THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

PUBLIC ASSESSMENT REPORT FOR TELDAY H (TELMISARTAN 40 MG AND HYDROCHLOROTHIAZIDE 12.5 MG) TABLETS

Version number 1.0
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1. Introduction

TELDAY H is a generic medicine of Telmisartan and Hydrochlorothiazide tablets. TELDAY H is an antihypertensive medicine belonging to C09DA07 - Angiotensin II antagonists and diuretics group. TELDAY H exerts is activity by antagonizing angiotensin II receptor subtype 1 (AT_1) and diuresis . TELDAY H is approved in Tanzania for use in adults.

Product details

Registration number	TAN 20 HM 0397
Brand name	TELDAY H
Generic name, strength and form	Telmisartan 40 mg and Hydrochlorothiazide 12.5 mg tablets
ATC classification	C09DA07 - Angiotensin II antagonists and diuretics
Distribution category	POM
Country of origin	India
Associated product	Not applicable
Marketing Authorization Holder	Torrent Pharmaceuticals Limited (TPL) Torrent House Off. Ashram Road Ahmedabad-380 009 Gujarat, India.
Local Technical Representative	Phillips Distributors Ltd P O Box 737, Dar-es-Salaam, Tanzania Cell: +255 784139240

1.1 Assessment procedure

The application for registration of TELDAY H was submitted on 2013. The product underwent full assessment. Assessment was completed in 2 rounds of evaluation. TELDAY H was registered on 25/09/2020.

1.2 Information for users

Visual description of the finished product	Biconvex two layered capsule shape, uncoated with Telmisartan as a white or off white to yellowish but may contain yellow specks and Hydrochlorothiazide layer as a pink but may contain white specks, plain on both sides
Primary packing material	Alu-Alu blister strips
Secondary packing materials	
Shelf-life and storage condition	24 Months Store below 30ºC, Protected from moisture
Route of administration	Oral

Effective date: 03/10/2022

Therapeutic indications	Treatment of essential hypertension. TELDAY H is indicated in adults whose blood pressure is not adequately controlled on telmisartan alone.

2. Labelling and product information

Summary of product characteristics
The SmPC included all the relevant information to ensure correct and safe use of the medicine by healthcare providers. The complete SmPC can be accessed here.

Package insert/leaflet
The package insert is confirmed to be derived from the SmPC and contains sufficient data for the end user. Since the product is POM that is intended for long term use, the package insert contains full prescribing information as per SmPC.

Container labels
The product label information is presented in English/Swahili>. Details in the secondary pack label include:
Brand name:
Composition: <generic name & strength, list of excipients (if applicable)>
Pack size: <primary & secondary pack>
Manufacturing details: <batch number, manufacturing date, expiry date>
Storage conditions: <state the condition as it appears on the label>
Manufacturer address: <physical address of release site>
Unique identifier: <state the unique identification used>
Special warnings/precautions or instructions for use: <include warnings or IFU if applicable>

The details of the primary pack include:
Brand name and strength:
Manufacturing details: <batch number, manufacturing date, expiry date>
Name of manufacturer: <name only>

The content of the primary and secondary labels was aligned to the requirements of the Part V of the Compendium: Guidelines on Format and Content of Product Labels for Medicinal products. The label contains sufficient information for proper identification of the medicine and post marketing follow up of the product.
Describe any approved deviation to the requirements and the justification for the deviation.

3. Scientific discussion

Quality of Active Pharmaceutical Ingredient(s)

Telmisartan
Information on quality of the API was submitted in form of CEP.

General properties
Telmisartan API is compendia in BP.

Molecular formula:
Chemical name:
Structure:

Critical physico-chemical properties of the API were <solubility, particle size, polymorphism>.

Manufacture
The API manufacturing sites, Matrix Laboratories Limited (UNIT 3), Plot No 38 to 40, 49 to 51, Phase IV IDA Jeedimetla, Hyderabad, Andhra Pradesh, India and Torrent Pharmaceutical Limited (TPL), Ahmedabad-Mehsana Highway, Taluka – Kadi, District: Mehsana, Indrad, Gujarat, India were noted to comply with WHO GMP requirements as evidenced by the GMP certificate issued by <state the issuing authority>. Telmisartan API is manufactured by <chemical/fermentation> synthesis using <conventional/novel> techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications
The API specifications were set as per <USP/BP/JP/International Ph/in-house> standards and ICHQ3A. The parameters monitored during quality control are: <list the specification tests>. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system
The <shelf-life/re-test> period of <molecule> API is <number> months when packed in <container closure system> and stored at <storage conditions>.

