EXPERIMENTAL PAPER

Morphological and pharmacokinetic properties of oral solid dietary supplements containing plant extracts

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Summary

Introduction: Dietary supplements are a good way to supplement the deficiency of certain micronutrients and organic components (therapeutic agents) in human body. They are most often available in concentrated form as tablets, capsules, powder or liquid. **Objective:** To investigate morphological parameters and the pharmaceutical availability of coated tablets – dietary supplements – that contain selected pharmacopeial titrated dry plant extracts. **Methods:** Testing of the effective time of the tablet surface erosion was performed in model acceptor fluids using pharmacopeial methods in static (Erweka apparatus) and dynamic (unlimited diffusion method) conditions. Furthermore, morphological parameters of tablets (the original shape of an ellipse) as well as their hardness were determined. **Results:** The effective erosion time was determined by conductometric method using carboxymethylcellulose sodium salt (NaCMC) contained in the tablet. The content of gum arabic and NaCMC in the tablet testifies that the granulate was produced using the “wet granulation” technique which resulted in high hardness of original, esthetic, elliptical tablets and in prolonged disintegration time (erosion). **Conclusions:** The used excipients: gum arabic and NaCMC for the production of the tested tablets containing selected dry plant extracts result in their high hardness. The tested dietary supplements are characterized by esthetic design, original shape, and prolonged disintegration time which affects the pharmaceutical availability.

Key words: *dietary supplements, extracts, erosion rate, pharmaceutical availability, flavonoids, coated tablets*

INTRODUCTION

The dynamic development of phytotherapy does not only represent a natural return to effective and safe pharmacotherapy. It also serves as a response to the falling number of registered new chemical compounds with profiled therapeutic effects, despite the significant progress made in the catalytic synthesis of complex organic structures [1-5].

Traditional herbal medicine is the basis of phytotherapy. That was an inspiration not only for the selection of plant extracts, but also for the determination of the optimal form of medicinal product which will guarantee appropriate pharmacological (therapeutic) effectiveness [6-11].

Plant preparations used in phytotherapy are available in two systems: well established use (WEU) and traditional herbal medicinal products (THMP). Herbal medicines are classified to appropriate categories based on the safety requirements given by an appropriate publication [12-16]. In order to demonstrate the expected pharmacotherapeutic or cosmetic effectiveness, the produced drug form should contain standardized herbal substances or their derivatives (liquid

or dry extracts) which meet the requirements of the pharmacopoeia - PP VI to X [17-23]. The production of solid dosage forms containing dry plant extracts, tablets, coated tablets or capsules, requires an indication of the active agent content, polarity of the extraction medium and the direct-compression (DC) polymeric carrier used to enable direct tableting [16, 24, 25]. However, it should be emphasized in the light of current legislation that dietary supplements do not necessarily meet the pharmacopoeial requirements, although their quality should be as high as possible.

The aim of the present study was to determine the morphological and pharmacokinetic parameters of selected solid oral dosage of medication in the form of coated tablets containing dried plant extract.

MATERIAL AND METHODS

Material

1. Solid oral dosage form – a coated tablet manufactured by COLFARM S.A. Pharmaceutical Plant (Mielec, Poland) containing dietary supplements as follows:
 - *Viola tricolor* (wild pansy), 100 mg extract per tablet,
 - *Urtica dioica* (nettle), 150 mg extract per tablet,
 - *Morus alba* (white mulberry), 160 mg extract per tablet,
 - *Epilobium parviflorum* (smallflower hairy willowherb), 170 mg extract per tablet,
 - *Melissa officinalis* (lemon balm), 150 mg of extract per tablet,
 - *Cynara scolymus* (artichoke), 400 mg extract per tablet, equivalent to 20 mg cinarine.
2. Model receptor fluids:
 - distilled water,
 - hydrochloric acid (0.1 mol/l) of declared osmolarity 200 m Osm/l, analytical grade (POCh Gliwice, Poland).

