Saudi Public Assessment Report

Turbo®

Active Pharmaceutical Ingredient(s): Sildenafil

ATC code/CAS no.: G04B E03

Pharmaceutical/Dosage Form: Orodispersible Tablets

Film Coated Tablets

Dosage Strength: Orodispersible Tablets: 50 mg

Film Coated Tablets: 50 mg - 100 mg

Marketing Authorization Holder: Medical and Cosmetic Products Company Ltd. (Riyadh Pharma)

Shelf life: 24 months

Storage conditions: Store below 30° C

Registration No.: 1307210863 - 271-325-16

Decision and Decision Date: Approved on 28/07/2021

Table of Contents

1. Terms, Definitions, Abbreviations

Terms	Definitions
AUC_{0-t}	Area under the concentration-time curve (time 0 to time of last quantifiable concentration
$AUC_{0-\infty}$	Area under the serum concentration-time curve from time 0 to infinite time
C.I	Confidence Intervals
C_{max}	Maximum serum concentration
GCC	Gulf Cooperation Council
GCP	Good Clinical Practice
GLP	Good Laboratory Practices
INN	International Nonproprietary Names
KSA	Kingdom of Saudi Arabia
SFDA	Saudi Food and Drug Authority
SA	Saudi Arabia
SDI	Saudi Drug Information System
SFDA	Saudi Food and Drug Authority
SPC	Summary of Product Characteristics
USAN	United States Adopted Names

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2. Background

2.1 Submission Details

Type of submission: Human Generic Drug

Reference product in SA: VIAGRA 50 mg orodispersible tablet

Pharmacological class: Urologicals; drugs used for erectile dysfunction

Submitted Indication: TURBO is indicated in adult men with erectile dysfunction, i.e. with the inability to reach or to maintain an erection suitable for satisfactory sexual activity. Sexual stimulation is required for TURBO to be effective

2.2 Regulatory Background

This product is considered a human generic drug for Saudi regulatory purposes. Furthermore, this product is qualified to follow the regular review pathway.

2.3 Product Information

The officially approved Summary of Product Characteristics (SPC) can be accessed via Saudi Drug Information System (SDI) at: https://sdi.sfda.gov.sa/

3. Scientific discussion about the product:

3.1 Quality Aspects

3.1.1 Drug Substance

- Sildenafil citrate is a white or almost white, slightly hygroscopic crystalline powder. Sildenafil citrate is slightly soluble in water and methanol, practically insoluble in hexane. Sildenafil citrate does not have any chiral centers. Polymorphism has been observed.
- The drug substance is manufactured by multiple-step chemical synthesis.
- The structure of sildenafil citrate has been fully elucidated using several spectroscopic techniques.

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

- Appropriate stability data have been presented and justified the established re-test period.

3.1.2 Drug Product

- Turbo 50 mg orodispersible tablet is available as a white to off white colored, diamond shaped tablet, debossed with “CT42” on one side and plain on the other side. Each tablet contains 50 mg of sildenafil (70.225 mg of sildenafil citrate is equivalent to 50 mg of sildenafil). 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 manufacturing process is described narratively and in sufficient detail, taking into account pharmaceutical development data. Batch manufacturing formulas and in-process controls are included.

- The drug product specification covers appropriate parameters 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 a consistent quality of the drug product.

- The drug product is packaged in a carton box, containing one or two Alu/Alu blisters, with 4 tablets in each blister.

- Appropriate stability data have 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 (24 months).

3.2 Clinical Aspects

3.2.1 Bioequivalence study

A randomized, open label, two-treatment, two-period, two-sequence, single dose, crossover, bioequivalence study of Turbo® (Sildenafil citrate) 100 mg of Riyadh pharma, KSA and Viagra® (Sildenafil citrate) 100 mg of Pfizer, UK, in healthy human adult subjects, under fasting condition. The study was conducted in accordance with GCC Guidelines for Bioequivalence, standards of Good Clinical Practice (GCP) and Good Laboratory Practices (GLP).

