



Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
DRUG REGULATORY AUTHORITY OF PAKISTAN
TF Complex, Sector G-9/4, Islamabad

“SAY NO TO CORRUPTION”

Updated till: 10th November 2020.

**LIST OF APPROVED BA/BE STUDIES,
UNDER THE BIO-STUDY RULES 2017.**

S.No.	Registration No.	BA/BE Studies	License Number	BA/BE Study Site	Status
01	BA/BE-0001	A Single Center, Open Label, Randomized, Single Dose, Two way Cross-over study to explore the Bioequivalence of Lamnet (Lamotrigine) 100mg tablet with the reference product Lamictal (Lamotrigine) 100mg tablet under fasting condition in healthy Pakistani male subjects.	BA/BE-0002	Center for Bioequivalence Studies and Clinical Research (CBSCR), International Center for Chemical and Biological Sciences (ICCBS), University of Karachi,	Approved. Dated 28 th August 2020.
02	BA/BE-0002	A Single Center, Open Label, Randomized, Single Dose, Two way cross-over study to explore the Bioequivalence Xaroban (Rivaroxaben) 20mg Tablet with reference product Xarelto (Rivaroxaben) 20mg Tablet under the fed conditions in Healthy Male Pakistani Subjects.	BA/BE-0002	Center for Bioequivalence Studies and Clinical Research (CBSCR), International Center for Chemical and Biological Sciences (ICCBS), University of Karachi,	Approved. Dated 28 th August 2020.
03	BA/BE-0003	A Single Center, Open Label, Randomized, Single Dose, Two Period, Two way Cross-over Study to explore the Bioequivalence Vaplor	BA/BE-0002	Center for Bioequivalence Studies and Clinical Research (CBSCR),	Approved. Dated 28 th August 2020.

		(Rosuvastatin) 20mg Tablet and Crestor (Rosuvastatin) 20mg Tablet under the fasting conditions in Healthy Male Pakistani Subjects.		International Center for Chemical and Biological Sciences (ICCBS), University of Karachi,	
04	BA/BE-0004	A Single Center, Open Label, Randomized, Single Dose, Two-way Cross-over Study to explore the Bioequivalence of ANPLAG (Ticagrelor) 90mg Tablets (M/s Pharm Evo (Pvt) Ltd.) with the reference product Brilinta 90 mg Tablet (M/s Astra Zeneca Pharmaceuticals, USA) under fasting conditions in healthy male Pakistani subjects	BA/BE-0002	Center for Bioequivalence Studies and Clinical Research (CBSCR), International Center for Chemical and Biological Sciences (ICCBS), University of Karachi,	Approved. Dated 28 th August 2020.

* errors and omission excepted.