Apparatus

1. Apparatus for testing the rate of release of the therapeutic substance from the drug form, DT 606/1000 HH, (ERWEKA, Germany),
2. Tablet hardness tester TB-200 TD, (ERWEKA, Germany),
3. Spectrophotometer UV-VIS Nicolet Evolution 300 with computer control system, PC, Microsoft Excel spreadsheet,
4. Multifunction mini-computer CX-551, Elmetron and conductometric sensors: (1 – EC-60, Elmetron, 2 – Eurosensor EPS-2 ZE No: 571, (Poland),
5. Absolute Digimatic Caliper, (Mitutoyo, Great Britain) – measuring accuracy to ± 0.01 mm,
6. Apparatus for the determination of tablet disintegration time, ZT 222 (ERWEKA, Germany).

Determination of the effective time of erosion and the dissolution rate of the hydrophilic components of the coated tablet.

The erosion rate and pharmaceutical availability were determined by a modified unlimited diffusion method incorporating a rotating disc. The geometric stability of the preparation was ensured during measurements by using four tablets fixed symmetrically to the disc (fig. 1). Measuring the process of pharmaceutical availability in this way ensured that eroding fragments of the tablets would not hinder the process of hydration of the coated tablet structure.

Figure 1.

Rotating disc (diagram)

As the manufacturer introduced NaCMC (carboxymethylcellulose sodium salt) into the tablet prescription composition (tab. 1), electrical conductivity was measured to calculate the rate of erosion in water: $\Delta\lambda_{\text{pom}} (\Delta\lambda_{\text{pom}} = \lambda_{\text{pom.roztw}} - \lambda_{\text{H}_2\text{O}}, \mu\text{s})$. The obtained results demonstrated in table 4, allowed the dependence $\Delta\lambda_{\text{pom}} = f(t, \text{min.})$ to be traced, the course of which enabled the effective time of tablet erosion at a rotation speed of 154 rpm to be determined.

Determination of the equilibrium content of flavonoids after erosion and disintegration of the coated tablet.

Flavonoid content was determined by UV spectroscopy after erosion and total disintegration of dietary supplement – coated tablets in water (receptor fluid) – without solution dilution.

Calibration curves were used for quantitative determination. The flavonoid content of dry extracts from *Ginkgo biloba* leaves as a model substance [24] was determined using the following alternative reference substances:

Quercetin ($A = 3.8704 \cdot 10^{-2} + 744.9264 \cdot c$; $\log A = 2.6121 + 0.9012 \log c$) and rutoside ($A = 0.1061 + 31.4565 \cdot c$; $\log A = 0.7389 + 0.5621 \log c$).

Conversion of the above equations to the form:

$$-c = A; (\log A) - a/b$$

allowed to calculate the flavonoid content of extracts used for the production of granulate and tablet compression. The obtained results are presented in table 2.

Ethical approval: The conducted research is not related to either human or animal use.

RESULTS AND DISCUSSION

According to the list of excipients used by the manufacturer to prepare coated tablets with plant extracts (the dietary supplements) given in table 1, the composition of the tablet, i.e. the granulate, includes gum arabic and carboxymethylcellulose sodium salt (NaCMC), which indicates that the granulate was produced by “wet granulation” with a significant change in $pH_{(aH+)}$ of the environment for plant extracts. This results in distinct hardening of the granulate during the process of drying and the components of plant extracts undergo hydrolytic processes such as moistening, changing $pH_{(aH+)}$ and drying at different temperatures.

Based on the morphological studies, potato and maize starch and microcrystalline cellulose were added into the tablet formulation using wet granulation to produce tablet cores for carrageenan coating and to promote the adsorption and incorporation of phytochemicals, with a significant prolongation of disintegration time. According to the European Pharmacopoeia VI and Polish Pharmacopoeia VIII, coated tablets immersed in purified water should disintegrate in no more than 30 minutes.

Disintegration tests for tablets coated in water and 0.1 mol HCl confirmed that the tablets underwent surface erosion rather than classical disintegration. This is reflected in the results demonstrated in table 2.

Therefore, pharmaceutical availability is not sufficient for required concentrations of therapeutic agents (phytochemicals) to be achieved from the tablet during digestion, due to “blurring” of the process of mass exchange at the phase boundary.

The ellipsoidal shape of the coated tablet and the release of phytochemicals through the process of surface erosion was an inspiration for calculating topological parameters and estimating the effective time of erosion by measuring the electrical conductivity (λ , μS) in the receptor fluid using unlimited diffusion. The measurements were performed while rotating the disc with 4 tablets at 154 rpm.

