# An investigation into the effects of excipients on quality characteristics of a dry herbal extract containing capsule

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*Abstract*
Nutrition and dietary supplements have a significant role in the prevention and treatment of cardiovascular disease. Olive and vine leaves, thanks to their constituents, represent powerful natural antioxidants exhibiting cardioprotective activity. High concentrations of active ingredients can be provided by means of extraction. Dry herbal extracts are highly sensitive to moisture and elevated temperature and from the pharmaceutical and technological point of view these are raw materials with inadequate technological properties. The aim of this study was to investigate and to compare the influence of different excipients in capsule formulation of these two dry extracts *i.e.* the selection of excipients that will ensure appropriate critical process parameters in the manufacturing procedure. The monitored quality characteristics include flowability, bulk density and tapped density that are critical for technological feasibility of the capsule-filling operation. The effects of excipients on the above parameters have been experimentally studied and the appropriate capsule formulations have been developed based on the obtained results, which will ensure homogeneity and stability of the preparation.

*Keywords*: *dry herbal extracts; olive leaf; vine leaf; capsules*.

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## 1. INTRODUCTION

Noncommunicable diseases, such as cardiovascular disease (CVD) and cancer, are the leading causes of death worldwide [1]. Dietary habits, such as the Mediterranean diet, can be involved in the regulation of blood pressure, decrease of oxidative stress, improvement of lipid profile and reduction of mortality rates due to cardiovascular diseases [2]. The rationale for taking dietary supplements including herbal extracts has been suggested by many *in vitro* as well as experimental animal studies that showed protection against inflammation and oxidative stress, both of which are suggested to be involved in the onset and progression of CVD [3]. Among the intensively studied plants, which are highly represented in the Mediterranean diet, are olive (*Olea europaea* L.) and grapevine (*Vitis vinifera* L.).

The olive leaf extract (OLE) contains oleuropein as an active ingredient, along with triterpens, flavonoids, chalcones and tannins. Owing to its composition, olive leaf is rated one of the most powerful natural antioxidants. The results of recent research have suggested beneficial effects of phenolic-rich olive leaf extracts as a dietary supplement in modifying cardiovascular risk biomarkers such as blood pressure, hyperglycemia, oxidative stress and inflammation, as well as in improving vascular function and lipid profiles [4-7]. The vine leaf extract (VLE) was found to contain high amount of polyphenols, *i.e.* resveratrol, quercetin, catechin, flavone, flavonols, anthocyanins, gallic acid and epicatechin, which have a high antioxidant potential and act protectively on the cardiovascular system [8]. It is the herbal medicinal product for treatment of chronic venous insufficiency, which is characterized by swollen legs, varicose veins, a feeling of heaviness, pain, tiredness, itching, tension and cramps in the calves [9].

In line with leading world trends in pharmaceutical industry, the use of dry herbal extracts standardized according to a specific active substance, instead of raw herbal drugs, is quite a widespread practice [10]. This ensures precise dosing during administration, which is not the case when using raw herbal drugs. Herbal extracts are highly sensitive to moisture and elevated temperatures and from the pharmaceutical and technological point of view, these are raw materials with inadequate technological properties, homogeneity and stability of the drug. Dry herbal extracts may be administered as dosage forms, such as capsules, tablets and instant mixtures. In formulating such preparations, it is

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necessary to select such excipients, which will ensure attaining of appropriate technological parameters in the manufacturing process. Monitored quality characteristics include flowability, bulk density and tapped density, these being the critical parameters for technological feasibility of the capsule-filling operation, tabletting or filling the instant mixture into an appropriate container [11].

The purpose of this work was evaluation of the formulation factors in capsules with two selected dry herbal extracts described above. The effects of excipients on the selected quality characteristics have been experimentally studied and based on the results obtained, the appropriate capsule formulations have been developed, resulting in two new products on the market.

## 2. MATERIALS AND METHODS

### 2. 1. Materials

Olive leaf extract EFLA® 943 and red vine leaf extract EFLA®945 were purchased from Frutarom Switzerland Ltd. (Wadenswil, Switzerland). The olive leaf extract was manufactured from the dried leaves of *Olea europaea* L., applying an ethanol (80 % m/m) extraction procedure and standardized to 18-26 % of oleuropein. Grapevine (*Vitis vinifera* L) leaf extract is standardized to total polyphenols, anthocyanins and trans-resveratrol. After a patented filtration process (EFLA® Hyperpure), the crude extracts were dried. Stability and microbiological purity were confirmed by the manufacturer.

