



Synokem Pharmaceuticals Ltd.

Plot No. 56-57 Sector - 6 A, I.I.E, (Sidcul) Ranipur (BHEL) Haridwar (Uttarakhand) 249403
MFG Lic No. - 27/UA/2018 & 27/UA/SC/P-2018

The Drugs & Cosmetics Act 1940 and the Rules there under

CERTIFICATE OF ANALYSIS

Plant Code : 9002

Division : 10

AR. NO. : DGLF305058

MATERIAL CODE : 4010010826

MATERIAL NAME : RIVASmart 10MG

GENERIC NAME : Rivaroxaban Tablets BP 10 mg

BATCH NO. : 23S2GTC672

BATCH SIZE : 200000 TABLET

RECEIVED ON : 14.10.2023

STAGE : FINISH

MFG. DATE : Oct 2023

EXP. DATE : Sep 2025

SAMPLE SIZE : 70 TABLET

TEST	RESULTS	SPECIFICATION
DESCRIPTION	Light pink coloured, round, biconvex, film coated tablets, plain on both sides.	Pink to light pink coloured, round, biconvex, film coated tablets, plain on both sides.
IDENTIFICATION		
(A) BY HPLC	Complies	The UV spectrum of the principal peak in the chromatogram obtained with the test solution is similar to the UV spectrum of the principal peak in the chromatogram obtained with reference solution (a).
(B) BY HPLC	Complies	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (a).
AVERAGE WEIGHT	90.57 mg	85.50-94.50 mg
UNIFORMITY OF WEIGHT	-0.63%; +1.69%	±7.5%
DISINTEGRATION TIME	2 - 3 minutes	NMT 30 Minutes
UNIFORMITY OF DOSAGE UNIT		
BY CONTENT UNIFORMITY	3.06	Maximum acceptance value L1=15
DISSOLUTION	86.73 - 93.12%	NLT 80% (Q) of labeled claim to be dissolve in 30 minutes.
RELATED SUBSTANCES (BY HPLC)		
SINGLE MAXIMUM UNSPECIFIED IMPURITY BDL		NMT 0.20%
TOTAL IMPURITIES	BDL	NMT 0.30%
ASSAY: _		
Each film coated tablet on an average weight contains:		

PREPARED BY

[Signature]
18/10/2023
(Sign/Date)

Date of Completion

18/10/2023

CHECKED BY

[Signature]
18/10/2023
(Sign/Date)

APPROVED BY

[Signature]
18/10/2023
(Sign/Date)



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TEST	RESULTS		SPECIFICATION
Ingredients	Obtained	Claim	Limit
RIVAROXABAN BP	9.82 MG	10.00 MG	9.50-10.50 MG

REPORT : In the opinion of the undersigned the sample referred above is of standard quality as defined in the act & rules made there under

REMARKS : The above sample/Material is ☒ Complies/☒ Does not comply as per approved specification IP/BP/USP/IH/JP.

PREPARED BY

(Sign/Date)

Date of Completion

18/10/2023

CHECKED BY

(Sign/Date)

APPROVED BY

(Sign/Date)