The calculated morphological values characterizing the coated tablet, i.e. the ellipsoid volume ($V_{\varepsilon} = 4/3 \pi \cdot a \cdot b \cdot c$), field inside the ellipsoid ($P_{\varepsilon} = \pi \cdot a \cdot b$), and the

Table 1.

Prescription composition of coated tablets – dietary supplements with plant extracts

Dietary supplement	<i>Viola tricolor</i>	<i>Urtica dioica</i>	<i>Morus alba</i>	<i>Epilobium parviflorum</i>	<i>Melissa officinalis</i>	<i>Cynara scolymus</i>
Type of extract	<i>Viola tricolor</i> extract	<i>Urtica dioica</i> extract	<i>Morus alba</i> leaf extract	<i>Epilobium parviflorum</i> extract	<i>Melissa officinalis</i> extract	<i>Cynara scolymus</i> extract
Dose per tablet	100 mg (600/100)	150 mg (900/150)	160 mg (1600/160)	170 mg (680/170)	150 mg (1050/150)	20 mg cinarizine (400 mg extr)
Relating Substances						
1. Microcrystalline cellulose	+	+	+	+	+	+
2. Potato starch	-	-	+	+	-	-
3. Maize starch	-	-	-	-	-	+
4. Magnesium salts of fatty acids	+	+	+	+	+	+
5. SiO ₂	+	+	+	+	+	+
6. NaCMC	+	+	+	+	+	+
7. Sorbitol	+	+	+	+	+	+
8. Fatty acids	+	+	+	+	+	+
9. Gum arabic	+	+	+	+	+	+
10. Carrageenan	+	+	+	+	+	+

Table 2.

Morphological and pharmacopeial parameters of the coated tablets – dietary supplements

Common name, preparation Species, family	Active components	Medical system	Hardness* [N]	Disintegration time* [min] – water medium	Disintegration time* [min] – 0.1mol HCl medium	Determined flavonoid content $\sim C_1$	Determined flavonoid content $\sim C_2$
1. Wild pansy <i>Viola tricolor</i> <i>Violaceae</i>	methylsalicylic acid flavonoids anthocyanins, mucilage triterpene	TEM	278.60±15.24	46.0	77.0	1.4.0819·10 ⁻³ 2.4.0637·10 ⁻³	1.9.1308·10 ⁻³ 2.3.0184·10 ⁻³
2. Nettle <i>Urtica dioica</i> <i>Urticaceae</i>	microelements silica (SiO ₂ -5%) amines (histamine) glycosides flavonoids β-sitosterol	TEM	264.60±45.13	70.5	92.0	1.6.4311·10 ⁻³ 2.6.6456·10 ⁻³	1.1.4694·10 ⁻³ 2.1.9914·10 ⁻³
3. White mulberry <i>Morus alba</i> <i>Moraceae</i>	flavonoids anthocyanins pectins saccharides artocarpin	TCM	198.80±16.84	153.0	136.0	1.3.4107·10 ⁻³ 2.1.3382·10 ⁻³	1.7.5413·10 ⁻³ 2.5.3312·10 ⁻³
4. Smallflower hairy willowherb <i>Epilobium parviflorum</i> <i>Onagraceae</i>	flavonoids phytosterols (0.95%) gallic acid derivatives sitosterol glycosides	TEM TNAM TCM	170.00±27.41	119.0	177.0	1.3.6456·10 ⁻³ 2.7.6238·10 ⁻³	1.1.4694·10 ⁻³ 2.1.9914·10 ⁻³
5. Lemon balm <i>Melissa officinalis</i> <i>Lamiaceae</i>	essential oil citronellal, neral geranial rosmarinic acid phenolic acids flavonoids monoterpenic glycosides	TEM	236.40±41.64	76.0	122.0	1.4.8873·10 ⁻³ 2.4.9346·10 ⁻³	1.1.1038·10 ⁻³ 2.4.779·10 ⁻³
6. Artichoke <i>Cynara scolymus</i> <i>Asteraceae</i>	phenolic acids caffeic acid chlorogenic acid flavonoids sesquiterpenes sesquiterpene lactones (cyanaropicrin)	TEM	257.75±19.00	100.5	120.0	1.8.3105·10 ⁻³ 2.1.5359·10 ⁻²	1.1.9144·10 ⁻³ 2.7.0779·10 ⁻²

