for MF in 2010 and received fast track designation in August 2014. This application is a 505 b (1) application. Pacritinib is a small-molecule, adenosine triphosphate-competitive multi-kinase inhibitor, with potent inhibitory activity against Janus kinase 2, including its mutated form, JAK2V617F, and interleukin 1 receptor associated kinase 1. The proposed indication for pacritinib is the treatment of adult patients with intermediate- or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis who have severe thrombocytopenia. The pacritinib capsule is an immediate release solid oral dosage form composed of a hard gelatin capsule containing 100 mg pacritinib. The recommended dose of pacritinib is 200 mg orally twice daily.

The drug substance, pacritinib citrate is a small, cyclic, achiral molecule isolated as a yellow crystalline powder. It is manufactured as a single crystalline form (b) (4). There are 3 related substance impurities that are controlled at the ICH Q3A qualification threshold of 0.15%. One impurity has been identified as potentially genotoxic and will be controlled to a limit of NMT (b) (4) ppm in the drug substance specifications at a level below the ICH M7 TTC limit of (b) (4) ppm. The proposed shelf life is (b) (4) months when stored at (b) (4).

The drug product manufacturing process involves (b) (4) (b) (4). Multiple facilities are involved in manufacturing, packaging and testing of the API and drug product. All facilities except the drug product manufacturing facility are approved based on previous history. The drug product manufacturing facility, (b) (4) was evaluated based on 704(a)4 assessment. No issues were identified during the assessment and the facility is acceptable.

The proposed dissolution acceptance criterion (NLT (b) (4) % (Q) in 15 min).

B. Quality Assessment Overview

Drug Substance

Pacritinib citrate is a small cyclic molecule with a molecular formula of $C_{28}H_{32}N_3O_3 \cdot C_6H_8O_7$ and a molecular weight of 664.7 g/mol as the citrate salt and a molecular weight of 472.6 as the free base. The drug substance is isolated as a yellow crystalline powder. It is not hygroscopic or light sensitive and is manufactured as a single crystalline form (b) (4).

Identity of the drug substance is supported by IR, ¹H and ¹³C NMR, MS, elemental analysis and XRPD. There are 3 related substance impurities that are controlled at the ICH Q3A qualification threshold of 0.15%. One impurity has been identified as potentially genotoxic and will be controlled to a limit of NMT (b) (4) ppm in the drug substance specifications at a level below the ICH M7 TTC limit of (b) (4) ppm. A retest date of (b) (4) months is granted for pacritinib citrate when stored at (b) (4) within (b) (4)

Drug Product

The pacritinib capsule is an immediate release solid oral dosage form composed of a hard gelatin capsule containing 100 mg pacritinib. The inactive ingredients are microcrystalline cellulose, polyethylene glycol 8000, and magnesium stearate. The inactive ingredients are well within the IID limits. The drug product release specification includes testing critical quality attributes like appearance, identification, assay, and degradation products, dissolution, uniformity of dosage unit and (b) (4). No specified degradation products are included in the drug product specification, Unspecified impurities are controlled to the ICH Q3B limit of NMT 0.2%. COAs are provided for 3 primary stability lots, 3 commercial validation lots, and 3 commercial scale lots. Test results showed they are within the specified limits and it is acceptable. The capsules are supplied in 200 mL high density polyethylene bottles with (b) (4) closures. The proposed shelf life is 60 months based on the available primary and supporting stability data. Photostability studies indicated that the unprotected capsules showed brittleness. Applicant included the following the instructions in the packaging insert: "Store in the original package. Keep the bottle tightly closed (b) (4) protect from light". Also, the drug product will be supplied as a 30-day supply package containing 120 capsules in a HDPE container. Hence, frequent opening and closing of the bottle and direct exposure of the product to light will be minimal and is expected to have no impact on the drug product CQAs.

C. Special Product Quality Labeling Recommendations: None

D. Life Cycle Knowledge Information: None

Application Technical Lead Name and Date: Dhanalakshmi Kasi, Ph.D.



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CHAPTER IV: LABELING

1.0 PRESCRIBING INFORMATION

Assessment of Product Quality Related Aspects of the Prescribing Information: Adequate with revisions provided below.

1.1 HIGHLIGHTS OF PRESCRIBING INFORMATION

Item	Information Provided in the NDA	Assessor's Comments
Product Title in Highlights		
Proprietary name	VONJO® (pacritinib) capsules, for oral use	Adequate
Established name(s)		
Route(s) of administration		
Dosage Forms and Strengths Heading in Highlights		
Summary of the dosage form(s) and strength(s) in metric system.	Capsules: 100 mg	Adequate
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"	NA	
For injectable drug products for parental 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.		

