

Topical formulations containing *Rosa Damascena* for the treatment of psoriasis: *in vitro/ in vivo* assessment

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Introduction

Rosa damascena is the vital species of the Rosaceae family and it is especially famous for its perfuming properties and pharmacological activity. Many compounds are present in *R. damascena* as flavonoids, anthocyanins, terpenes, glycosides, and polyphenolic acids, which have therapeutic effects. Psoriasis is a chronic inflammatory skin disease characterized by erythrosquamous plaques, skin dryness, and various degrees of pruritus.

The aim of this study was to evaluate the phytochemical profile of the extracts, to develop and investigate topical formulations with lyophilized forms of three *Rosa* species (*Rosa damascena*, *Rosa canina* and *Rosa cairo*).

Materials and methods

Preparation and characterization of dry extract: Flower petals were collected from rose planters from Bihar county, Romania, in May 2020 and were dried at 70 °C for 2 h. The alcoholic extract solutions were prepared by maceration using 10 g of petals in 100 mL ethanol 70%, at room temperature for 7 days.

Formulation and investigation of self-nanoemulsifying drug delivery system: Different self-emulsifying combinations have been formulated by the water and oil dilution method with a tenside (Cremophor RH 40) and a co-tenside (Transcutol HP). The surfactants were mixed at 37 °C by Schott Tritronic dispenser (SI Analytical, Mainz,

Germany). The applied concentration of rose extract was dissolved in the system at room temperature by permanent agitation.

Formulation of ointments containing lyophilized rose extracts and rose-SNEDDS: Different rose extracts, in suspended (lyophilized) form or in a self-emulsifying drug delivery were given to the ointment base.

Texture analysis: A compression test was performed and the resistance of formulations was measured by a CT3 Texture Analyzer (Brookfield, Middleboro, MA, USA).

In vitro diffusion studies: Six Franz cells (Hanson Microette TM Topical and Transdermal Diffusion Cell System) were used for *in vitro* membrane diffusion studies.

Superoxide Dismutase (SOD) Assay: The antioxidant activity of formulations was determined on HaCaT cells after UV-B exposure. UV-B (Oriel® Sol-UV-4 UV Solar Simulator, Bozeman, MT, USA) radiation was used to induce oxidative stress and free radical formation after the treatment.

Cell Viability Study (MTT Assay): The experiments were carried out on HaCaT cell lines. Test solutions were applied and the cells were incubated with them for either 15, 30 or 60 min, Then the cells were incubated with the MTT paint for 3 h. The viable cells will transform the water-soluble tetrazolium-bromide into formazan precipitate. The absorbance of these solutions was measured by spectrophotometer (Fluostar Optima, Debrecen, Hungary).

Clinical Study: 20 patients were recruited, of which 10 received a topical treatment that contained *Rosa*

damascena extract in a self-emulsifying drug delivery system and 10 patients received a placebo cream that was applied twice a day for six weeks. The clinical assessment of the severity of the psoriasis lesion was performed at the initial time, during, and at the end of the treatment using the scores of erythema, induration, and desquamation, on a scale from 0–4. Elements related to the patient's quality of life were also assessed using DLQI score.

Results and discussion

Investigation of Self-Nano-Emulsifying Drug Delivery System: Pseudoternary phase diagrams were constructed by using a conventional water titration technique. The distribution of droplet size and the zeta potential of each composition were also determined and presented in Table 1. All compositions are in nanometer size and stable.

MTT Assay: According to the results, Rosa damascena extract did not show cytotoxicity. *Texture Analysis.* The results showed that ointments containing the active ingredient in SNEDDS demonstrated lower resistance to deformation compared to those formulations where rose extract was in suspended form. A lower resistance value indicates a lower level of firmness, which is a desirable factor for spreading on the skin.

In vitro diffusion studies: The highest diffused amount of quercetin was obtained in the formulations with SNEDDS.

Superoxide Dismutase Activity of the Topical Formulations: According to the results, ointment containing rose extract in SNEDDS formulation showed a significant increase in free radical scavenging activity.

Clinical investigation: Following treatment, we can see an improvement in patient's quality of life using PASI and DLQI values. Figure 1 shows the erythema value according to PASI score at the three visits. After six weeks treatment both the erythema, induration and desquamation showed a more significant improvement at the patients with psoriasis.

Table 1. Droplet size and zeta potential value of SNEDDS with different Rose extract

Composition	Droplet size (nm)	Zeta potential (mV)
SNEDDS-Rosa damascena	91.75 ± 4.12	-33.1 ± 0.21
SNEDDS-Rosa cairo	127.12 ± 3.22	-31.5 ± 0.18
SNEDDS-Rosa canina	131.35 ± 5.21	-31.8 ± 0.24

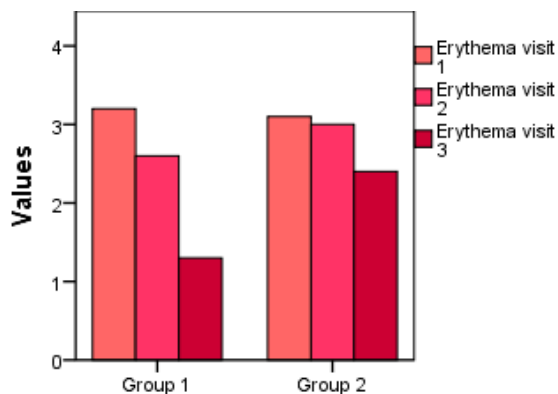


Fig. 1. Results of erythema in the 3 visits for patients. The value indicates the PASI score for erythema. Group 1 is treated group, Group 2 placebo group. The treated group shows lower values which indicates the improvement of erythema.

Conclusion

Our study showed that ointments containing Rosa damascena extract in SNEDDS had better in vitro characteristics. These results correlated with the in vivo clinical study. The patients with psoriasis showed better PASI and DLQI values after six weeks treatment with the formulation.

References

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