Other materials that were used in this study are: corn starch (Amylum, Bulgaria), calcium hydrogen phosphate dihydrate (JRS Pharma, USA), colloid silicon dioxide–(Evonik, Germany), lactose monohydrate (Meggle, Germany), talk (Luzenac, France) and magnesium stearate (Galenika ad, Serbia).

### 2. 2. Characterization of starting materials, extracts and excipients

2. 2. 1. Particle size

The average particle size was determined by Malvern, Mastersizer X, (Worcestershire, UK). The measurements were carried out at least 3 times for each sample. The average and the median particle size of all samples were measured using MS 64-Dry powder feeder (Model MSX 64, Malvern Instruments, Worcestershire, UK).

The following instrument settings had been done: the air pressure was set between 1-3 bars, the number of sweeps was set to 30000 in the time frame of 60 s; the active beam length was set to 10 mm with the range lens of 1000 mm; a minimum obscuration value of 1-10% was obtained in all measurements. The particle size distribution of the samples including mean and medium particle size was calculated from the raw data using the software (Malvern).

2. 2. 2. Flowability

Flowability values were determined by using the flowability tester Erweka tip GTB (Germany), with a hopper made of plexiglas (centre angle: 37.5 °C, orifice diameter: 9 mm), which was connected to a balance (PC 8000 Mettler Toledo Gmbh, Greifensee, Switzerland). The increase in weight could be measured 375 times per minute. The data were collected using the software Balance link (Mettler Toledo, Balance link V 3.01, Greifensee, Switzerland). The flowability of all materials was determined using approximately 100 g of the sample. The measurement was carried out 5 times for each sample. The flowability (*f*) was calculated as:

$$f = \frac{m}{\Delta t} \tag{1}$$

where $m$ is the sample mass (g) and $\Delta t$ is the flowing period (s).

2. 2. 3. Bulk and tapped density

Bulk and tapped densities were measured so that the Hausner ratio was calculated. The measurements were carried out 3 times for each sample.

The bulk and tap densities were determined using an apparatus Erweka Type STAV 2003 (Engelsmann AG, Germany). The sample (100 g) was placed into a graduated cylinder. The volumes at the beginning (bulk volume $V_O$) and after tapping 1250 times (tap volume $V_{1250}$) were noted. The bulk density ($\rho_b$) was calculated based on the initial volume $V_O$, while the tapped density ($\rho_t$) was calculated based on the tapped volume $V_{1250}$. The Hausner ratio (HF) was calculated according to following equation:

$$HF = \underline{\rho_t}\,\rho_b \tag{2}$$

HR values lower than 1.25 indicate good flowability, whereas values greater than 1.25 indicate poor flowability. For values between 1.25 and 1.5 added glidant would normally improve the flowability.

2. 2. 4. Residual moisture

The residual moisture content was determined by an infrared drying unit, Mettler Toledo Type LP 16 M (Mettler Instruments, Nanikon-Üster, Switzerland). Samples (~1 g) were prepared and heated up to 20 minutes to 110 °C exhibiting the loss of moisture. The results are expressed as a weight percentage. The measurements were carried out 3 times for each sample.

2. 2. 5. Morphology examination

A suspension of the powder in the single drop of paraffin oil was made on a microscopic plate. Then a drop of xylene was added, with the aim of brightening and obtaining a clearer the picture. The sample was covered with the cover glass, observed under a microscope and the representative images were photographed (ZEISS Axiophot-Option with integrated camera, Germany).

**2. 3. Analysis of the product**

2. 3. 1. Content of extracts

For olive leaf extract standardized to oleuropein, the content of oleuropein was determined on a HPLC apparatus with DAD detection at the wavelength of 254 nm, using the Zorbax RX C18 150x4.6 mm, 5 µm column, both by Agilent Technologies (USA). Gradient elution at 1 ml/min was used, with 1 %v/v acetic acid as the eluent A and methanol as the eluent B, starting with 15 % B, reaching 50 % B in 5 min and keeping isocratic conditions for 7 min, followed by a 5 min postrun. The injection volume was 10 µl and the column temperature was 25 °C. Retention time of oleuropein was around 9 min.