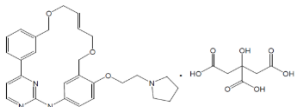
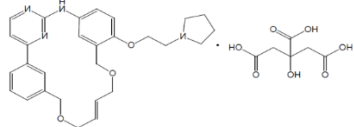
1.2 FULL PRESCRIBING INFORMATION

1.2.1 Section 2 (DOSAGE AND ADMINISTRATION)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE AND ADMINISTRATION section		
Special instructions for product preparation (e.g., reconstitution and resulting concentration, dilution, compatible diluents, storage conditions needed to maintain the stability of the reconstituted or diluted product)		

1.2.2 Section 3 (DOSAGE FORMS AND STRENGTHS)

Item	Information Provided in the NDA	Assessor's Comments
DOSAGE FORMS AND STRENGTHS section		
Available dosage form(s)	• The 100 mg capsule is an oblong, size 0 hard gelatin capsule with an opaque scarlet cap printed with "Pacritinib 100 mg" and opaque gray body printed with "C78837".	• Revision: • Capsule: 100 mg, oblong, size 0 hard gelatin capsule with an opaque scarlet cap printed with "Pacritinib 100 mg" and opaque gray body printed with "C78837".
Strength(s) in metric system		
If the active ingredient is a salt, apply the USP Salt Policy per FDA Guidance		
A description of the identifying characteristics of the dosage forms, including shape, color, coating, scoring, and imprinting		
Assess if the tablet is scored. If product meets guidelines and criteria for a scored tablet, state "functionally scored"		
For injectable drug products for parental administration, use appropriate labeling term (e.g., single-dose, multiple-dose, single-patient-use). Other package type terms include pharmacy bulk package and imaging bulk package.		

Item		Assessor's Comments
DESCRIPTION:		
Proprietary and established name(s)	VONJO is a kinase inhibitor with the chemical name	Revision:
Dosage form(s) and route(s) of administration	(2E,16E)-11-[2-(pyrrolidin-1-yl)ethoxy]-14,19-dioxa-	VONJO contains pacritinib citrate, a kinase inhibitor with the chemical name
If the active ingredient is a salt, apply the USP Salt Policy and include the equivalency statement per FDA Guidance.	5,7,27-trizatetracyclo[19.3.1.1(2,6).1(8,12)]heptacos-	11-[2-(pyrrolidin-1-yl)ethoxy]-14,19-dioxa-5,7,27-
List names of all inactive ingredients. Use USP/NF names. Avoid Brand names.	1(25),2,4,6,8,10,12(26),16,21,23-decaene citrate and a molecular weight of 664.7 as citrate salt and 472.59 as a free base. VONJO has the molecular	1(25),2,4,6,8,10,12(26),16,21,23-decaene citrate and a molecular weight of 664.7 as citrate salt equivalent to
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.	formula $C_{28}H_{32}N_4O_3 \cdot C_6H_8O_7$ and the following structural formula:	472.59 as a free base. The molecular formula is $C_{28}H_{32}N_4O_3 \cdot C_6H_8O_7$ and the structural formula is
If alcohol is present, must provide the amount of alcohol in terms of percent volume of absolute alcohol	 VONJO (pacritinib) capsule is for oral administration. Each capsule contains	 VONJO capsule is for oral administration. Each capsule contains 100 mg of pacritinib equivalent to 140.65 mg of pacritinib citrate and the inactive ingredients are microcrystalline cellulose NF, polyethylene glycol 8000 (PEG 8000) NF, and magnesium stearate NF. The gelatin capsule is bovine derived. The capsule shell contains gelatin, titanium dioxide, black iron oxide, erythrosine, red iron oxide, and printing ink containing shellac, propylene glycol, titanium dioxide, sodium hydroxide, and povidone.
Statement of being sterile (if applicable)	(b) (4)	
Pharmacological/therapeutic class	(b) (4) the inactive ingredients microcrystalline cellulose National Formulary (NF), polyethylene glycol 8000 (PEG 8000) NF, and magnesium stearate NF. The gelatin capsule is bovine derived. The capsule shell contains gelatin, titanium dioxide, black iron oxide, erythrosine, red iron oxide, and printing ink containing shellac, propylene glycol, titanium dioxide, sodium hydroxide, and povidone.	
Chemical name, structural formula, molecular weight		
If radioactive, statement of important nuclear characteristics.		
Other important chemical or physical properties (such as pKa or pH)		

Section 11 (DESCRIPTION) Continued

Item	Information Provided in the NDA	Assessor's Comments
For oral prescription drug products, include gluten statement if applicable	None.	
Remove statements that may be misleading or promotional (e.g., "synthesized and developed by Drug Company X," "structurally unique molecular entity")	None.	

