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Method Development and Validation for the estimation of Azilsartan in Bulk and Pharmaceutical Dosage Form by using HPLC

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Abstract: ***A simple, sensitive and rapid stability indicating HPLC method was developed and validated for the determination of Azilsartan in bulk and pharmaceutical dosage form. The method was developed by HPLC using a Inertsil C18 (250x4.5mm ID) 5µm column in a isocratic mode with mobile phase constituted by buffer: Methanol and water, p^H 3.5 flow rate was 1.0ml/min, column temperature at 20-25°C, UV detection wavelength 240nm and 20µL of injection volume. The retention time of Azilsartan was 3.084min. The validation parameters were in accordance with ICH specifications, assay exhibited a linear range of 50-250µg/ml with regression coefficient 0.998. The limit of detection and quantification were 0.46 µg/ml and 1.42 µg/ml. Accuracy was between 98-102%. The drug was subjected to various stress conditions like peroxide, photolytic, acidic, alkaline, thermal degradations. Stress study of Azilsartan was found susceptible to degrade under hydrolytic (acid and base) conditions. The proposed method has stability indicating the resolution of the main peak from their degradation peak.***

Keywords: *Azilsartan, Water, Methanol, HPLC.*

1. INTRODUCTION

Azilsartan Medoxomil is an Angiotensin II Receptor Antagonist indicated for the Treatment of mild to moderate essential hypertension. Azilsartan Medoxomil is a prodrug of Azilsartan marketed as "edarbi" by takeda.

1.1 Preparation of Standard Solution

10 mg Of Azilsartan Was Weighed and Transferred In To 100 ml Volumetric Flask And Dissolved In Mobile Phase And Then Make Up To The Mark With Mobile Phase And Prepare 10 µg /ml Of Solution By Diluting 1ml To 10ml With Mobile Phase.

1.2 Preparation of Sample solution

Sample Name: Azilsartan Medoxomil Tablets 40 mg
Crush 20 Tablets Then Weigh A Quantity of Powder Equivalent To 40mg Of Azilsartan And Transferred In 100 ml Volumetric Flask and Add 70ml Of Mobile Phase Then Sonicated It For 30min Intermittent Shacking After 30min Make Up Volume with Mobile Phase. Pipetted 5 ml of the Clear Solution in to 50 ml Volumetric Flask and Make Up Volume With Mobile Phase. Filter The Solution Through 0.45µm Filter Paper. The Resulting Solution Is Used to Record the Chromatogram

2. TABLE

1	Mobile phase	Methanol: Water
2	Column	Inertsil C18 Column (250*4.5 mm &1.5mm)
3	Flow rate	1.0 mL/min
4	Column temperature	Room Temperature (20-25°C)
5	Wavelength	240 nm
6	Injection volume	20 µl
7	Run time	8 min
8	Retention time	3.084min

