

Extract from *Zingiber officinale* Rosc. in oral solid form of a drug

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Summary

It has been decided to investigate the usefulness of selected acrylic acid polymers (*Carbopols*), chitosan and microcrystalline cellulose as dominating carriers of dry extract from ginger rhizome (*Zingiber officinale* Rosc.) in an oral solid form of a drug. The aim of the study was to obtain tablets in the course of direct tableting of controlled release of biologically active substances. Seven batches of tablets were manufactured in reciprocating instrumented tableting machine and the effect of the kind of applied adjuvant substances on the rate of biologically active substances release from the produced tablets was evaluated.

Physicochemical parameters were determined in order to test the produced tablets. The tablets containing acrylic acid polymers (Carbopol 71 GNF, Carbopol 974 PNF) demonstrated the highest hardness.

The tests of pharmaceutical availability of biologically active substances from tablets to the acceptor fluid 0,1 mol/l HCl and comparatively to hydrating intervention hypotonic fluid and to pediatric compensating fluid were performed. The investigations fulfilled general and detailed requirements of Polish Pharmacopoeia VII.

Tablets containing Carbopol 71 GNF as dominating carrier of the extract, Vivapur 112 and Prosolv HD 90 demonstrated high pharmaceutical availability. Introduction of Prosolv SMCC 50 together with dominating carriers of the extract had a beneficial effect on pharmaceutical availability of biologically active substances from the tested tablets.

It results from the carried out investigations that the kind of the applied adjuvant substances and differentiated osmolarity of model acceptor fluids significantly decide on pharmaceutical availability of hydrophilic therapeutic agents contained in dry extract from ginger rhizome. The adjuvant substances applied in adequate proportions appeared to be useful for manufacturing tablets containing dry extract from ginger rhizome.

Key words: *Zingiber officinale* Rosc., Carbopol, chitosan, microcrystalline cellulose, direct tableting

INTRODUCTION

Ginger (*Zingiber officinale* Rosc., Zingiberaceae family) has been known for ages as spice and therapeutic plant. It belongs to the oldest subtropical cultivated plants which has been proved with a fact that that it does not grow wild in any place. Ginger is a herbaceous perennial of strong tuberlike rhizomes which are warty and branched with a foliage stem. The rhizomes can be coated (brown ginger) or decorticated (white ginger), bleached with milk of lime, chalk or plaster [1, 2]. Ginger rhizome (*Rhizoma Zingiberis*) mentioned in the detailed monograph of Polish Pharmacopoeia VII is a pharmaceutical material [3]. At present, the technology of a plant drug is aimed at obtaining active complexes of substances in a form of dry titrated herbal extract (hydrophilic- water, lipophil- ethanol). They serve as standardized preparations almost utterly devoid of ballast substances in the form of extracts used for the production of granulated drugs, tablets, capsules, pastes and liquid forms of drug.

Zingiberol ($C_{15}H_{25}OH$) – a volatile oil (1.5–3.3%) is rich in alcohol and zingiberene $C_{14}H_{24}$ – in hydrocarbon, citreol, borneol, bisabolene, citral, cineol and camphene. These are main pharmacologically active chemical compounds of the extract from ginger rhizome. Ginger rhizome also contains phenylalkanes – gingerol to 1.5%, shogaols and lipids (6–8%), amino acids, carbohydrates and starch [1,4, 5]. Owing to shogaol content, ginger exerts effect similar to that of nonsteroidal anti-inflammatory drugs with no adverse effects (such as those accompanying typical drugs blocking COX-1).

Ginger rhizome applied orally for over 3 months decreases ailments related to the course of rheumatic diseases: pain, swelling and exudate. It demonstrates positive effect on joint mobility, improves general feeling, prevents osteoarticular cartilage degeneration and contributes to its regeneration [6, 7]. Furthermore, it shows the following activities:

- controlling vomiting,
- antioxidative,
- antiviral, antibacterial,
- detoxicating,
- analgesic,
- heats up and improves blood circulation,
- stimulates digestion and production of gastric juices and saliva,
- decreases cholesterol level,
- decreases blood platelets aggregation.

The studies have been carried out on ginger application in cancer chemoprevention e.g. colour [8-11].

Only a few substances can be directly tableted, that is why the tableting method is of greater importance with the use of adjuvants which are, for instance, the carriers of dry herbal extracts.