* mean values of measurements; C_1 – quercetin standard; C_2 – rutoside in g/100 cm³

TEM – European traditional medicine; TCM – Chinese traditional medicine; TNAM – North American traditional medicine

approximate circumference of the ellipsoid ($o_{\varepsilon} = \pi (3 \cdot \frac{a+b}{2} - \sqrt{a \cdot b})$), which allowed the density to be calculated ($d_{(n)} = m/V_{\varepsilon}$), together with effective erosion time, are demonstrated in table 3.

The measurements of electrical conductivity (λ_{roz} , μS) against time (t, min.) taken during the erosion of the coated tablet in the receptor fluid are presented in table 4. These allowed the dependence $\Delta\lambda_{pom.roz.} = f(t, \text{min.})$ to be traced, and for the rate of erosion and the time of total disintegration of the coated tablet to be estimated (tab. 3, fig. 2).

Figure 2.

Rate of erosion of tablets in water medium according to the function $-\Delta\lambda_{pom.} (\mu S) = f(t, \text{min.})$ for $V = 1000 \text{ cm}^3$, four tablets of each preparation.

Table 3.

Selected morphological parameters of coated tablets together with effective erosion time determined by unlimited diffusion; $V = 1000 \text{ cm}^3$ of water; measurement temp. – $25.0 \pm 0.1^\circ\text{C}$ at 154 rpm.

Preparation	m_i [g]	Ellipsoid semi axes a, b, c – [mm]	Ellipsoid internal field $\sim P_{(g)} - \text{mm}^2$	Ellipsoid approximate circumference $\sim O_{(g)} \text{ mm}$	Ellipsoid volume $\sim V_{(g)} \text{ mm}^3$	Density $\sim d_{(g)} \text{ [g/cm}^3]$	Erosion time $\sim t \text{ [min]}$
1. <i>Viola</i>	0.5089	$a=4.364$ $b=8.653$ $c=2.53$	118.57	42.01	399.98	1.2723	45
2. <i>Urtica dioica</i>	0.5379	$a=4.354$ $b=8.627$ $c=2.644$	117.94	41.89	415.78	1.2937	55
3. <i>Morus alba</i>	0.5273	$a=4.323$ $b=8.583$ $c=2.464$	116.51	41.66	382.76	1.3776	100
4. <i>Epilobium parviflorum</i>	0.5323	$a=4.324$ $b=8.556$ $c=2.47$	116.16	41.56	382.57	1.3914	80
5. <i>Melissa officinalis</i>	0.5201	$a=4.349$ $b=8.623$ $c=2.613$	117.75	41.86	410.24	1.2677	55
6. <i>Cynara scolymus</i>	0.5263	$a=4.329$ $b=8.603$ $c=2.365$	116.94	41.74	368.75	1.4272	35

Table 4.

The rate of the erosion of coated tablets containing dry plant extracts; V=1000 cm³, measurement temp. = 25.0 ± 0.1°C, spatula method

τ [min.]	Δλ. pom; μs					
	Viola tricolor	Urtica dioica	Morus alba	Epilobium parviflorum	Melissa officinalis	Cynara scolymus
5	30.5	60.57	29.24	18.53	7.88	102.08
10	61.5	110.67	45.41	35.33	18.01	224.88
15	95.29	161.57	68.51	50.33	23.81	311.88
20	130.79	228.37	78.31	63.53	29.51	461.89
25	158.29	284.37	102.51	74.13	41.01	535.88
30	179.39	319.37	113.31	86.03	45.61	579.88
35	183.79	353.37	135.81	96.63	49.91	613.88
40	188.19	373.37	144.21	108.33	54.41	612.88
45	192.59	391.37	156.73	117.53	56.41	612.88
50	192.59	393.37	172.31	128.23	57.31	612.88
55	193.59	397.37	181.91	132.93	58.01	612.88
60	192.59	397.37	191.83	140.53	59.21	610.88
65	192.59	397.37	200.61	145.03	59.31	
70	192.59	397.37	208.61	150.83	59.61	
75			217.61	153.33		
80			226.61	154.33		
85			231.61	154.33		
90			237.61	154.82		
95			242.61			
100			244.61			
105			244.61			
110			244.61			

The correlation between hardness and erosion time, $t_{\text{erosion}} = f(T, w, N)$, (fig. 3) was calculated basing on the hardness of the coated tablets (T, N) given in table 2, and the erosion time in water and 0.1 mol HCl was determined by unlimited diffusion (154 rpm) under pharmacopeial conditions.

