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QUALITY CONTROL OF PELARGONIUM CONTAINING PHARMACEUTICAL PREPARATIONS

By

Basma Abdel Raheem Hafez Othman

A Thesis Submitted in
Partial Fulfillment of the
Requirements for the Degree of
Master of Science
in Pharmaceutical Sciences

at

Petra University,
Amman-Jordan

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Major Supervisor
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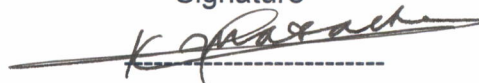
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Examination Committee
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1. Prof. Khalid Matalka

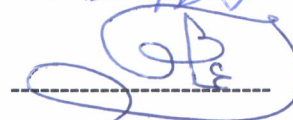
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Abstract

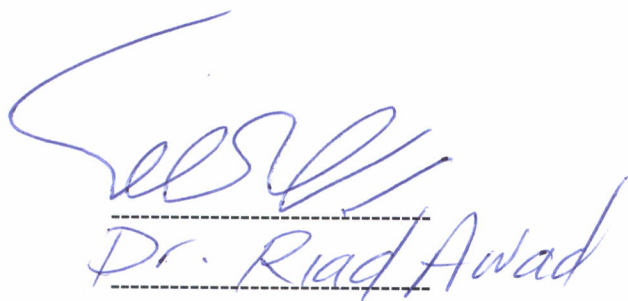
QUALITY CONTROL OF PELARGONIUM CONTAINING PHARMACEUTICAL PREPARATIONS

By

Basma Abdel Raheem Hafez Othman
Petra University, 2009
Under the Supervision of Dr. Riad Awad

Pelargonium sidoides DC (Geraniaceae) is an important herb that is used by traditional medical practitioners and modern phytotherapy to treat bronchitis and infections of the upper respiratory tract. Based on science, proven efficacy and safety, clinical trials and patents, the remedy is marketed in Germany and abroad with great success. EPs[®] 7630 is a special aqueous-ethanolic (11 % m/m) root extract of *Pelargonium sidoides* is listed in European Pharmacopoeia. The pharmacopoeial method used for control of *Pelargonium sidoides* and/or *Pelargonium reniforme* root and pharmaceutical preparations is based on determination of tannins. This conventional method is not adequate enough to ensure the quality of plant drugs or their formulations. Subsequently, this prompted the present study to prepare new syrup and capsule formulations from *Pelargonium sidoides* and to develop a validated high pressure liquid chromatography (HPLC) method for quantitative estimation of gallic acid (GA) as a bioactive marker compound in these formulations. Chromatographic analysis of Pelargonium liquid extract and the prepared formulas was performed before and after hydrolysis to quantify amounts of free and total GA. Using a Purospher[®] C-18 reverse phase analytical column (4 mm X 250 mm, 5 µm), a step binary gradient elution program consisting of acetonitrile and 0.9% acetic acid and many sample pretreatment methods were performed. Quantification of free GA in syrup and

capsules was achieved by a simplified sample pretreatment method. The assay of free GA in three syrup batches ranges from 102-105.76% over six months of storage at room temperature (RT). In contrast, quantification of total GA necessitates much more laborious procedures which involved boiling syrup samples with conc. HCL for three hours. The assay of total GA was within the allowed range ($\pm 10\%$) after six months of storage at RT and 40°C but it did not follow certain pattern throughout the time of the study. The total GA concentration fluctuates with a minimum value of 86.5% to a maximum value 124.98 % within the three syrup batches over the six months of the study at RT and 40°C. The same HPLC method was also suitable to analyze free GA contents in the developed capsules. As another potential marker, (+)-catechin could also be separated by the HPLC method in the developed Pelargonium formulas. The developed HPLC method was precise, accurate and reproducible. Quantification of free GA contents using HPLC was found to be reliable and suitable method for quality control of Pelargonium containing pharmaceutical preparations.



Dr. Riad Awad

To
My Mother
With Love