Carbopols (carbomers) are acrylic acid synthetic polymers. Carbopols introduced into solid forms of a drug in the amount of 1–5% improve their durability, prevent crushing which is of great importance during the mechanical process of packing tablets in blisters. In such insignificant quantity Carbopols rather do not affect the tablet disintegration time and active substance release. In higher concentration they are used in the process of tableting as a binder hydrophilizing and controlling active substances release. In consequence of water absorption and the process of swelling a diffusion barrier is formed owing to which at high solubility of therapeutic substance, the curve of the substance release is close to a straight line. Then, the process of mass exchange is of “0” or nearly “0” order, which is an ideal profile for therapeutic agent release. Carbopols do not create incompatibility in the environment of systemic fluids even in multidrug therapy [12-14].

Basing on earlier published results of studies concerning the application of chitosan in the technology of production of tablets containing dry herbal extracts, it has been decided in this study to investigate its usefulness as a carrier of dry extract from ginger rhizome in the process of tableting [15-17].

Chitosan is a linear polysaccharide and it is produced by deacetylation of chitin. The degree of deacetylation and chitosan molecular weight influence its penetration through epidermis. Indirectly, the process of deacetylation and high molecular weight change in a reversible way the structure of corneal layer of epidermis and thus it can play a role of a transport promoter. It swells in water and preserves its construction. Chitosan structure resembles the structure of cellulose, however, its polycationic character gives it the properties which can be used in the technology of a drug form ensuring comfort of application and adequate therapeutic level. Owing to the capability of gel formation it can be used in the process of tablet coating, which fulfills the function of the drug form of the therapeutic agent controlled release [18-21].

Silicified microcrystalline cellulose, a mixture of microcrystalline cellulose (98%) and colloidal silicon dioxide (2%) appeared to be a very useful technological solution. Its nanostructural surface is five times greater in relation to initial material. Owing to that, this kind of adjuvant substance enables to produce a pharmaceutical product with dry labeled plant extracts using the technique of direct tableting [22].

The aim of the carried out investigations was to obtain a solid form of a drug –uncoated tablets containing dry extract from ginger rhizome with the use of selected acrylic acid polymers (Carbopols), chitosan and other adjuvant substances.

It has been decided to assess the effect of both the way of formulation (direct tableting) and the kind of the adjuvants used on physicochemical properties and rate of release of biologically active substances from the manufactured tablets.

MATERIALS AND METHODS

Materials

Dry extract from ginger rhizome (Extractum Zingiberis e rhiz. aq. siccum, Phytopharm Kłęka S.A.) – extraction medium-water was the study material.

Adjuvant substances included:

- shrimp chitosan of deacetylation level 90.3% and mean molecular mass 201.7 kDa (Tech-Food Trading Sp. z. o. o., Warsaw),
- acrylic acid polymers – Carbopol 71 GNF, Carbopol 974 PNF (Noveon),
- microcrystalline cellulose – Vivapur, 112, Vivapur 102 SI (IRS Pharma),
- microcrystalline cellulose with 2% addition of SiO₂ - Prosolv SMCC50, Prosolv HD90 (JRS Pharma),
- sodium stearyl fumarate (PRUV – JRS Pharma).

Reagents (acceptor fluids)

- hydrochloric acid (HCl) 0,1 mol/l of declared osmolarity 200 mOsmol/l analytical grade (P.O.Ch. S.A. Gliwice),
- hydrating intervention hypotonic fluid of declared osmolarity 143 mOsmol/l (Baxter Terpol – Polfa Lublin S.A.),
- pediatric compensatory fluid of declared osmolarity 272 mOsmol/l (Baxter Terpol – Polfa Lublin S.A.)

Apparatus

- reciprocating instrumented tableting machine Korsch EKO (Erweka),
- apparatus for testing therapeutic substance rate of release from the form of drug (Erweka DT 606/ 1000HH),
- apparatus for testing abrasiveness/ tablet friability (Erweka Tar 220),
- spectrophotometer UV-VIS Nicolet Evolution 300 with computer control system (PC computer, Microsoft Excel spreadsheet),
- laboratory equipment,
- sieve with mesh diameter of 0.16–0.25 mm,
- electronic balance (Radwag),
- electronic slide caliper.

