



Bayer AG Kaiser-Wilhelm-Allee  51368 Leverkusen, Germany		Certificate of Analysis		Page: 1 of 2 Date: 2025-09-18	
Material: 88174976 Your material:		VERQUVO 5MG TAFI BLI 2X14 VERQUVO 5MG TAFI BLI 2X14			
Batch: BXK9RK1 Date of manufacture: 2025-01-29 Expiry date: 2028-01-31		Country: Chile Delivery number: 137780718 Order number: 720238979			
From material: 90140293 Batch: BXA9JLN Inspection lot: 040002973590		VERICIGUAT TAFI 5MG FL		Insp. instruction: P.5.2.01 - 8 Specification: P.5.1.02 - 16	
Inspection	Acceptance criterion	UoM	Result		
Formulation	coated tablet		coated tablet		
Form	round		round		
Colour	brown red		brown red		
Markings tablet top side	5		5		
Markings tablet bottom side	VC		VC		
Identity (HPLC, retention time)	must comply		complies		
Identity (HPLC, UV-spectrum)	must comply		complies		
Uniformity of dosage, accept.value(n=10)	max. 15.0	%	2.5		
Uniformity of dosage, accept.value(n=30)	max. 15.0	%	---		
Uniformity of dosage, min.(based on M)	min. 75.0	%	---		
Uniformity of dosage, max.(based on M)	max. 125.0	%	---		
Dissolution aft.30min,6 s.units average	min. 85	%	101		
Dissolution aft.30min,6 s.units minimum	min. 85	%	100		
Dissolution aft.30min,12 s.units average	min. 80	%	---		
Dissolution aft.30min,12 s.u.minimum	min. 65	%	---		



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Dissolution aft.30min,24 s.units average	min. 80	%	---
Dissolution after 30min, 24 s.u. minimum	min. 55	%	---
Dissol.af.30min,24 s.u.numb.o.sing.val.	min.22 s.u.in min.65%		---
Any unspecified degradation product	max. 0.2	%	<= 0.1
Sum of all degradation products	max. 1.0	%	<= 0.1
Assay (based on label claim)	94.0 - 105.0	%	101.8
Total aerobic microbial count (TAMC)	max. 1000	CFU/g	<= 50
Total combined yeast/mould count (TYMC)	max. 100	CFU/g	<= 50
Escherichia coli	Absence in 1 g		not detectable in 1 g

This batch complies with the specification.

I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country /countries.

The release documentation is signed by the Qualified Person (Supply Center Leverkusen)

Batch release electronically signed:  
Date/time:  
Inspection lot:

Dr. Sabine Ullrich (PHULL)  
2025-07-16 07:46:40 a.m. CET ( UTC + 1 hour )  
040003064922