Blood samples were taken pre-dose (0.0) and at specified time points up to 24 hours after administration of test or reference product. Plasma levels of Sildenafil were detected by a validated LC-MS/MS method.

Twenty four (24) volunteers completed the study and all data were analyzed. No significant protocol deviations were reported. There were no serious adverse events reported in the study.

The ratio and 90% Confidence Intervals of Test versus Reference for Sildenafil are tabulated below:

Table 1: Ratio and 90% Confidence Intervals (C.I) of Test versus Reference for Sildenafil:

Pharmacokinetic Parameter	**Point Estimate**	**90% Confidence Intervals (%)**
C_{max}	110.15	97.57 - 124.34
AUC_{0-t}	94.41	87.88 - 101.43
$AUC_{0-\infty}$	93.49	87.01 - 100.45

Based on the results obtained in this study, Turbo® (Sildenafil citrate) 100 mg of Riyadh pharma, KSA is **bioequivalent** to Viagra® (Sildenafil citrate) 100 mg of Pfizer, UK, under fasting conditions.

4. Risk Management Plan

4.1 Artwork and Trade Name assessment (Artwork available in appendix)

Proposed trade Name	Dosage Form
Turbo	Orodispersible

Look –alike/Sound-alike (LA/SA) Error Risk Potential:

Turbo name LA/SA confusion risk potential has been assessed based on the evaluation of LA/SA similarities from our data sources (SFDA registered Drug List, Martindale, ISMP Confused Drug Name List, INN International Nonproprietary Names and USAN United States Adopted Names STEM) and the pharmaceutical characteristic of the product:

LA/SA for Product name	SFDA	Shared File/ Excel Sheet	Martindale	Stem Book 2018
Turbo	NO	NO	NO	NO

Trade Name Recommendation:

Based on the submitted data, the proposed name Turbo is accepted.

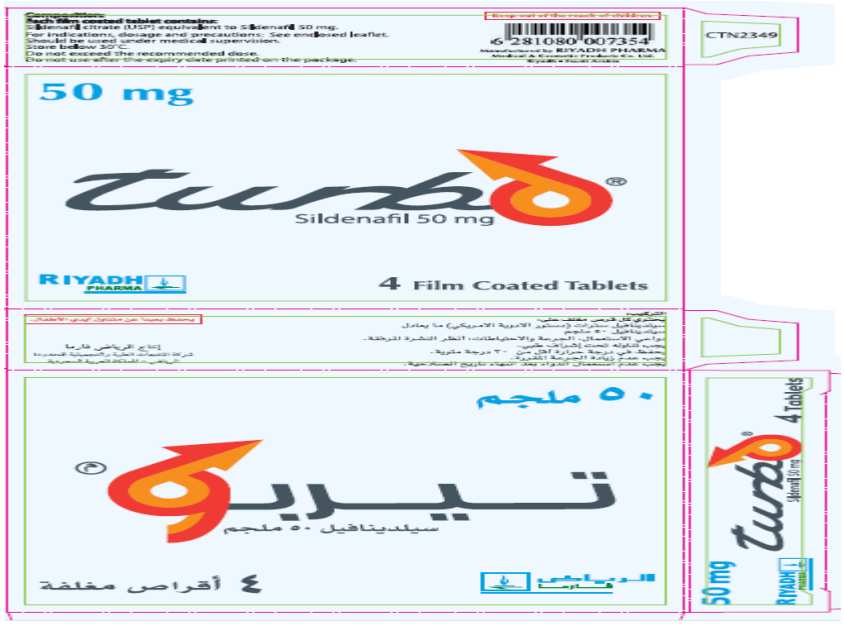
Outer and Inner Package:

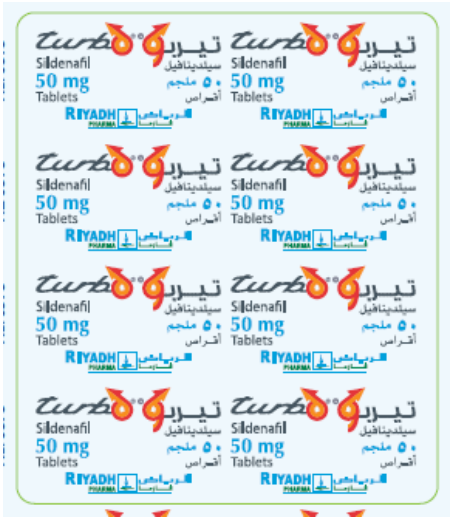
Based on the submitted data, the proposed artwork is accepted.