Technology of model tablets manufacturing

Seven batches of tablets containing dry extract form ginger rhizome (300mg, 60% in a tablet) with 39% portion of fillers and disintegrants (Carbopol 71 GNF, Carbopol 974 PNF, chitosan, Vivapur 112, Vivapur 102 SI, Prosolv HD 90, Prosolv SMCC 50) and 1% content of lubricant- sodium stearyl fumarate were produced. All components were weighed and expressed in appropriate number of tablets

500 mg each, mixed thoroughly. The obtained tablet mass was passed through a sieve with mesh diameter of 0.16–0.25 mm and subjected to direct tableting in reciprocating instrumented tableting machine (Erweka). Flat punches of $\varnothing 12$ mm in batch 2–7 and spherical punches of $\varnothing 11$ mm for batch 1 were used. The composition of particular batches is presented in table 1. In case of batches 1 and 3 Carbopol 71 GNF was used as dominating carrier and in the case of batches 2, 4, 5 – Carbopol 974 PNF and in smaller percentage adjuvants (Vivapur 112, Vivapur 102 SI, Prosolv HD 90, Prosolv SMCC 50). Chitosan was used in batch 6 as a main carrier of the extract and in batch 7 chitosan with Carbopol 71 GNF and other adjuvants (Vivapur 112, Prosolv SMCC 50).

Table 1.

Tablet composition	batch number						
	1	2	3	4	5	6	7
extract from <i>Zingiber officinale</i>	+	+	+	+	+	+	+
Carbopol 71 GNF	+		+				+
Carbopol 974 PNF		+		+	+		
chitosan						+	+
Vivapur 112	+	+	+	+		+	+
Vivapur 102 SI					+		
Prosolv HD 90	+	+					
Prosolv SMCC 50			+	+	+	+	+
sodium stearyl fumarate	+	+	+	+	+	+	+
tablet mass [mg]	500	500	500	500	500	500	500

Sodium stearyl fumarate was used as a lubricant in all 7 batches. It demonstrated less potent inhibitory effect on tablet disintegration rate than magnesium stearate and better parameters of tablet hardness. In further stage the manufactured uncoated tablets were tested to determine their technological parameters which conditions their therapeutic usefulness.

Morphological tests of tablets with dry extract from ginger herb

The tests comprised evaluation of the tablet size, determination of the dosage accuracy (determination of mass uniformity of individual tablets), tests of mechanical resistance (crushing strength). The statistical hardness of the manufactured tablets was also estimated. Methodology of the study, the size of the samples collected for the analysis and the limit of acceptable deviation from standard were based on general and detailed principles of PPVII [23].

Testing pharmaceutical availability of active substances from a tablet to acceptor fluid

A standard curve was determined for an extract from ginger rhizome – *Extractum Zingiberis e rhiz. aq. sicc.* in 0.1 mol/l HCl. The dependence of absorbance (A) in concentration function (c) was described with correlation equation $A=3.2471 \times c$, at the level of significance $p=0,05$ obtaining determination coefficient $R^2>0,9997$. The rate of active substances release from the obtained tablets to acceptor fluid (0.1 mol/l HCl) was determined. The test was performed in an apparatus for therapeutic substance release with the method of rotating basket in accordance with PPVII [23].

In order to compare, a test was performed of the release of biologically active substances to 2 fluids which considering their parameters refer to systemic fluids of upper gastrointestinal tract (hydration intervention hypotonic fluid and pediatric compensatory fluid).

The concentration of the released biologically active substances from the obtained tablets to acceptor fluid was determined spectrophotometrically with Nicolet Evolution 300 spectrophotometer (1 cm cuvette) at analytical wave length ($\lambda=277$ nm) in comparison with reference material which was obtained from tablets manufactured only from adjuvant substances. The results of the measurements were worked out with Microsoft Excel spreadsheet.

RESULTS AND DISCUSSION

Estimation of the quality of tablets containing dry ginger extract

Physicochemical properties of the tablets are presented in table 2.

Table 2.

parameter	batch							norm	
	1	2	3	4	5	6	7		
mean mass, mg	496.2	499.0	492.4	494.1	495.4	494.8	491.7	500.0	
deviation from mean mass (%)	0.99	1.04	1.03	1.02	2.17	1.68	1.27	< 5.0	
mean tablet diameter [cm]	1.100	1.201	1.202	1.202	1.203	1.201	1.202	1.200	
mean tablet height [cm]	0.47	0.36	0.35	0.35	0.37	0.38	0.34	–	
mean tablet surface [cm ²]	3.53	3.63	3.59	3.61	3.70	3.70	3.54	–	
mean tablet density [g/cm ³]	1.1114	1.2215	1.2404	1.2447	1.1785	1.1500	1.2751	–	
abrasiveness F (%)	0.11	0.09	0.09	0.09	0.12	0.08	0.06	< 1.0	
hardness [N/cm ²]	T(\bar{x})	414.1	357.0	313.6	341.9	253.8	207.7	338.7	> 98
	± dt	33.45	33.02	28.61	36.28	50.03	56.38	72.84	–

