ZABITA®

Rivaroxaban

Appropriate Balance of Efficacy and Safety

- Superior protection against DVT, PE and VTE prevention[1]
- Simple dosing with once daily profile[1]
- Good safety profile with low rate of major bleeding[1]
- Rapid absorption[1]
- No dose adjustment in adult patients[1]
- No routine coagulation monitoring[1]
- No dietary restrictions[1]

Highest Quality API Approved by USFDA[2]

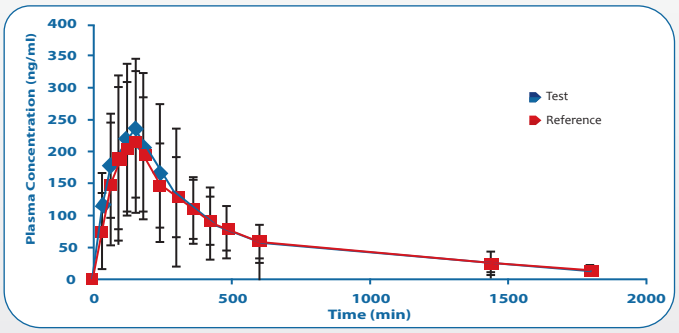
How do we assure the quality of ZABITA®?

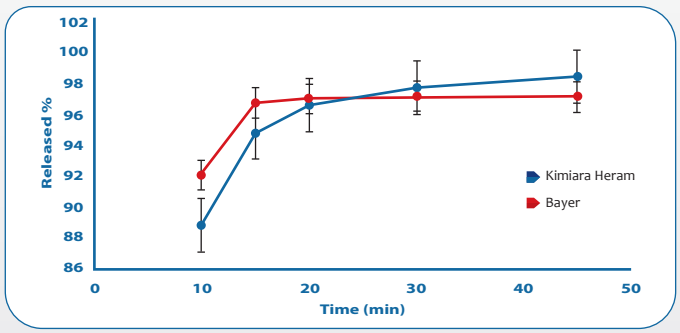
According to comparative studies named BIOEQUIVALENCE :

- The test product is claimed to be bioequivalent to the reference product if the calculated 90% confidence interval around the ratio of geometric means of the primary study endpoint (AUC* or Cmax**) is totally within the bioequivalence limits of 80% to 125%.[3]

Kimiara Heram Company has done Bioequivalence Studies for ZABITA® with objective of pharmacokinetic parameters comparison with brand[4]

ZABITA® Bioequivalence Studies





In Vivo Study Design:

- Assessment of the rate and extent of absorption based on plasma concentration data
- Randomized, double-blind, crossover, 2 treatments,2 sequences, 2 periods with two week wash out between each treatment
- Test Product: ZABITA® Manufactured By: Kimiara Heram
- Reference Product: Xarelto® Manufactured By: Bayer
- 24 healthy adult male volunteers / receiving a single oral dose under fasting condition

Result:

Mean Concentration-time profile of Rivaroxaban after administration of 20 mg single dose of Zabita® and Brand was similar

In Vitro Study Design:

Comparing the release profiles of Zabita® 20 mg with Xarelto® 20 mg (Originator's product) based on dissolution rate data.

Result:

Both formulations are considered as very rapid dissolving sine more than 85% dissolved in less than 15 min and two formulations considered similar

ZABITA® was found to be bioequivalent with the originator based on the FDA requirements for bioequivalence studies.[4]

ZABITA® is high qualified Rivaroxaban which its API is supplied by NEULAND Co. with FDA approved manufacturing line.[2]

References:

1. Uptodate.com
2. Neulandlabs.com
3. Chow SC , Endrenyi L, Chi E , Yang LY, Tothfalusi L. (2011). Statistical Issues in Bioavailability/Bioequivalence Studies, Journal of Bioequivalence & Bioavailability.S1 . 1-8 .
4. Bioequivalence study of Zabita has been done by TAM POUYA research and consulting Co.

* Area under the plasma concentration-time curves
** The peak plasma concentration

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