

# SOTALOL IN PLASMA BY FLUORIMETRY - FAST

Code Z78110





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This product fulfills all the requirements of Directive 98/79/EC on in vitro diagnostic medical devices (IVD).

The declaration of conformity (CE) is available upon request.

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## INTRODUCTION

Sotalol is an active ingredient specifically used in the treatment cardiac arrhythmias. Among nonselective beta-blockers, sotalol is one of the most water-soluble and in addition to beta-blocking activity, is able to block the potassium channel, acting as an antiarrhythmic class III. This allows the use of the drug for atrial fibrillation in conjunction with ventricular tachyarrhythmias.

Sotalol is a drug that has long been studied because of its unique pharmacological properties, showing both beta-blocking and blocking activity of the potassium channels.

The intake of sotalol is indicated in the case of ventricular arrhythmias, both for the treatment of life-threatening ventricular tachyarrhythmias and for the symptomatic treatment of unsupported ventricular tachyarrhythmias. It is also used in supraventricular arrhythmias, in particular in the prophylaxis of paroxysmal atrial tachycardia, paroxysmal atrial fibrillation from re-entry into the atrioventricular node through accessory pathways and in maintaining sinus rhythm after atrial fibrillation.

## TECHNICAL FEATURES

<b>RECOVERY:</b>	102,4%		
<b>SENSITIVITY (LLOD):</b>	3 ng/ml		
<b>MINIMUM CONCENTRATION ANALYZABLE (LLOQ):</b>	11 ng/ml		
<b>LINEARITY:</b>	11 – 45,8 ng/ml		
<b>NORMAL RANGE:</b>	500 – 4.000 ng/ml		
<b><u>Accuracy intra serie (relative error %):</u></b>	<b>Ci</b>	<b>Cs</b>	
	450 ng/ml	2.300 ng/ml	
	4,02%	0,80%	
<b><u>Accuracy inter serie (relative error %):</u></b>	<b>Ci</b>	<b>Cs</b>	
	450 ng/ml	2.300 ng/ml	
	5,52%	2,16%	
<b><u>Reproducibility intra serie (coefficient of variation %)</u></b> :	<b>C LLOQ</b>	<b>Cm</b>	<b>CUP</b>
	11 ng/ml	1.150 ng/ml	4.500 ng/ml
	4,09%	1,03%	3,89%
<b><u>Reproducibility inter serie (coefficient of variation %)</u></b> :	<b>C LLOQ</b>	<b>Cm</b>	<b>CUP</b>
	11 ng/ml	1.150 ng/ml	4.500 ng/ml
	6,93%	6,92%	7,39%
<b><u>Coefficient of Correlation R2 + Dev Std:</u></b>	0,9976 ± 0,0011		

## COMPONENTS OF THE KIT (100 TEST)

<b>Reagent A</b> – Diluting Solution	<b>1 x 20 ml</b>	
<b>Reagent B</b> – Deproteinization Solution	<b>1 x 20 ml</b>	
<b>Reagent C</b> – Test Solution	<b>1 x 2 ml</b>	<b><u>Store at 2-8°C</u></b>
<b>Reagent D</b> – Internal Standard Solution	<b>1 x 4 ml</b>	<b><u>Store at 2-8°C</u></b>
<b>Calibrator in plasma</b>	<b>1 x 1 ml</b>	<b>Code Z78116</b> (Packed separately – see data sheet)
<b>Reagent M</b> – Mobile Phase	<b>4 x 500 ml</b>	

All the reagents are ready to use and stable for 3 years at room temperature, except for Reagents C and D which must be stored at 2-8 °C. The storage method of the Lyophilic Calibration Standard is described in the dedicated data sheet.