The applied adjuvant substances appeared to be useful in the process of direct tableting of dry extract from ginger herb. Variability of quantitative share allows to determine its effect on mechanical resistance and biologically active substances release. The manufactured model tablets demonstrated smooth surface with no stains, uniform shape and light yellow color originating from the extract within each batch. Low values of deviation from mean mass point to high uniformity of mass of the tested tablets. The obtained results prove the homogeneity of the produced tablet mass and symmetrical filling of the mass into the tableting machine niche over the lower punch. There were no chips or mechanical defects, which was confirmed while testing the tablets mechanical resistance to abrasion (the loss of total mass did not exceed 1%). The hardness coefficient for all produced batches is greater than 98 N/cm². The hardness of the designed tablets ranges from 207.7 to 414.1 N/cm². The highest hardness was measured for the tablets of 1–4 batches which contained in their composition Carbopol 71 GNF, Carbopol 974 PNF. High hardness was noted for batch 7 tablets containing in their composition Carbopol 71 GNF and chitosan. The lowest hardness was observed for batch 6 tablets containing in their composition chitosan as the dominating carrier of ginger extract. Batch 1 tablets containing mainly Carbopol 71 GNF, Vivapur 112, Prosolv HD 90 and sodium stearyl fumarate – a lubricant, presented the best physicochemical properties. Equally good physicochemical properties demonstrated batch 2 tablets but their hardness was lower. This batch compared to batch 1 contained Carbopol 974 PNF instead of Carbopol 71 GNF. The use of microcrystalline cellulose Prosolv HD 90 in both batches decided also about high hardness and higher viscosity in relation to Prosolv SMCC 50 used in other batches. It resulted in significantly higher hardness of batch 1 (to 414.1 N/cm²) and batch 2 (to 357.0 N/cm²) in relation to the other batches. In the case of batch 1 these tablets also demonstrated high pharmaceutical availability of about 90% of biologically active substances. Optimal hardness of tablets at low abrasiveness (predisposition to crushing) translates technologically into easy packing of tablets in blisters (ensures morphological durability of the preparation at the moment of tablet pulling out from the blister niche).

The rate of active substances release

Figure 1 and 2 compare the effectiveness of biologically active substances release from particular tablet batches to acceptor fluid 0.1 mol/HCl of osmolarity 200 mOsmol/l. Batch 1 tablets containing Carbopol 71 GNF as a dominating carrier of an extract and Vivapur 122 and Prosolv HD 90, demonstrated high pharmaceutical availability. Already after 2 hours about 90% of biologically active substances were released. In the case of batch 3 the exchange of Prosolv 90 for Prosolv SMCC 50 did not affect significantly the rate and quantity of the released active substances. The quantity of the released substances was comparable to batch 1. Tablets of batch 2 containing Carbopol 974 PNF released after 2 hours 45% and after 6 hours

70% of active substances. Introduction of Prosolv SMCC 50 (batch 4) instead of Prosolv HD 90 (batch 2) appeared to be more beneficial. The quantity of the released substances reached 80%.

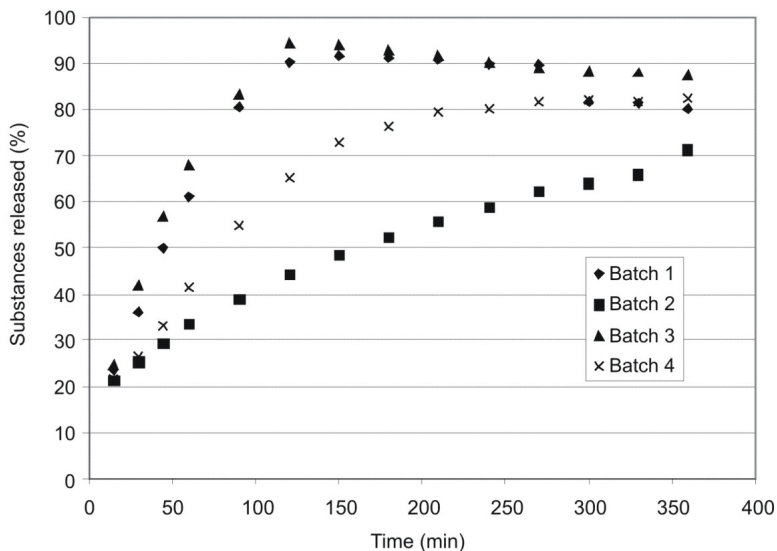


Figure 1. Profile of biologically active substances release from tablets to 0.1 mol/l HCl (batch 1-4)