Section 16 (HOW SUPPLIED/STORAGE AND HANDLING) (Continued)

Item	Information Provided in the NDA	Assessor's Comments
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.)	N/A	
If the product contains a desiccant, ensure the size and shape differ from the dosage form and desiccant has a warning such as "Do not eat."	N/A	
Storage conditions. Where applicable, use USP storage range rather than storage at a single temperature.	See above.	
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."	N/A	
Include information about child-resistant packaging	No Information included.	

1.2.3 Manufacturing Information After Section 17 (for drug products)

Item	Information Provided in the NDA	Assessor's Comments
Manufacturing Information After Section 17		
Name and location of business (street address, city, state and zip code) of the manufacturer, distributor, and/or packer	Manufactured by: CTI Biopharma Corp. Marketed by: XXX VONJO is a (b) (4) trademark of CTI Biopharma Corp. All rights reserved. ©XXXX All rights reserved. Issued: Date	Adequate

2.0 PATIENT LABELING

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

No Information included.

3.0 CARTON AND CONTAINER LABELING



Assessment of Carton and Container Labeling: *Adequate*

(b) (4) DMEPA was notified and they send the IR to the Applicant.

Overall Assessment and Recommendation:

The labeling/labels will be adequate from a quality perspective after the recommended changes have been made.



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CHAPTER VI: BIOPHARMACEUTICS
[IQA NDA Assessment Guide Reference](#)

Product Information	
NDA Number	208712
Assessment Cycle Number	# 1
Drug Product Name/ Strength	Pacritinib Capsules, 100 mg
Route of Administration	Oral
Applicant Name	CTI BioPharma Corp
Therapeutic Classification/OND Division	Myeloproliferative/Myelodysplastic Syndromes (DNH)
RLD/IND Number	IND 078406
Proposed Indication	Treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF)
Primary Assessors	<i>Zhuojun Joan Zhao, Ph.D.</i>
Secondary Assessors	Poonam Delvadia, <i>Ph.D.</i>
Assessment	Adequate
Recommendation	Based on the review of the overall information, from a Biopharmaceutics perspective, NDA 208712 for Pacritinib Capsules is recommended for APPROVAL .

Assessment Summary:

CTI Biopharma CORP submitted a 505(b) (1) application for the proposed Pacritinib Capsules, 100 mg for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).

The proposed drug product is an immediate release hard gelatin capsule containing 100 mg Pacritinib. The proposed dosing is (b) (4). The capsule can be administered with or without food.

The Biopharmaceutics review is focused on the evaluation and acceptability of the proposed quality control dissolution method and acceptance criterion, and the evaluation of the need for bridging.

Dissolution method and Acceptance Criterion:

Based on the provided dissolution data, the proposed dissolution method and dissolution acceptance criterion are found acceptable:

Medium	0.08 M HCl/0.034 M NaCl, pH 1.2
Apparatus	USP II (Paddle) with 4-coil spiral sinker
Volume	900 mL

Rotation Speed	75 RPM
Temperature	37°C
Acceptance Criterion	Q= (b) (4)% in 15 minutes

Bridging Formulations:

The Applicant conducted an in vivo BE study (PAC108) to bridge the Phase 2/3 capsules using (b) (4) drug substance and the proposed commercial capsules using (b) (4) drug substance, which was found acceptable by the Clinical Pharmacology reviewer. The Applicant also provided dissolution profiles to support the drug substance manufacturing site change, which is for information only.