For vine leaf extract standardized to trans-resveratrol, the content of trans-resveratrol was determined on a HPLC apparatus with DAD detection at the wavelength of 306 nm, using the Zorbax RX C18 150x4.6 mm, 5 µm column, both by Agilent Technologies (USA). The mobile phase consisting of 83 % of 0.1 %v/v phosphoric acid and 17 % acetonitrile was used, with the flow rate of 1 ml/min for 30 min, followed by 10 min at 3 ml/min, and 5 min postrun. The injection volume was 20 µl and the column temperature was 25 °C. Retention time of trans-resveratrol was around 25 min.

Total polyphenols were determined colorimetrically at the wavelength of 715 nm, with pyrogallol as the standard, using the Folin-Ciocalteu`s reagent in a 15 % w/v sodium carbonate solution, using the UV/Vis 8453 spectrophotometer (Agilent Technologies, USA).

Colorimetric determination of total anthocyanins was also determined colorimetrically in 0.1 %v/v methanolic hydrochloric acid at the wavelength 528 nm, based on specific absorbance of cyanidol 3-glucoside using the same spectrophotometer.

2. 3. 2. Disintegration of capsules

The disintegration study of the capsules was performed using Erweka disintegration tester type ZT-322, Germany. The test was performed at following conditions: 800 ml of water as a medium during 15 min of examination at temperature 37 ± 5 °C using discs. Six capsules are placed into a basket using the device for raising and lowering the basket in the immersion fluid–water, at the constant frequency rate of 29-32 rpm. During 15 min in water all capsules should be disintegrated.

2. 3. 3. Loss on drying

The loss on drying was determined using the apparatus Sartorius type MA 40 (Germany). The residual moisture content was determined by an infrared drying unit Mettler Toledo Type LP 16 M (Mettler Instruments, Nanikon-Üster, Switzerland). Samples of approximately 1 g were prepared and heated for up to 2 h to the temperature of 105 °C. The obtained loss of moisture is presented in weight percentage.

**2. 4. Preparation of dry extract containing capsules**

The Active Pharmaceutical Ingredient (API) (vine leaf dry extract or olive leaf dry extract) was mixed with excipients using a granulator mixer Lődige MGT 250G (Germany). The obtained homogenous mixtures were capsulated using a capsuling machine Zanasi nigris S.p.A, AZ/60-R (Italy) providing capsules with a target mass of 350 mg for olive leaf and target mass of 300 mg for vine leaf.

**2. 5. Stability study**

During formulation development, long-term stability was investigated for both products during the shelf life at following conditions: 25 °C / 60 % RH during 36 months while intermediate stability was investigated at 30 °C / 65 % RH

during 12 months. Both products during these studies were evaluated regarding the organoleptic appearance, API content, and capsule disintegration in media imitating GIT conditions.

## 3. RESULTS AND DISCUSSION

A recent increase in the popularity of natural products has revitalized interest in traditional remedies that have been used for the treatment of CVDs through centuries [12]. The use of dried extracts has received special attention for the development and production of solid forms because of higher stability, homogeneity of constituents and ease in handling. On the other hand, it is a complex task because dried extracts do not exhibit necessary properties regarding rheology and compressibility [13]. Both olive leaf and vine leaf extracts as standardized herbal extracts are attractive for a broad range of uses in the food and functional food industries. In this study, the aim was to determine the optimal capsule formulation containing these two dry herbal extracts including stability testing.

Dry herbal extracts have shown to be significantly more stable regarding environmental conditions such as relative moisture and high temperature, as compared to classical herbal extracts. Characterisation of two dry herbal extracts was performed in the present study in order to evaluate influence of excipients on their stability. Based on the results for relative moisture assessments, dry extracts are most stable in mixtures with lubricants talc or magnesium stearate and least stable with maize starch and calcium phosphate dihydrate. As shown in Table 1, maize starch and calcium phosphate dihydrate are hygroscopic and tend to increase the moisture level, which can cause degradation of the API and therefore a decrease in therapeutic effects. Based on the results of characterisation and evaluation of selected quality parameters, optimal excipients for the formulation were chosen, which can provide optimal filling and capsulating process, as shown in Table 2a. The most important parameters for capsulating process are flowability, bulk and tapped density of powders. Formulation with lubricants and glidants colloid silicon dioxide, talc and magnesium stearate had optimal flowability properties with lactose monohydrate as a filler. The formulation with starch and calcium hydrogen phosphate as a filler had poor flowability and the powder could not enter the capsule, the capsulating process was difficult, with powder sticking to the device, so that the process had to be stopped often, loosing continuity and inducing losses. Hausner ratio less than 1.25 for the optimal formulation shows good flowability for both Olive leaf and Vine leaf products. Optimal formulations for both products are shown in Table 2b.