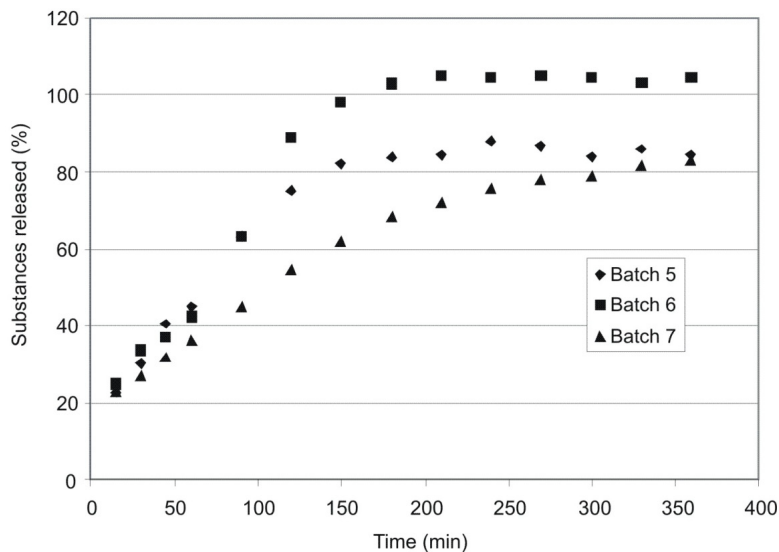


Figure 2. Profile of biologically active substances release from tablets to 0.1 mol/l HCl (batch 5-7)

Batch 6 tablets containing in their composition chitosan as a main carrier of the extract released the most of the biologically active substances (approximately

100% of substances after 150 min.). In batch 5 tablets the quantity of the released substances after 2 hours was >80% and remained at this level despite further exposure. The release of active substances from batch 7 tablets was gradual in time and reached >80% after 6 hours of exposure. Carbopol 71 GNF combined with Prosolv HD 90 appeared to be the best carriers for tablets production. Also the use of chitosan with Vivapur 112, Prosolv SMCC 50 and a lubricating agent resulted in obtaining tablets of the highest pharmaceutical availability in the shortest time in relation to the remaining tablet batches.

The next figures present the profiles of biologically active substances release from batch 1 (fig. 3) and batch 2 (fig. 4) tablets into three different acceptor fluids. Sixty per cent of active substances released from tablets of both batches to pediatric fluid of high osmolarity 272 mOsmol/l and it was comparatively less than 0.1 mol/l HCl. Even fewer (<60%) active substances released to hydrating hypotonic fluid. Similar dependence was noted for remaining tablet batches.

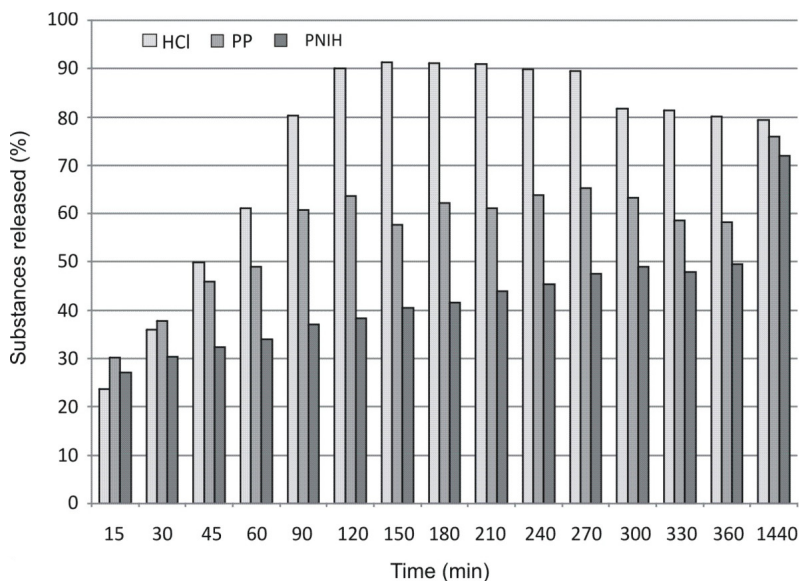


Figure 3. Comparison of active substance release from batch 1 tablets to three acceptor fluids: HCl, pediatric compensatory fluid (PP) and hydrating intervention hypotonic fluid (PNIH)

