




CERTIFICATE OF ANALYSIS		
PRODUCT: RIVAROXABAN		
BATCH:	ANALYSIS DATE: 24/06/2021	
ANALYTICAL CODE: PF21/110	CERTIFICATE DATE: 24/06/2021	
SPECIFICATION REFERENCE: Current Ph. Eur. 2932	MANUFACTURING DATE: 30/04/2021	
KINSY SPECIFICATION REFERENCE: ETP145, REV.9	RETEST DATE: 30/04/2024	
ANALYTICAL DATA		
<u>PARAMETER</u>	<u>SPECIFICATION</u>	<u>RESULT</u>
APPEARANCE	White to yellowish powder	Complies
IDENTIFICATION A	IR: Spectrum conforms to that of the reference standard	Complies
IDENTIFICATION B	Conforms with enantiomer purity test	Complies
IDENTIFICATION C	HPLC: Retention time of the mayor peak of the test solution corresponds to that of the reference solution as obtained in the assay	Complies
WATER CONTENT (KF)	NMT 0.5%	0.08%
SULPHATED ASH	NMT 0.1%	0.02%
HPLC CONTENT	98.0%-102.0% on anhydrous basis	101.0%
RELATED SUBSTANCES (HPLC)	Any unspecified imp: NMT 0.10% Sum of impurities: NMT 0.3%	<0.05% <0.05%
OPTICAL PURITY (HPLC)	Rivaroxaban Enantiomer R (Imp. A): NMT 0.5% area	<0.05%
RESIDUAL SOLVENTS (I) (GC HEADS SPACE)	Acetonitrile: NMT 410 ppm	Not detected
RESIDUAL SOLVENTS (II) (HPLC)	DMSO: NMT 5000 ppm	1295 ppm
MICROBIOLOGICAL CONTENT	TAMC: NMT 10 ³ cfu/g TYMC: NMT 10 ² cfu/g <i>E. coli</i> : absent/g	< 10 cfu/g < 10 cfu/g Absent/g
QUALITY ASSURANCE		
<p style="text-align: center;">REVIEWED BY:</p> <p style="text-align: center;"></p> <p>Name/charge JOSE CARLOS GUIRAO, QA det Date: 24.06.2021</p>	 A P P R O V E D	<p style="text-align: center;">APPROVED BY:</p> <p style="text-align: center;"></p> <p>Cristina Salinas / Q.A. Manager Date: 24.06.2021</p>

CoA, rev.6