List Submissions being assessed:

Document Assessed	Date Received
Resubmission (SN0011)	December 21, 2020

Highlight Key Issues from Last Cycle and Their Resolution: NA

Concise Description of Outstanding Issues): None

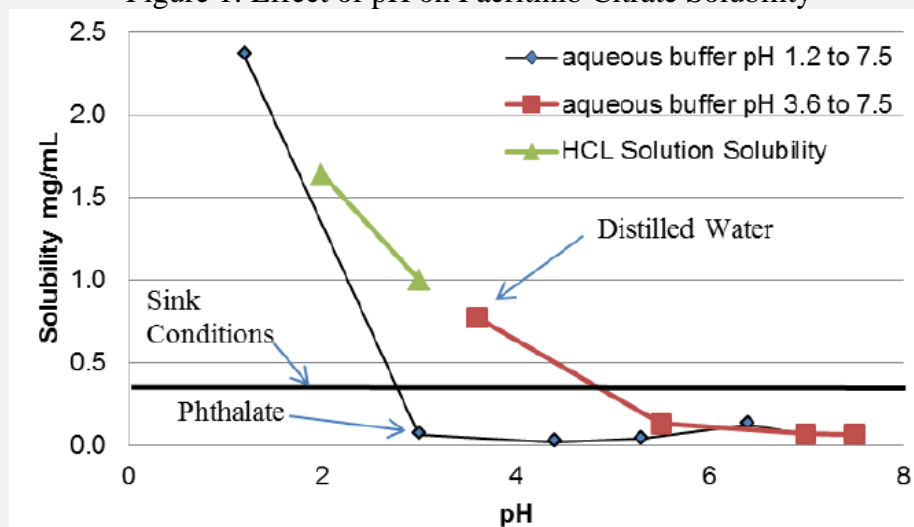
B.1 BCS DESIGNATION

Solubility:

The drug substance, Pacritinib Citrate, is a crystalline solid, which consists of one molecule each of pacritinib and citric acid.

The Applicant determined the solubility of Pacritinib Citrate in a range of buffers. Figure 1 graphically illustrates results from the Applicant’s three solubility studies: aqueous buffer pH 1.2 through 7.5 (pH 1.2 used HCl, all other pH’s used phthalate buffer—the graph notes the change to phthalate buffer), aqueous buffer pH 3.6 through 7.5, and HCl buffer solution between pH 2 and 3.

Figure 1: Effect of pH on Pacritinib Citrate Solubility



Assessment:

The Applicant did not request an official BCS designation. The drug substance, Pacritinib Citrate, shows pH dependent solubility. As per BCS solubility definition, Pacritinib Citrate is considered as a low solubility drug substance¹.

B.2 FORMULATION

The proposed pacritinib drug product is an immediate-release solid oral dosage form containing 140.7 mg of the drug substance, pacritinib citrate, equivalent to 100 mg of pacritinib in a hard gelatin capsule. The inactive ingredients microcrystalline cellulose, polyethylene glycol 8000, and magnesium stearate make up the remaining dry powder formulation. The composition of pacritinib capsules is presented in **Table 1**.

Table 1: Commercial Drug Product Components and Composition

Component	Quality Standard	Function	Component Quantity	
			mg	% of fill weight ^a
Pacritinib citrate	In-house	Drug substance	140.7	(b) (4)
Microcrystalline cellulose	NF ^b			(b) (4)
Magnesium stearate	NF			
Polyethylene glycol 8000	NF			
Hard gelatin capsule	USP ^c <1151>			

^a Percent of target capsule fill weight; not total capsule weight

^b National Formulary

^c USP = United States Pharmacopeia

B.3 DISSOLUTION METHOD

The Applicant proposed the following dissolution method for the proposed Pacritinib Citrate Capsules.

Medium	0.08 M HCl/ 0.034 M NaCl (pH 1.2)
Apparatus	USP II (Paddle) with 4-coil spiral sinker ²
Volume	900 mL
Rotation Speed	75 RPM
Temperature	37°C

The Applicant provided dissolution method development data for the choice of dissolution conditions of the above proposed dissolution method in the Pharmaceutical Development RPT.PTB017 ([Module 3.2.P.2](#)), mainly as shown below:

Apparatus:

¹ The proposed strength 100 mg divided by 250 mL is 0.4 mg/mL.

² (b) (4)

(b) (4)

Volume:

The Applicant selected 1 L vessel, which contains 900 mL medium.

Rotation Speed:

(b) (4)

Dissolution Medium/pH:

Based on the obtained pH-solubility profile of the drug substance, the Applicant selected acidic conditions (i.e., pH 1.2) as the dissolution medium for the following reasons:

(b) (4)

Discriminatory Power of the Method:

The proposed Pacritinib capsules, 100 mg are an immediate release (IR) oral dosage form. T_{max} for pacritinib following oral administration in humans is around 5 hours post-dose, while complete in vitro dissolution occurs within 1 hour under the physiologically relevant pH range (i.e., pH 1.2 & 4.5), which suggests that in vitro dissolution is not correlated to in vivo performance of the pacritinib capsules. Therefore, the Applicant states that the proposed in vitro dissolution method is more suited as a QC tool.