Hydrochlorothiazide
Information on quality of the API was submitted in form of CEP.

General properties
Hydrochlorothiazide API is compendia in BP.
Molecular formula:
Chemical name:
Structure:

Critical physico-chemical properties of the API were <solubility, particle size, polymorphism>.

Manufacture
The API manufacturing site, Unichem Laboratories Limited, Plot no 99, MIDC Area, Dhtav-Roha, Dist-Raigad-402 116 India was noted to comply with WHO GMP requirements as

evidenced by the GMP certificate issued by <state the issuing authority>. Hydrochlorothiazide API is manufactured by <chemical/fermentation> synthesis using <conventional/novel> techniques. Sufficient controls of quality of materials and in-process checks were employed throughout the manufacturing process.

Specifications

The API specifications were set as per <USP/BP/JP/International Ph/in-house> standards and ICHQ3A. The parameters monitored during quality control are: <list the specification tests>. Compliance to these specifications were established via batch analysis data and stability studies.

Stability and container closure system

The <shelf-life/re-test> period of <molecule> API is <number> months when packed in <container closure system> and stored at <storage conditions>.

Quality of the Finished Pharmaceutical Product

Formulation

TELDAY H is a biconvex two layered capsule shape, uncoated with Telmisartan as a white or off white to yellowish but may contain yellow specks and Hydrochlorothiazide layer as a pink but may contain white specks, plain on both sides. TELDAY H contains Telmisartan and Hydrochlorothiazide and other ingredients listed hereafter mannitol, sodium hydroxide, meglumine, polyvinylpyrrolidone (PVP K30), sodium stearyl fumarate, lactose monohydrate, hydroxy propylmethyl cellulose (3 Cps) and ferric oxide. The quantities of all ingredients are confirmed to be in line with the recommendations of Handbook of Pharmaceutical Excipients, Edition number in terms of function and quantities. Ingredient, <excipient> is of safety concern therefore appropriate warnings were included in the product label.

Manufacture

The finished product was manufactured at Torrent Pharmaceutical Limited (TPL), Ahmedabad-Mehsana Highway, Taluka – Kadi, District: Mehsana, Indrad, Gujarat, India. The compliance of the site to TMDA GMP standards was confirmed through site inspection on 19 - 20 August 2019.

Specifications

The FPP is non-compendia. The manufacturer controls the quality of the finished product as per in-house and ICHQ3B requirements. The parameters monitored during quality control are: <list the specification tests>. Compliance to the standard was established using batch analysis data and stability data.

Stability and container closure system

Stability studies were conducted on 3 batches of the finished product stored at 30ºC ± 2/75 ±5% RH for 24 months and 40ºC ± 2/75 ±5% RH for 6 months. Based on the stability data presented, the approved shelf-life is 24 months when stored in Alu-Alu blister strips at below 30ºC.

Safety and efficacy information

Safety and efficacy of TELDAY H was established through biowaiver application.

Comparative dissolution> report number <number> was submitted.

The biowaiver was approved based on additional strength.

TELDAY H fulfilled the criteria for waiving an in-vivo bioequivalence study as per relevant TMDA guidance. Dissolution profiles of TELDAY H (Telmisartan Hydrochlorothiazide 40mg/12.5mg tablets was compared to Telmisartan Hydrochlorothiazide 80mg/25mg. Less than 85% of the labelled amount of Telmisartan and Hydrochlorothiazide had dissolved in all three media. Therefore, necessitating calculation of similarity factor f2, which was noted to be above 50.

4. Benefit-Risk Assessment and Conclusion

On basis ofthe data submitted, the current state of knowledge and compliance to Good Manufacturing Practice, the benefit of the product outweighs the risks associated with its use when used in accordance to the summary of product characteristics. TELDAY H is recommended for registration.

5. Post-approval updates

Variation applications

Reference number	Date submitted	Change requested	Recommendation	Granting date

Feedback from pharmacovigilance, post marketing surveillance and enforcement activities

Type of feedback	Impact	Response

Re-registration applications

Application for renewal of registration was submitted on <DDMMYYYY>. The application was finalized in <number> rounds of evaluation. The product was confirmed to still be compliant to the standards of quality, safety and efficacy, hence registration was renewed on <DDMMYYYY>.

PART 5: CHANGE HISTORY

Version number	Date	Description of update	Section(s) Modified	Approval date

Annex I: Mock up label