## ACCESSORIES AND CONSUMABLES

<b>CODE</b>	<b>DESCRIPTION</b>	<b>PACKAGING</b>
<b>Z78116</b>	Calibrator in plasma for Sotalol	4 x 1 ml
<b>Z78119</b>	Control in plasma for Sotalol – Levels 1 and 2	2 x 5 x 1 ml
<b>Z699975902</b>	Poroshell 120-EC-C 18 (50 x 4,6mm –2,7 µm) Analytical Column	1 Pc
<b>S90199511</b>	Prefiltri Javelin	1 x 10 Pcs
<b>S51843550</b>	Glass Vial with reduced volume from 1,5 ml to 15 µl	1 x 100 Pcs
<b>S51820717</b>	Caps for Glass Vial with reduced volume from 1,5 ml to 15 µl	1 x 100 Pcs

### MINIMUM INSTRUMENTAL EQUIPMENT REQUIRED

Instrument HPLC isocratic with loop of 10  $\mu$ l

Fluorimetric Detector

$\lambda_{ex}$	$\lambda_{em}$
235 nm	310 nm

Chromatograms Recorder

### OPTIONAL EQUIPMENT

Autosampler  
Operational Computer

### COLLECT PROCEDURE OF *BLOOD SAMPLE*

Take 3 ml of venous blood in a tube with HEPARIN as anticoagulant. Centrifuge at 4000 rpm for 5 minutes. Separate the plasma in a glass tube and then store at -20°C.  
Stable 1 month.

## PREANALYTICAL PROCEDURE

### STEP 1

Preparation of Test Solution

Pipette in a vial:

- 
- 200  $\mu\text{l}$  of Reagent C – Test Solution
- 100  $\mu\text{l}$  of Reagent D – Internal Standard Solution

### INJECTION :

Inject 5  $\mu\text{l}$  of solution in chromatographic system.

Verify that the Test Solution has retention times similar to those shown in the figures below. If the Test has been successful, the analytical session can be carried out. If this is not the case, check the functionality of the analytical system.

## ANALYTICAL PROCEDURE

### STEP 1

Dispense in eppendorf:

- 200 µl of Sample/Calibrator/Control
- 20 µl of **Reagent D** – Internal Standard Solution
- 200 µl of **Reagent B** – Deproteinization Solution

**Vortex for 10 seconds**

**Centrifuge at 14.000 rpm for 10 minutes in microcentrifuge**

### STEP 2

Take 200 µl of supernatant and dispense in glass vial

Add 200 µl of **Reagent A** – Diluting Solution

**Vortex for 10 seconds**

**N.B.: at this step, the sample is stable 24 hours at 2-8 °C**

#### INJECTION :

Inject 5 µl of solution in chromatographic system.



## SOTALOL IN PLASMA - Warnings

### HPLC COLUMN PROTECTION

To save the analytical column Reverse Phase POROSHELL EC C18 (50 x 4,6 mm – 2,7  $\mu$ ), the use of Javelin Prefilters (1 x 10 pcs), code S90199511 is obligatory.

### HPLC COLUMN CONDITIONING

Install a new analytical column Reverse Phase POROSHELL EC C18 (50 x 4,6 mm – 2,7  $\mu$ ). Disconnect the detector and flux a solution of H<sub>2</sub>O : Acetonitrile ( 20 : 80 v/v ) set flow at 0,8 ml / min for 25 min. **Don't recycle the washing solutions**. Condition the column with the mobile phase at a flow of 1ml / min. for 30 min. Condition further on the column for 30 min. also at recycling phase. Finally inject the derivatized Chemical Standard and verify the quality of the HPLC run. **It is NOT possible to make analysis at recycling phase**. If room temperature is > 20 °C store the Mobile Phase at 2-8 °C between an analytical session and another.

