



Bayer AG Kaiser-Wilhelm-Allee  51368 Leverkusen, Germany	<b>Certificate of Analysis</b>		Page: 1 of 3 Date: 2025-06-23
Material: 88174941 Your material:	VERQUVO 10MG TAFI BLI 2X14 VERQUVO 10MG TAFI BLI 2X14		
Batch: BXK9RB1 Date of manufacture: 2025-02-04 Expiry date: 2028-02-29	Country: Chile Delivery number: 137389189 Order number: 720015166		
From material: 90298806 Batch: BXA9JLP Inspection lot: 040002973603	VERICIGUAT 10MG TAFI FL MINAKEM		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	yellow-orange		yellow orange
Markings tablet top side	10		10
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	%	1.8
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	%	100
Dissolution aft.30min,6 s.units minimum	min. 85	%	99
Dissolution aft.30min,12 s.units average	min. 80	%	---
Dissolution aft.30min,12 s.u.minimum	min. 65	%	---



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Inspection	Acceptance criterion	UoM	Result
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	%	100.5
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. Christian Wiese (GFRCI)  
2025-06-20 04:12:42 p.m. CET ( UTC + 1 hour )  
040003052667



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