الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Saudi Public Assessment Report

(Summary Report)

Ticagrelor SPC® film coated tablets

Type of Product: Human Generic Drug.

Active Pharmaceutical Ingredient(s): Ticagrelor.

ATC code: B01AC24.

Dosage Form: Film-coated tablet.

Dosage Strength: 90 mg.

Pack Size: 30 tablets.

Shelf life: 36 Months.

Storage Conditions: Do not store above 30°C.

Reference Product in SA: Brilinta®

Marketing Authorization Holder: Sudair Pharma Company.

Manufacturer: MSN Laboratories Private Limited.

Registration No.: 2205233681

Date of Decision: 22/05/2023

Proposed Indications:

Ticagrelor SPC Tablets, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with

- Treatment of patients with acute coronary syndromes (ACS).
- Treating patient with 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 regulatory Regular pathway

The SFDA approval for Ticagrelor® SPC 90 mg F.C. tablets is based on a review of the quality, safety and efficacy of the product information -which provided as an e-CTD- in accordance with the relevant guidelines as summarized hereinafter:

Quality information:

Drug Substance

The active pharmaceutical ingridient in Ticagrelor® 90 mg is Ticagrelor which is a triazolopyrimidine that is an adenosine isostere; the cyclopentane ring is similar to ribose and the nitrogen-rich [1,2,3]triazolo[4,5-d]pyrimidine moiety resembles the nucleobase adenine. A platelet aggregation inhibitor which is used for prevention of thromboembolic events in patients with acute coronary syndrome. It has a role as a platelet aggregation inhibitor and a P2Y12 receptor antagonist. It is a member of triazolopyrimidines, an organofluorine compound, an aryl sulfide, a secondary amino compound and a hydroxyether as shown in the structure below.

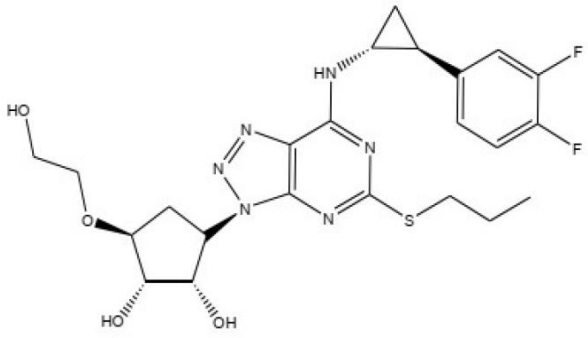

FIGURE 1: TICAGRELOR STRUCTURE

Ticagrelor is a white or off-white to pale pink powder freely soluble in N,N-dimethyl formamide, slightly soluble in Methanol and practically insoluble in Water. Polymorphism has been observed, The manufacturing process employed by the manufacturer is consistently produces the Form-II of drug substance Ticagrelor. Ticagrelor (Form-II) consists of six chiral centers and hence it exhibits stereoisomerism.

The drug substance is manufactured by a multiple-step chemical synthesis, validation of Ticagrelor (Form-II) manufacturing process has been performed on a prospective basis, according to cGMP principles and the international guidelines on validation. Moreover the manufacturing process has been ensured for reproducibility through consistent manufacturing of Ticagrelor (Form-II) drug substance to the predetermined specifications.

The drug substance specification includes relevant tests for proper quality control. The control methods are validated according to international guidelines.

Appropriate stability studies have been conducted and data have been presented support the and justify the established re-test period.

Drug Product

The finished product is available as yellow, round, biconvex, film coated tablets, debossed with "M" on one side and '90" on other side. Each tablet contains 90 mg of Ticagrelor,the composition of the drug product is adequately described, qualitatively and quantitatively. comprehensive pharmaceutical development data had been provided for the finished product composition and manufacturing process is described narratively and in sufficient detailes.the batch manufacturing formulas and in-process controls are included.

Excipient used in the manufacturing of Ticagrelor Tablets 90 mg were provided. Specification of these excipients are based on the respective Pharmacopoeial monographs. The pharmacopoeial excipients shall be tested in line with the limits specified in the current version of the monograph in the pharmacopoeia.

The drug product specification covers appropriate parameters according to the *ICH Q6A guidline* for this dosage form which allow for proper control of the finished drug product. The control methods are validated according to international guidelines. Batch data show consistent quality of the drug product.

Each 10 Tablets of Ticagrelor Tablets 90 mg are sealed with Clear PVC/PVdC base foil on one side and plain peel push Lidding foil on other side in the form of a Alu-PVC/PVdC blister pack and such blisters are further packed in printed carton along with instructions for use.

The Stability Studies are carried out as per *ICH – Q1 Guidelines*, stability data had been generated in the packaging material intended for commercial use and following relevant international guidelines. The data show good stability of the finished product and support the shelf life of 36 months at not more than 30ºC.

Bioequivalence Study

Ratio and 90% Confidence Intervals (CI) of Ticagrelor SPC® (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, Ticagrelor SPC® (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