Figure 3.

The correlation between the time for tablet erosion determined under pharmacopeial conditions – t_{erosion} (min.) and hardness – T (N).

The dependence indicates that the erosion times substantially exceed the pharmacopeial standard of 30 minutes for coated tablets. This may be caused by the high hardness of the coated tablets created by the technique of core preparation for coating.

Following unlimited diffusion, i.e. the complete erosion of the tablets in water at $25^{\circ} \pm 0.1^{\circ}\text{C}$, the flavonoid content of the tablets was measured. The lack of information on the preparation of the extract and the extraction medium prevents any comparison between the results of the present study with those in the cited references with regard to the process of formulating the solid form of the medicine with a dissolution time specified by the Pharmacopoeia.

CONCLUSIONS

1. The morphological studies indicate that the applied technique of obtaining granulate, i.e. „wet granulation” using gum arabic and NaCMC, produces a coated tablet with high hardness, resulting in delayed surface erosion, blurred pharmaceutical availability and impaired mass exchange at the phase boundary.

2. The presence of NaCMC and gum arabic in the composition of tablet formulation (granulate), along with the erosive nature of its disintegration, may increase the viscosity of the medium ($D = k \cdot T / G \pi \cdot \eta \cdot 1/f_1$), thus impeding the diffusion of the phytochemicals and resulting in troubles in the phase of biopharmaceutical pharmacotherapy in the case of polypharmacy.

Conflict of interest: Authors declare no conflict of interest.

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WŁAŚCIWOŚCI MORFOLOGICZNE I FARMAKOKINETYCZNE STAŁYCH DOUSTNYCH SUPLEMENTÓW DIETY ZAWIERAJĄCYCH EKSTRAKTY ROŚLINNE

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Streszczenie

Wstęp: Suplementy diety to dobry sposób na uzupełnianie braków niektórych mikroelementów i składników organicznych (środków leczniczych) w organizmie człowieka. Najczęściej są oferowane w postaci skoncentrowanej jako tabletki, kapsułki proszek lub płyn. **Cel:** Celem pracy było zbadanie parametrów morfologicznych i dostępności farmaceutycznej tabletek powlekanych, suplementów diety, które zawierają wybrane farmakopealne mianowane suche ekstrakty roślinne. **Metody:** Metodami farmakopealnymi w modelowych płynach biorczych przeprowadzono badania nad efektywnym czasem erozji powierzchniowej tabletek w warunkach statycznych (urz. Erweka) i dynamicznych (metodą nieograniczonej dyfuzji). Ponadto oznaczono parametry morfologiczne tabletek (oryginalny kształt elipsy) i ich twardość. **Wyniki:** Wykorzystując zawartość w masie tabletkowej soli sodowej karboksymetylocelulozy (NaCMC), metodą konduktometryczną wyznaczono efektywny czas erozji. Zawartość w masie tabletkowej gumy arabskiej i NaCMC świadczy o tym, że granulaty przygotowano metodą „na mokro”, co przekłada się na wysoką twardość oryginalnych, estetycznych tabletek o eliptycznym kształcie i wydłużony czas rozpadu (erozji). **Wnioski:** Zastosowane substancje pomocnicze – guma arabska i NaCMC (sól sodowa karboksymetylocelulozy) – do wytworzenia badanych tabletek, zawierających wybrane suche ekstrakty roślinne, powodują ich wysoką twardość. Przebadane wybrane suplementy diety charakteryzują się estetycznym wyglądem i oryginalnym kształtem oraz wydłużonym czasem rozpadu, co wpływa na dostępność farmaceutyczną.

Słowa kluczowe: *suplementy diety, ekstrakty roślinne, szybkość erozji, dostępność farmaceutyczna, flawonoidy, tabletki powlekane*