*Table 1: Relative moisture values for extract mixtures with different excipients*

| | Relative moisture: Average / RSD, % | |
|---|---|---|
| Excipient | Olive leaf | Vine leaf |
| Colloid silicon dioxide | 3.91 / 1.03 | 3.65 / 1.06 |
| Magnesium stearate | 2.01 / 2.58 | 3.69 / 1.96 |
| Talc | 3.20 / 2.65 | 3.46 / 2.87 |
| Lactose monohydrate | 5.92 / 4.13 | 5.86 / 6.97 |
| Calcium hydrogen phosphate dihydrate | 6.13 / 5.01 | 5.72 / 6.14 |
| Maize starch | 6.55 / 5.44 | 6.70 / 6.19 |

*Table 2a. Selected quality characteristics for optimal formulations*

| | Olive leaf | Vine leaf |
|---|---|---|
| Particle size, µm | 850 | 760 |
| RSD, % | 3.56 | 3.17 |
| Flowability, s/100g | 10 | 8 |
| RSD, % | 1.24 | 2.03 |
| Bulk density, g/ml | 0.59 | 0.69 |
| RSD, % | 4.63 | 3.97 |
| Tapped density, g/ml | 0.73 | 0.80 |
| RSD, % | 3.81 | 2.53 |
| Hausner ratio, % | 1.23 | 1.16 |

*Table 2b. Optimal formulations for both products*

| Olive leaf formulation | Content, % | Vine leaf formulation | Content, % |
|---|---|---|---|
| Dry olive leaf extract | 54.26 | Dry vine leaf extract | 50.0 |
| Lactose monohydrate | 43.21 | Lactose monohydrate | 47.43 |
| Talc | 1.00 | Talc | 1.00 |
| Magnesium stearate | 1.00 | Magnesium stearate | 1.00 |
| Colloid silicon dioxide | 0.5 | Colloid silicon dioxide | 0.56 |

Micrographs of the optimal formulation powder at 15× magnification presented in Figure 1a shows uniform, spherical particles with narrow particle size distribution, which is essential for good powder flowing and for uniform

capsule filling. Figure 1b shows powder formulation with irregularly shaped particles with broad particle size distribution and with sharp edges, which tend to agglomerate.

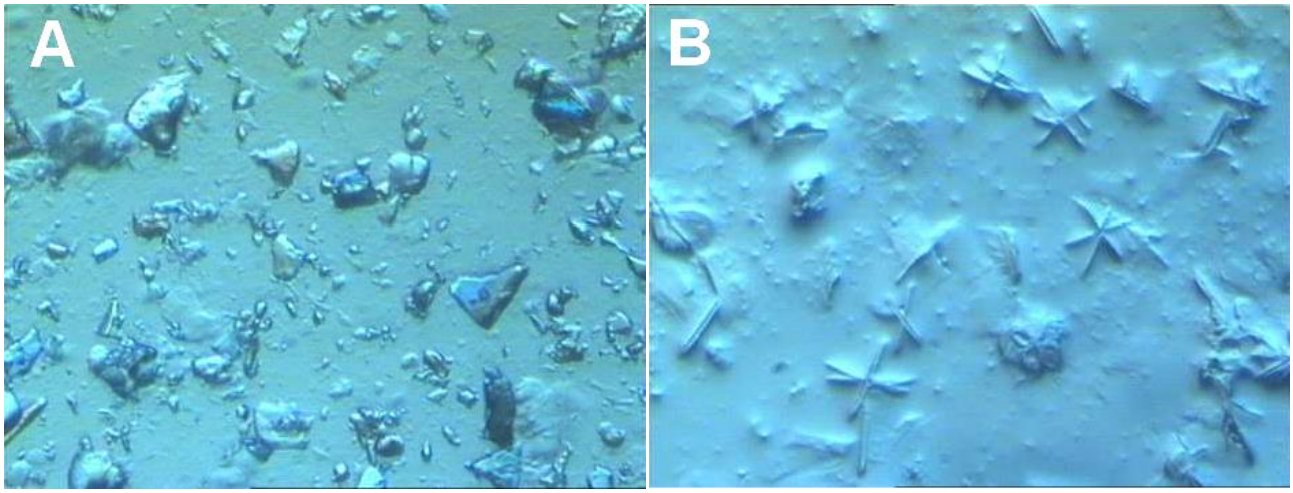


*Figure 1. Representative microphotographs of A - "optimal" formulation; B - "incorrect" formulation (15× magnification)*

