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**QUALITY CONTROL OF *CISTUS INCANUS*
CONTAINING PHARMACEUTICAL
PREPARATIONS**

**By
Hiba Hani Mohammed Ali Al-Sheikh Hamed**

**A thesis Submitted in Partial Fulfillment of the
Requirements for the Degree of Master of Science**

at

Petra University

Faculty of Pharmacy

Amman- Jordan

December 2009

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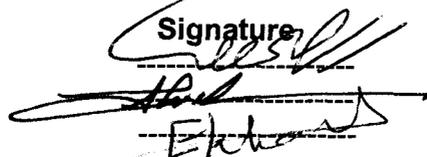
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Abstract
QUALITY CONTROL OF CISTUS CONTAINING
PHARMACEUTICAL PREPARATIONS

by

Hiba Hani Mohammed Ali Al-Sheikh Hamed

Petra University, 2009

Under the supervision of Dr. Fadi Q´adan

Cistus incanus L. (Cistaceae), a shrub widely distributed in the Mediterranean area, is traditionally used in various skin diseases, Rheumatism, fever, diarrhea, anti-inflammatory agents, antimicrobial, antiviral and antitumor, while in Jordan traditionally used for the treatment of gout. Recent research in Turkey shows that, of seven plants used as folk remedies for ulcers, the one with the greatest efficacy was *Cistus incanus*.

Several polyphenols were isolated from the air-dried herb material of *Cistus incanus* and were characterized. Among the flavan-3-ols as; catechin, galocatechin, epicatechin, epigallocatechin, epicatechin-3-*O*-gallate and epigallocatechin-3-*O*-(4-hydroxybenzoate) were isolated. The presence of the

dimeric prodelphinidins such as epigallocatechin-(4 β →8)-epigallocatechin, epigallocatechin-3-*O*-gallate-(4 β →8)-epigallocatechin, and epigallocatechin-(4 β →6)-epigallocatechin-3-*O*-gallate were also reported. This knowledge is of great importance for being interested in *Cistus* herb due to their role in the traditional use as antiviral, antibacterial, anti-inflammatory agents and antioxidant activity of the extract.

Reviewing the available data about the phenolic composition of *Cistus* extract indicate high medicinal importance of *Cistus* containing products, and since then up to now few studies have been carried out using *Cistus* extract, the present work developed two formulations, liquid dosage form and capsule from *Cistus incanus* extract and accelerated stability studies were done on them according to ICH for preclinical studies to ensure quality of final *Cistus* extract products has to go through battery of quality control parameters. A proper integration of physical, chemical, microbial, spectral and chromatographic analysis will ensure proper analysis of *Cistus* herb by comprising of organoleptic, microscopical, physical, chemical, chromatographic testing.

To
My Family

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CHAPTER ONE

INTRODUCTION

Chapter One

1. Introduction

1.1. Cistaceae

The Cistaceae, a medium-sized family, consists of eight genera and 180 species (herbaceous plants and shrubs). The common name is rockrose. In open areas on poor soils Cistaceae occur. Distributed in temperate and subtropical regions of the northern hemisphere, Cistaceae show the highest genus and species in the Mediterranean region. Five of the eight genera (*Cistus*, *Fumana*, *Halimium*, *Helianthemum*, *Tuberaria*) are native to this region while the remaining three (*Crocanthemum*, *Hudsonia*, *Lechea*) inhabit temperate regions in America (Guzmán and Vargas, 2006).

The taxonomy of Cistaceae has been based on vegetative and reproductive characters. Phylogenetic relationships among Cistaceae genera indicate that *Cistus* is related to *Halimium* and *Helianthemum* (Guzmán and Vargas, 2005; Guzmán and Vargas, 2009).

1.2. *Cistus* genus

The genus *Cistus* is one of the most characteristic Genera containing about twenty species (Table1) commonly found in the Mediterranean region from Morocco and Portugal through to the Middle East, and also on the Canary Islands which are perennial shrubs found on dry or rocky soils (Fig. 1.1.). The history of this plant starts already in the 4th century before Christ (Guzmán and Vargas, 2005; Attaguile et al., 2006; Bouamama et al., 2006).

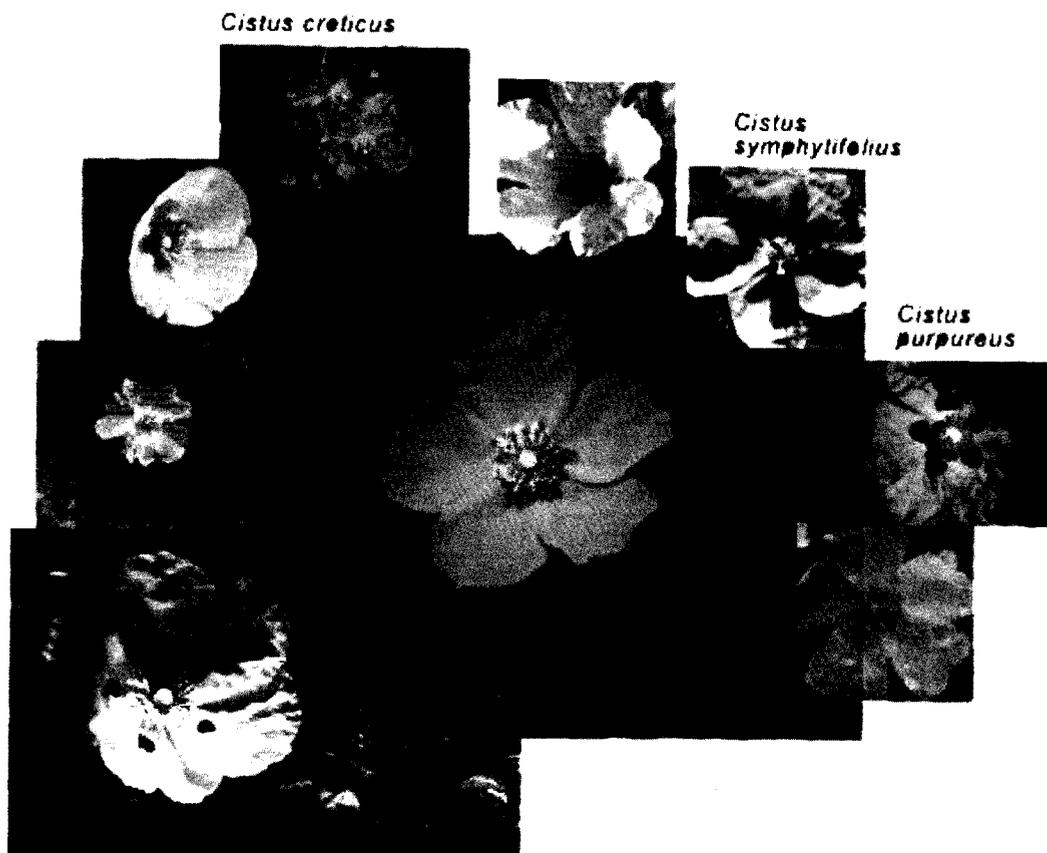


Figure1.1. Cistus species



Figure1.2. Cistus incanus