الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Ticagard®

Type of Product: Generic Drug.

Active Pharmaceutical Ingredient(s): Ticagrelor.

ATC code: B01AC24.

Dosage Form: Film-coated tablet.

Dosage Strength: 90 mg.

Pack Size: 30.

Shelf life: 36 Months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA: Brilinta®

Marketing Authorization Holder: Al Razi Pharma Industries.

Manufacturer: Msn Laboratories Private Limited.

Registration No.: 2301244792.

Date of Decision: 23/01/2024

Proposed Indications:

Ticagrelor Tablets, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndromes (ACS) or a history of myocardial infarction (MI) and a high risk of developing an atherothrombotic event.

Product Background

This product is considered as a human generic drug for Saudi regulatory purposes qualified to follow the SFDA's regular generic review regulatory pathway.

The SFDA approval for Ticagard® 90 mg film-coated tablet is based on a review of the quality, safety and efficacy of the product provided as an e-CTD in accordance with the relevant guidelines, basic product information summarized hereinafter:

Quality aspects

Drug Substance:

Ticagrelor is a white or almost white to pale pink powder, practically insoluble in water, freely soluble in methanol, soluble in anhydrous ethanol and practically insoluble in heptane. Ticagrelor contains six chiral centres and herewith exhibits isomerism. The active substance exhibits polymorphism. The polymorphic form (Form II) has been demonstrated to remain stable. It is not impacted by micronisation.

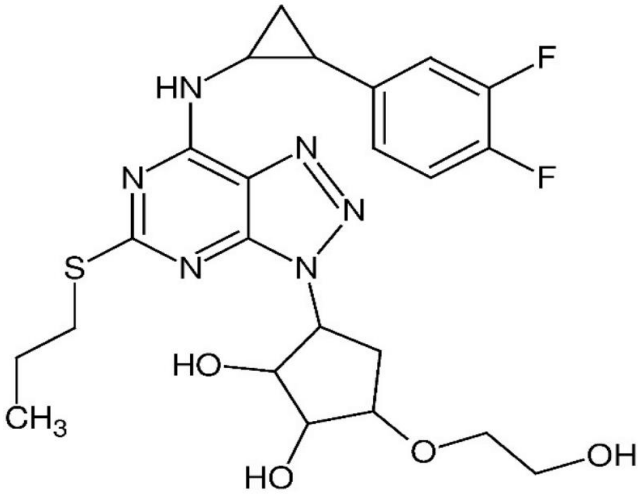

FIGURE 1: TICAGRELOR STRUCTURE

The manufacturing process had been described in sufficient details, the selected starting materials had been justified and are in line with principles of *ICH Q11 guidlines*. The active substance specifications, which are in line with the *Ph. Eur. monograph* for Ticagrelor, are considered adequate to control all the required quality parameters. The batch analyses data provided from the

drug substance manufacturer and from the finished product manufacturer for sufficient number of batches of ticagrelor, demonstrate compliance with the proposed specifications.

The stability studies had been conducted in line with *ICH relevant guidelines*. The proposed retest period is for both micronized and non-micronized API are supported by the provided stability data.

Drug Product

The finished product is available as film coated tablets. Each tablet contains 90 mg of Ticagrelor. The composition of the drug product is adequately described, qualitatively and quantitatively. Suitable pharmaceutical development data have been provided for the finished product composition and manufacturing process.

The chosen manufacturing process is a conventional wet granulation process, described in sufficient details. The drug product manufacturer's specifications are in line with the *ICH Q6A guidelines.* The analytical procedures have been sufficiently described and the in-house analytical procedures have been fully validated.

The drug product is packaged in a transparent PVC/PVdC-Alu blister. Stability studies are carried out in accordance with current relevant guidelines. Based on the available stability data, the proposed shelf-life of 36 months at 30°C is justified.

Bioequivalence Study

Ratio and 90% Confidence Intervals (CI) of Ticagard® (Ticagrelor) 90 mg Tablet versus Brilinta® (Ticagrelor) 90 mg Tablet:

Pharmacokinetic Parameter	**Point Estimate**	**90% CI**
C_{max} (ng/mL)	105.6270	100.1358 - 111.4192
AUC_{0-t} (ng/mL)	105.5865	100.9363 - 110.4509
$AUC_{0-\infty}$ (ng/mL)	106.0710	101.6697 - 110.6628

Based on the results obtained in this study, Ticagard® (Ticagrelor) 90 mg of MSN Laboratories Private Limited, India, is **bioequivalent** to Brilinta® (Ticagrelor) 90 mg of AstraZeneca, Sweden under fasting Conditions.

Product Information

The approved Summary of Product Characteristics (SPC) with the submission can be found in Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

The date of revision of this text corresponds to that of the Saudi PAR. New information concerning the authorized medicinal product in question will not be incorporated into the Saudi PAR. New findings that could impair the medicinal product's quality, efficacy, or safety are recorded and published at (SDI or Summary Saudi-PAR report).

For inquiry and feedback regarding Saudi PAR, please contact us at Saudi.PAR@sdfa.gov.sa