Result of such powder is a very difficult capsulating process, and non-homogenous dosing. Optimal formulations were investigated regarding long term and intermediate stability during shelf life of the product as shown in Tables 3 and 4. During 36 months at 25 °C/60 % RH the content of oleuropein in the product Olive leaf was in accordance with the Specification during the whole study (Fig. 2). During the intermediate study (Fig. 3), a significant decrease in oleuropein content was observed after six months but still within the requirements in the Specification. Results of Vine leaf capsules in all stability tests have shown stable contents of anthocyanins and trans-resveratrol while the content of polyphenols during the long-term study has shown a significant decrease after 9 and 18 months but still within the Specification limits. During the intermediate study, the content of polyphenols decreased after six and twelve months (Fig. 3) but still within the Specification limits. Based on the obtained results, optimal formulations for both products are very stable during the shelf life under conditions of increased relative humidity and temperature.

*Table 3. Results of the long-term stability study for the Vine leaf formulation during 36 months*

| Test term (months) | Test condition | Appearence | Polyphenols content, mg/cps | Anthocyanins content, mg/cps | Trans-resveratrol content, µg/cps | Disintegration time, min |
|---|---|---|---|---|---|---|
| REQUIREMENTS | | Hard gelatine capsules filled with red brown powder | 45.00-78.75 | 0.45-1.50 | 7.5-43.05 | Less than 15 min, in water at 37 °C |
| Initial result | | Complies | 67.80 | 1.22 | 15.17 | 6 |
| 0 | 25°C 60 % RH | Complies | 63.84 | 0.88 | 15.00 | 10 |
| 6 | | Complies | 57.65 | 0.86 | 15.03 | 10 |
| 9 | | Complies | 56.04 | 0.84 | 15.12 | 9 |
| 12 | | Complies | 56.93 | 0.86 | 14.24 | 8 |
| 18 | | Complies | 52.37 | 0.87 | 14.52 | 4 |
| 24 | | Complies | 58.68 | 0.86 | 13.64 | 3 |
| 36 | | Complies | 58.03 | 0.85 | 13.95 | 8 |
| 3 | 30°C 65 % RH | Complies | 66.24 | 0.94 | 15.62 | 9 |
| 6 | | Complies | 57.71 | 0.86 | 14.99 | 9 |
| 9 | | Complies | 56.33 | 0.83 | 14.53 | 5 |
| 12 | | Complies | 54.14 | 0.82 | 13.86 | 4 |
| 3 | 40°C 75 % RH | Complies | 54.12 | 0.85 | 14.89 | 4 |
| 6 | | Complies | 60.24 | 0.88 | 15.12 | 6 |

*Table 4. Results of the long-term stability study for the Olive leaf formulation during 36 months*

| Test term (months) | Test condition | Appearence | Oleuropein content, mg/cps | Disintegration time, min | Loss on drying (2h / 105°C), wt% |
|---|---|---|---|---|---|
| REQUIREMENTS | | Hard gelatine capsules filled with brown powder | 30.00-50.00 | Less than 15 min in water at 37 °C | Information |
| Initial result | | Complies | 35.20 | 6 | 6 |
| 0 | 25°C/ 60 % RH | Complies | 32.30 | 4 | 10 |
| 6 | | Complies | 34.09 | 10 | 10 |
| 9 | | Complies | 33.18 | 10 | 9 |
| 12 | | Complies | 32.52 | 5 | 8 |
| 18 | | Complies | 32.40 | 5 | 4 |
| 24 | | Complies | 33.42 | 4 | 3 |
| 36 | | Complies | 32.52 | 6 | 8 |
| 3 | 30°C/ 65 % RH | Complies | 31.57 | 9 | 9 |
| 6 | | Complies | 31.24 | 10 | 9 |
| 9 | | Complies | 31.97 | 8 | 5 |
| 12 | | Complies | 32.27 | 7 | 4 |
| 3 | 40°C/ 75 % RH | Complies | 35.46 | 9 | 4 |
| 6 | | Complies | 37.81 | 10 | 6 |