To demonstrate power of discrimination of in vitro dissolution method, the Applicant altered key CMC parameters, such as drug substance particle size, excipient content, (b) (4) using the initial dissolution method (pH 1.2 0.08 M HCl/ 0.034 M NaCl in Apparatus II at (b) (4)). Discrimination was not observed for hold time, (b) (4), or differing formulation composition but appeared to be observed between particle sizes and (b) (4). However, after further study, the Applicant identified that the observed difference is likely due to an artifact of the method being run

(b) (4)
(b) (4)

Assessment: {Adequate}

The Applicant has adequately demonstrated and justified the suitability of the proposed dissolution method for batch release and stability testing.

However, any discriminating ability study towards any key changes in critical CMC parameters using the proposed dissolution method (75 rpm) was not conducted. The dissolution data alone might not be sufficient to support formulation and process changes in the future. Since the Applicant controls critical material (b) (4) (b) (4) API particle size) and process attributes (e.g., (b) (4)), which helps mitigate the dissolution risk, the proposed dissolution method (US Apparatus II (paddle) at 75 rpm using 900 mL pH 1.2 0.08 M HCl/0.034 M NaCl) is found acceptable for the QC of the proposed drug product. The adequacy of proposed API and process controls are under the purview of drug substance and manufacturing assessor.

B.4 DISSOLUTION ACCEPTANCE CRITERION

The Applicant used a dissolution acceptance criterion of O = (b) (4)% at (b) (4) minutes during the clinical development and later revised to Q = (b) (4)% at (b) (4) minutes. Based on further review of the data (b) (4) the Applicant proposes the acceptance criterion of Q = (b) (4)% at 15 minutes with the following justification:

1. Typical disintegration time for empty capsules is up to 10 to 15 minutes and setting acceptance criteria close to 15 minutes may lead to significant variability in the data. The proposed acceptance criteria of 15 minutes accounts for variability in disintegration of hard gelatin capsules and represents dissolution of product.
2. Historic batches (Batch Analysis for batch release in [Section 3.2.P.5.4](#) and Stability Data for stability data in [Section 3.2.P.8.3](#)) have met this requirement and that shows dissolution remains consistent throughout the expiry period with no discernible trends. The dissolution data from the Phase 3 drug product lots and from the establishment and validation lots met the specification the time of release and through all the stability time points tested when tested with S1-S3 level of dissolution testing. The lots evaluated were 16151, 17180, 19584, 59745, 59746, 60873, 61049, 61404, 23936, 62082, 62100, 62109, and 68461. All of the above batches were tested using 75 rpm paddle speed.

Assessment: {Adequate}

Based on the submitted dissolution profiles, the Applicant's proposed dissolution acceptance criterion on NLT (b)(4) % (Q) at 15 minutes is deemed acceptable.

B.7 BRIDGING OF FORMULATIONS

A pacritinib capsule formulation was initially established with the drug substance (b)(4) consisting of magnesium stearate, microcrystalline cellulose, and (b)(4) ([Appendix 1](#)). The Applicant initially developed two product strengths (early stage 50 and 100 mg capsule formulations) using (b)(4) form of the drug with the amount of drug substance (b)(4) while maintaining the same level of (b)(4) for the filled capsule.

Following a switch from the pacritinib (b)(4) form to the pacritinib citrate salt form in early clinical development, the Applicant used the same 100 mg (free base equivalent) formulation with the increased level of drug substance in the citrate form offset by (b)(4) to maintain the same total capsule weight (Phase 1 100 mg capsule formulation). The (b)(4) content remained constant. The pacritinib citrate drug product, which was used throughout most of the clinical development program, was only manufactured at the 100 mg strength.

The Applicant changed (b)(4) used in the Early Stage and Phase 1 capsule formulations to PEG 8000 in the Phase 2/3 capsule formulation. The commercial scale manufacturing process for the Phase 2/3 capsule formulation was validated with the manufacture of three full-scale commercial drug product lots, including the

