



“RACING WITH GLOBAL GIANTS”



No. 1 ranking in USA DMF filings with world wide expansion

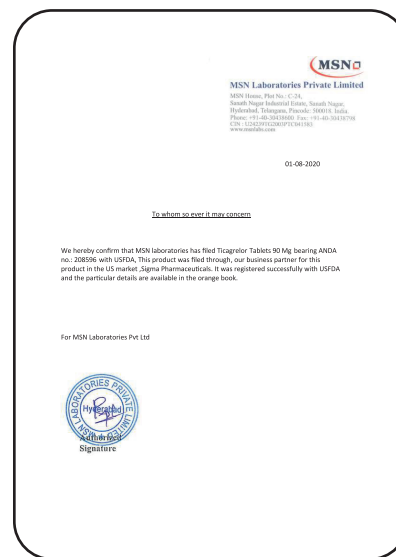
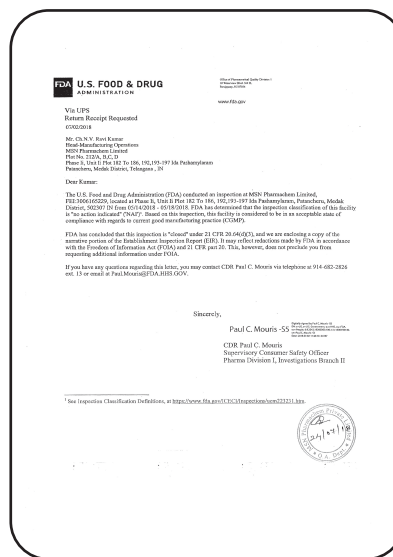
Sourcing of all the major U.S generic pharmaceutical companies by MSN's finished APIs

Asia's biggest state of R&D center with 1400 dedicated scientists & 42 scientific labs

Introduced 17 first in the world generics

Regulatory Accreditations:

● USFDA ● WHO:GMP ● EUGMP ● Germany FDA ● Korean FDA



References:

1. www.msnlabs.com
 2. Chow SC, Endrenyi L, Chi E, Yang LY, Tothfalusi L. (2011). Statistical Issues in Bioavailability/Bioequivalence Studies, Journal of Bioequivalence & Bioavailability, SI, 1-8.
 3. Bioequivalence study of Ticagrelor has been done by Accutest Research Laboratories (I) Pvt. Ltd. (Unit-I).
- * Area under the plasma concentration-time curves
** The peak plasma concentration



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Excellent



Quality

Good

Average

Brelor[®] 90 is a high-profile Ticagrelor brand in Iran market due to:

- USFDA approved API
- Supplied from **MSN** pharmaceutical company which is first in the world in active US DMF filings¹
- Formulated under technical supervision of **MSN** labs (Dossier ANDA No. 208596)
- Bioequivalent to originator based on BE studies



Brelor

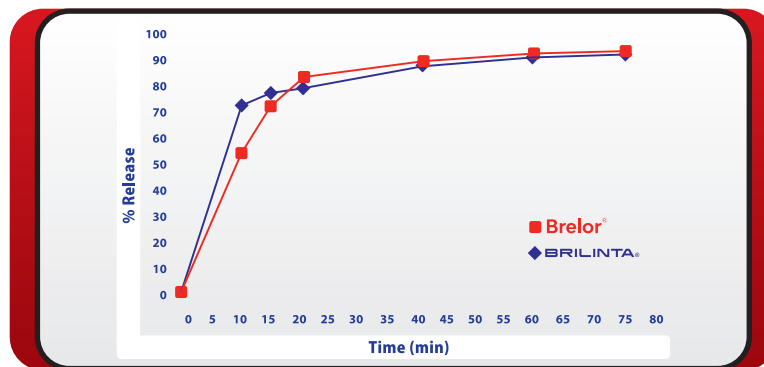
How do we assure **Brelor[®] 90** quality ?

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%.²

Brelor[®] 90 is therapeutically equivalent to the originator based on Bioequivalence Studies with objective of pharmacokinetic parameters³

In vitro study



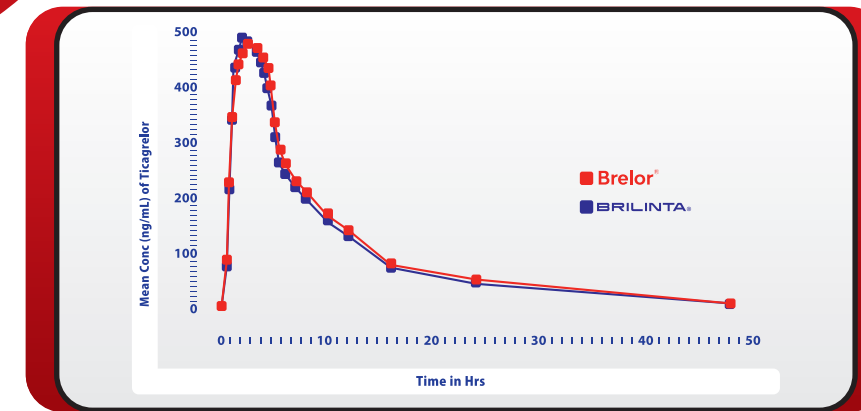
Objective

Comparing the release profiles of **Brelor[®] 90** with **BRILINTA[®] 90** based on dissolution rate data

Result

Brelor[®] 90 is equivalent to the originator based on release profile

In vivo study



Objective

Assessment of the rate and extent of absorption based on plasma concentration data

Study design

- Randomized, open label, balanced, 2 treatments, 2 periods, 2 sequences, single dose, crossover design with 10 day wash out between each study period
- Test Product: MSN Ticagrelor
- Reference Product: AstraZeneca Ticagrelor
- 43 healthy, adult, male and female volunteers /receiving Ticagrelor under fasting condition

Result

Brelor[®] 90 is equivalent to the originator based on blood absorption profile

Conclusion

- **Brelor[®] 90** was found to be bioequivalent to the originator based on the FDA requirements for bioequivalence studies
- **Brelor[®] 90** high quality makes it a reliable replacement for Brilinta