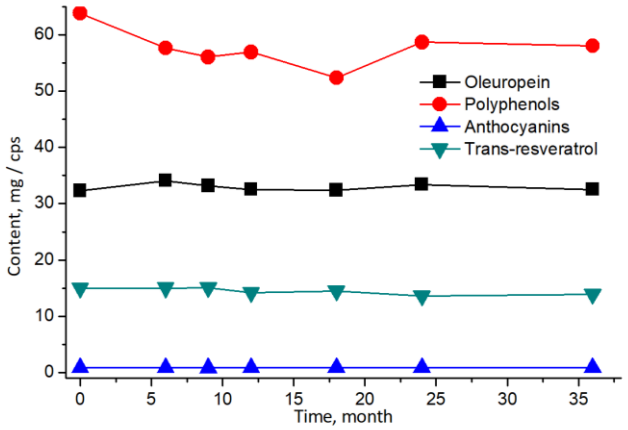


*Figure 2. Contents of active ingredients in the long-term stability study during 36 months*

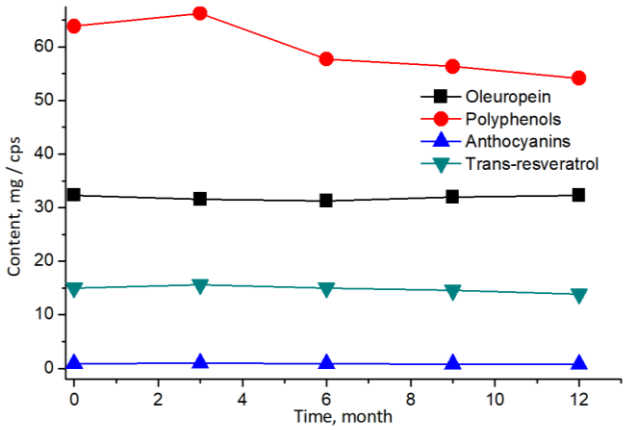


*Figure 3. Contents of active ingredients in the intermediate stability study during 12 months*

## 4. CONCLUSION

The selected quality characteristics of dry herbal extracts from olive leaf and vine leaf revealed promising properties, such as low residual moisture and stability in a humid atmosphere, supports use of these extracts in an intermediary product for manufacture of solid dosage forms. On the other hand, rheological properties of the powder indicated limited applications in processes that depend on flow as well as in development of solid dosage forms such as capsules. However, the use of excipients such as lactose monohydrate and colloidal silicon dioxide provided significant improvements of the extract properties, demonstrating feasibilities for production of capsules. Results presented in this study demonstrated development of optimal capsule formulations with dry herbal extracts confirmed in stability studies. Thus, precise dosing during administration of API from the herbal drug is ensured. Development of our own formulation and capsule technology with dry herbal extracts can be carried out using conventional devices: a granulator mixer and a capsule machine as illustrated in this manuscript. Floralend® Galenika dietary product portfolio is thus expanded with new products.

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## SAŽETAK

### Ispitivanje uticaja ekscipijenasa na tehnološke parametre u formulaciji kapsula sa suvim biljnim ekstraktima


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(Stručni rad)


U prevenciji i lečenju kardiovaskularnih bolesti, ishrana i dodaci ishrani imaju značajnu ulogu. List masline i list vinove loze, zahvaljujući svojim sastojcima, svrstavaju se u red moćnih prirodnih antioksidanasa i deluju protektivno na kardiovaskularni sistem. Njihovom ekstrakcijom se postiže veća koncentracija aktivnih sastojaka. Suvi biljni ekstrakti su veoma osetljivi na prisustvo vlage i povišenu temperaturu, te sa farmaceutsko-tehnološkog aspekta predstavljaju sirovine nepovoljnih tehnoloških karakteristika. Cilj ovog rada je bio ispitivanje i poređenje uticaja različitih pomoćnih materija u formulaciji kapsula sa ova dva suva biljna ekstrakta, odnosno odabir ekscipijenasa koji će svojim prisustvom obezbediti odgovarajuće tehnološke parametre u procesu proizvodnje. Tehnološki parametri koji su praćeni su protočnost, nasipna i sabijna gustina jer od njih najviše zavisi da li će moći da se izvede tehnološka operacija punjenja kapsula. Ispitivan je uticaj pomoćnih supstanci na navedene parametre i na osnovu dobijenih rezultata došlo se do odgovarajućih, optimalnih formulacija kapsula koje garantuju homogenost i stabilnost preparata.



*Ključne reči*: suvi biljni ekstrakt, list masline, list vinove loze, kapsule