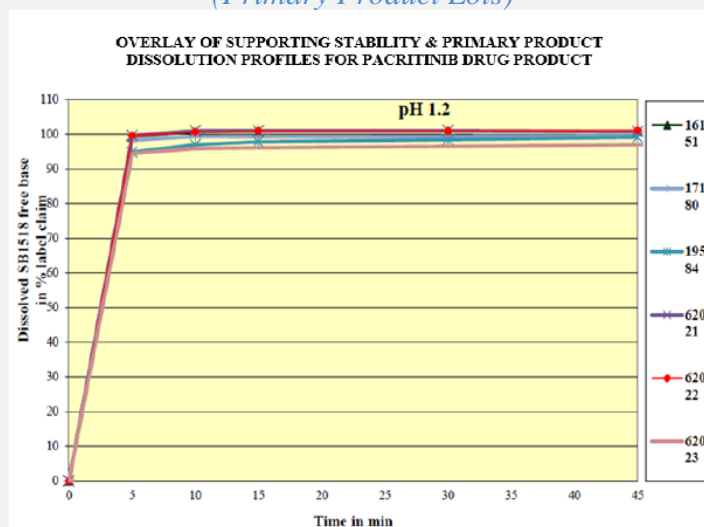
commercial (final market image [FMI]) capsule formulation tested in clinical BE Study PAC108³.

The Applicant transferred the manufacturing of the drug substance early in the Phase 3 program from (b) (4) to (b) (4). Drug product used in the Phase 2 studies and the initial Phase 3 study (PERSIST-1) was manufactured with drug substance from (b) (4) and most of the drug product used in PERSIST-2, the pivotal Phase 3 study was manufactured with drug substance from (b) (4) which will manufacture the commercial drug product.

Assessment: {Adequate}

The Applicant provided comparative dissolution profiles (Figure 3) to support drug substance manufacturing site change from (b) (4) to (b) (4). The dissolution comparison between the Phase 2/3 capsules using (b) (4) drug substance (lots 16151, 17180 and 19584) and commercial (FMI) formulation batch using (b) (4) drug substance (lots 62021, 62022 and 62023) indicated comparable/similar dissolution (rapid dissolved >85% within 15 minutes).

Figure 3: Dissolution Profiles Comparing Phase 2/3 Capsule Formulation (100 mg) (Supporting Stability Lots) and Commercial (FMI) Capsule Formulation (100 mg) (Primary Product Lots)



In addition, a clinical bridging study PAC108 was conducted comparing Phase 2/3 capsules formulation batch# 16151 manufactured using (b) (4) drug substance lot DBIHS1002 and Pacritinib Commercial (FMI) formulation batch #62082 manufactured by (b) (4) using (b) (4) drug substance lot LTM7A1004, which was found acceptable by the Clinical Pharmacology reviewer.

³ PAC108: Bioequivalence of Pacritinib Phase 2/3 Capsule Formulation ((b) (4) drug substance) and Pacritinib Commercial (FMI) Capsule Formulation ((b) (4) Drug substance) in Healthy Subjects

B.8 BIOWAIVER REQUEST

Assessment: N/A

A biowaiver is not submitted nor required for this NDA.

R. REGIONAL INFORMATION

Comparability Protocols: N/A

Post-Approval Commitments: N/A

Lifecycle Management Considerations: N/A

APPENDIX 1: Drug Product Formulation History

Components	Composition (mg/capsule)			
	Early Stage (b) (4)		(Citrate Salt) (Phase 1)	Phase 2, 3, Commercial
	50 mg Capsule	100 mg Capsule	100 mg Capsule	100 mg Capsule
Pacritinib (b) (4)	(b) (4)			
Pacritinib citrate				
Magnesium stearate				
Microcrystalline cellulose				
(b) (4)				
Polyethylene glycol 8000				
Capsule, hard gelatin				
Time period	2007-2009		2009	2009-Present
Manufacturer(s)	(b) (4)			
Drug product lots	071114, 080221, 080707, 081201	080222, 080709, 090101, 090201, 090401, 090702	090102, 090703	090905, 100101, 100401, 15573, 16151, 17180, 19584, 59745, 59746, 60873, 61049, 61404, 61925, 62082, 62100, 62109, 68461, 68462, 68469
Clinical studies				
Phase 1/2	SB1518-2007-001 SB1518-2007-002 SB1518-2008-003	SB1518-2007-001 SB1518-2007-002 SB1518-2008-003	SB1518-2007-001 SB1518-2007-002 SB1518-2008-003	SB1518-2007-001 SB1518-2007-002 SB1518-2008-003 SB1518-2010-004 SB1518-2010-005 SB1518-2010-006 SB1518-2011-0427 PAC203
Phase 3	-	-	-	PAC325 PAC326 PACIFICA PAC-319 COVID-19
COVID-19 = coronavirus disease 2019; (b) (4)				



Poonam
Delvadia

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