3. FIGURES

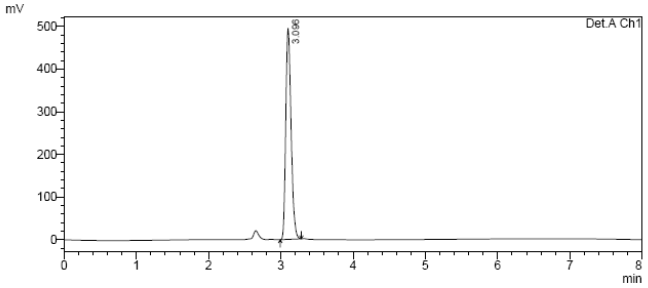

Fig. 1. Chromatogram of Assay Standard-01

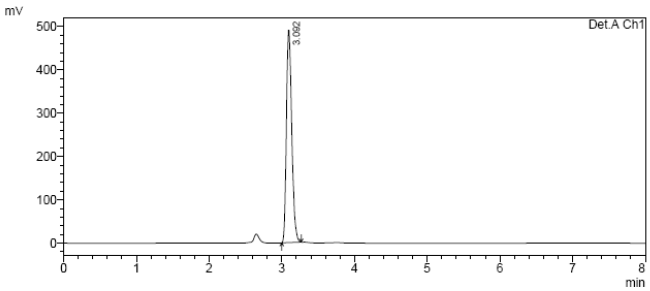

Fig. 2. Chromatogram of Assay Standard-02

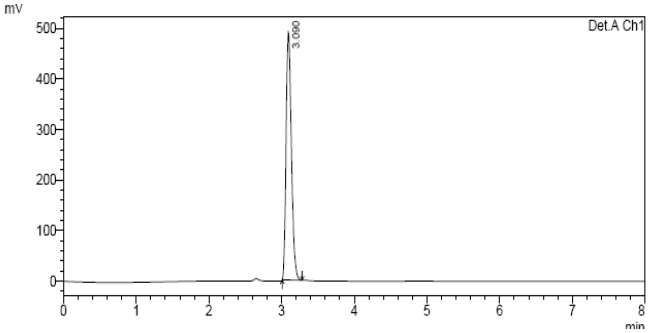

Fig. 3. Chromatogram of Assay Standard-03

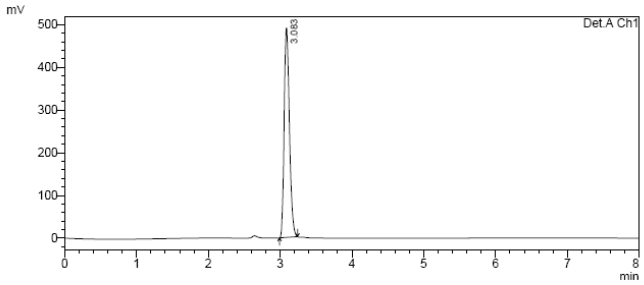

Fig. 4. Chromatogram of Assay Standard-04

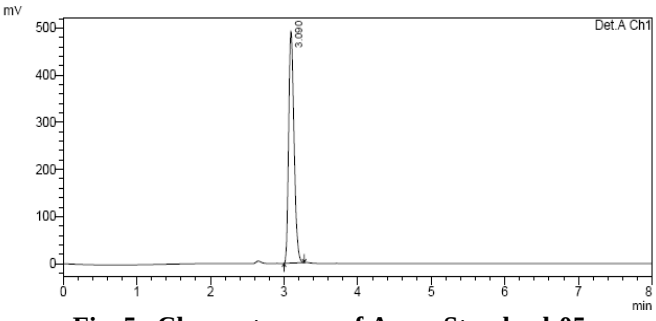

Fig. 5. Chromatogram of Assay Standard-05

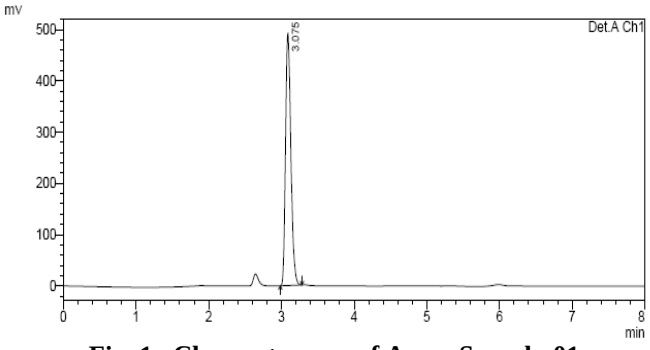

Fig. 1. Chromatogram of Assay Sample-01

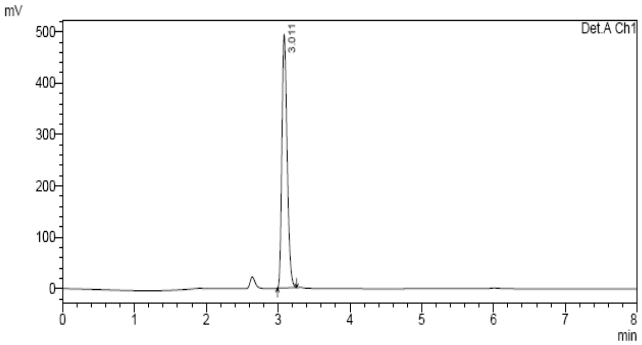

Fig. 2. Chromatogram of Assay Sample-02

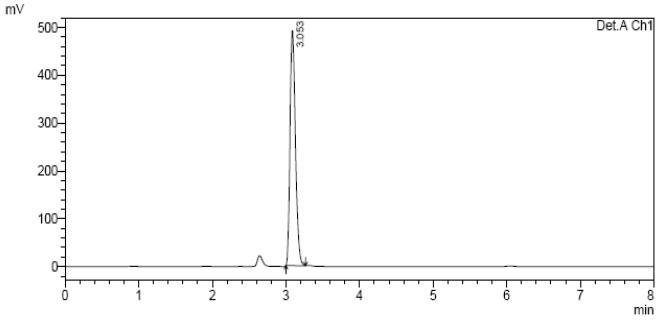

Fig. 3. Chromatogram of Assay Sample-03

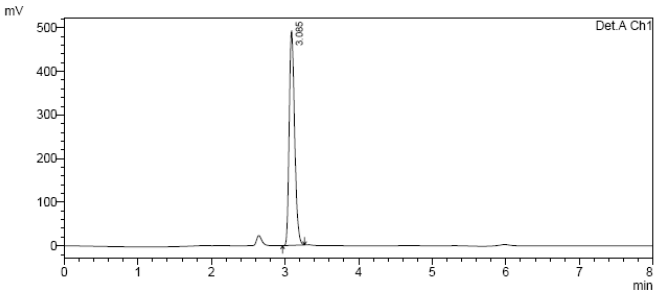

Fig. 4. Chromatogram of Assay Sample-04

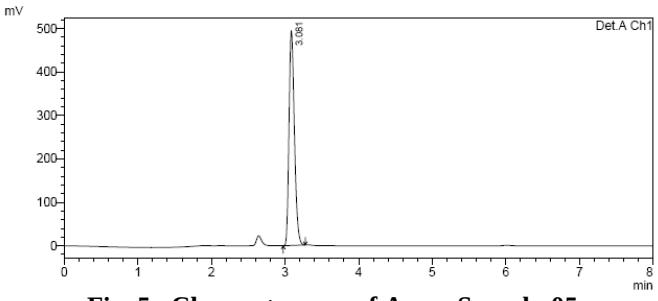

Fig. 5. Chromatogram of Assay Sample-05

4. RESULTS FOR AZILSARTAN

Azilsartan		
	Standard Area	**Sample Area**
Injection-1	2527548	2526136
Injection-2	2516884	2515827
Injection-3	2495644	2510709
Injection-4	2497496	2525250
Injection-5	2507449	2523113
Average Area	2509004.2	2520207
Assay (%purity)	100.45	

5. OBSERVATION

The amount of Azilsartan present in the taken dosage form was found to be 100.45%.

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