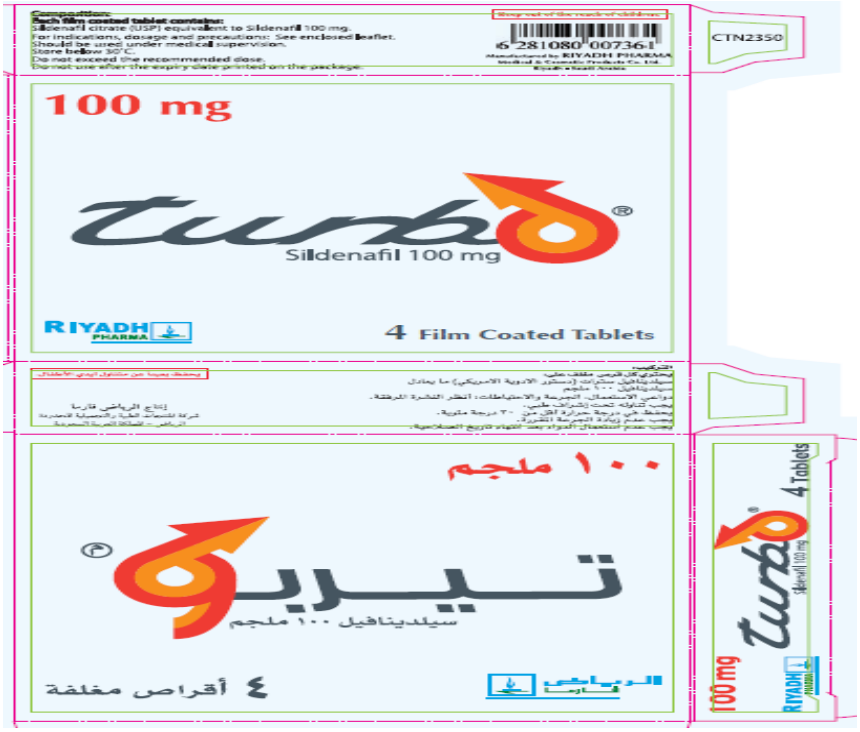
5. Overall Conclusion

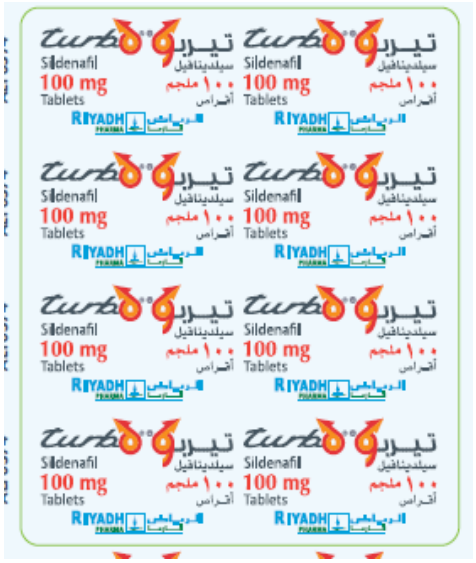
Based on data reviewed from a quality, safety and efficacy perspective, the SFDA considered that the benefit/risk profile of TURBO was favorable and decided to grant the marketing authorization. TURBO is indicated in adult men with erectile dysfunction, i.e. with the inability to reach or to maintain an erection suitable for satisfactory sexual activity. Sexual stimulation is required for TURBO to be effective.

6. Appendix









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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 only at SDI.

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

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