

Module 2.7
Clinical Summary

**THIOPECTOL THYM SANS SUCRE EDULCORE AU
MALTITOL, 6.5 g/100 ml
Sirop**

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List of Abbreviations

AUC	area under the concentration-time curve;
CL	clearance
C_{\max}	peak plasma concentration
CYP	cytochrome P450
DER	Drug Extract Ratio
EMA	European Medicines Agency
ESCOF	European Scientific Cooperative on Phytotherapy
MAT	mean absorption time
MRT	mean residence time
$t_{1/2}$	elimination half-life
t_{\max}	time to reach C_{\max}
Vdss	volume of distribution at steady state
WHO	World Health Organization

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2.7.1 Summary of Biopharmaceutic Studies and Associated Analytical Methods

2.7.1.1 Background and Overview

The purpose of this report is to support an application for marketing authorization of *THIOPECTOL THYM SANS SUCRE EDULCORE AU MALTITOL, 6.5 g/100 ml, sirop* with an abridged dossier as allowed under Article 16a(1) (traditional-use registration) of Directive 2001/83/EC: Thyme syrup has been on the market in the European Community for several decades.

The principal active components in *THIOPECTOL THYM SANS SUCRE EDULCORE AU MALTITOL, 6.5 g/100 ml, sirop* are thymol and carvacrol.

The efficacy of *Thymus vulgaris* L. liquid extract has been well-documented over many years of widespread traditional use.

2.7.1.2 Summary of Results of Individual Studies

This medicinal product will be registered as a traditional herbal medicinal product as defined in Directive 2001/83/EC under Article 16a(1) (traditional-use registration) and as such this section is not applicable.

2.7.1.3 Comparison and Analyses of Results Across Studies

Not applicable as no such studies were performed.