### COLUMN CLEANING

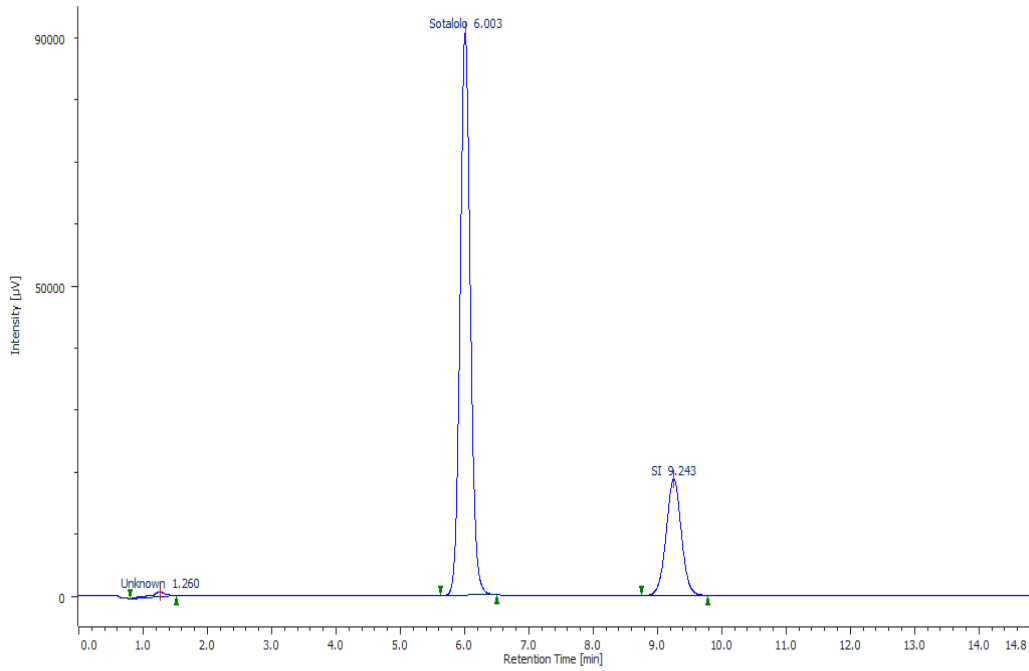
Disconnect the detector. Flush 30 ml of H<sub>2</sub>O: methanol or Acetonitrile (80: 20 v/v) and download. Flush a solution of H<sub>2</sub>O: methanol or Acetonitrile (70: 30 v/v) for 30 minutes for download. When the column will be used again, pass 15 ml of H<sub>2</sub>O: methanol (20: 80 v/v) before made conditional with the Mobile phase. It is recommended to wash the analytical column at the end of each session.

### HPLC PARAMETERS

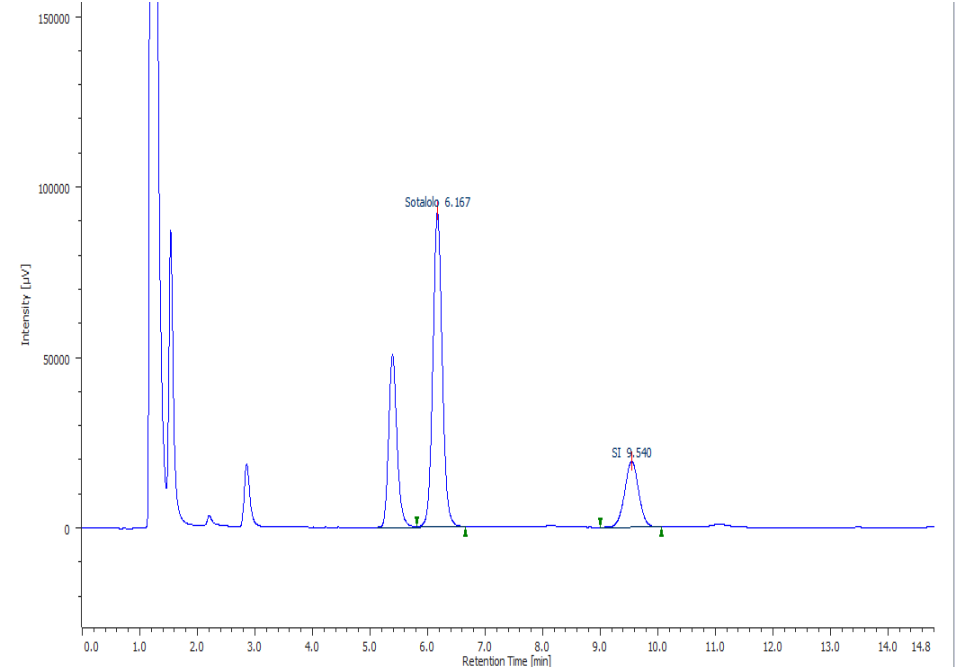
<b>LOOP</b>	10 $\mu$ l
<b>Recommended Flow</b>	1 ml/minute
<b>Pressure</b>	About 100 bar

# SOTALOL IN PLASMA BY FLUORIMETRY

(Reference Chromatograms)



<b>Fig. 1 :</b>	<b>Test Solution</b>
	R.T. 6.00 Sotalol
	R.T. 9.24 Internal Standard



<b>Fig. 2 :</b>	<b>Plasma Sample</b>
	R.T. 6.16 Sotalol 5 µg/ml
	R.T. 9.54 Internal Standard



**eureka kit**

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