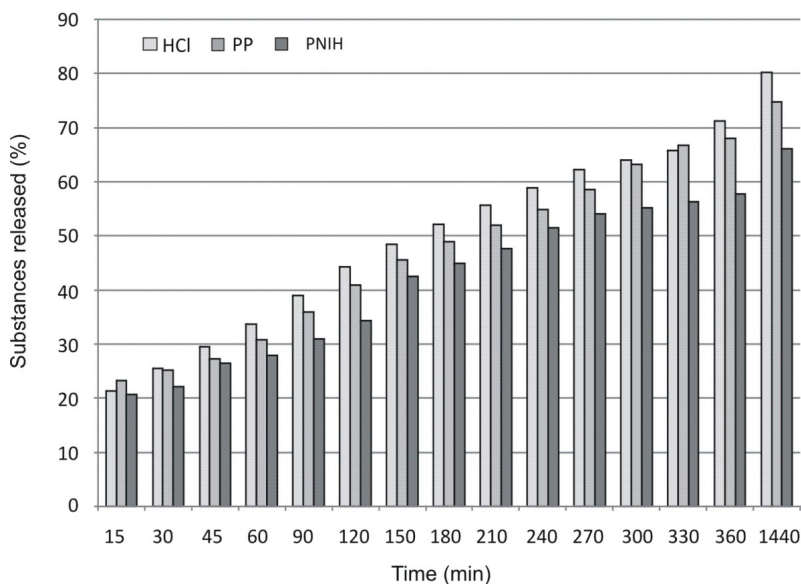


Figure 4. Comparison of active substance release from batch 2 tablet to three acceptor fluids: HCl, pediatric compensatory fluid (PP), and hydrating intervention hypotonic fluid (PNIH)

Summing up, it can be stated that in the course of release to acceptor fluids of variable osmolarity and ionic strength, a model tablet during 2-6 h exposure is characterized by controlled release of biologically active substances. The applied adjuvants and model acceptor fluids osmolarity decide significantly about pharmaceutical availability of hydrophilic therapeutic agents contained in dry extract from ginger rhizome.

The obtained tablets can be a supplement for medications found on the market, applied in motion sickness, treatment of rheumatic diseases and alimentary tract disorders. In comparison with the forms available on the market they may be more comfortable in use due to less frequent administration. The method of direct tableting is cost-effective and time-effective as compared to wet granulation method.

The worked out method of manufacturing a solid form of a drug is optimal, ensures technological repeatability and high durability of the suggested form of a drug.

CONCLUSIONS

1. Application of selected acrylic acid polymers (Carbopol 71GNF, Carbopol 974 PNF), chitosan and microcrystalline cellulose as dominating carriers of dry extract from ginger rhizome appeared to be useful in the process of direct tableting. The obtained tablets fulfill the requirements as regards to physico-chemical properties.

2. Tablets containing Carbopols as dominating carriers of the extract from ginger rhizome demonstrate the highest hardness. The tablets with chitosan as a dominating carrier of ginger rhizome extract are characterized by the lowest hardness.
3. The highest pharmaceutical availability of biologically active substances was obtained from tablets of the lowest hardness, containing in their composition chitosan as a main carrier of the extract. Addition of Carbopol to tablets containing chitosan as dominating extract carrier has an influence on the increase of their hardness and simultaneously it slows the rate of biologically active substances release.
4. The kind of the applied Carbopol as a dominating carrier of the extract has an influence on the quantity of biologically active substances released from the tested tablets. The tablets containing Carbopol 974 PN demonstrated lower pharmaceutical availability. Addition of microcrystalline cellulose Prosolv SMCC 50 has a beneficial effect on pharmaceutical availability of biologically active substances from tablets.
5. From all tablet batches the most biologically active substances were released to 0.1 mol/HCl, less to pediatric fluid of osmolality >272 mOsmol/l, and the least to hydrating hypotonic fluid of the lowest osmolality 143 mOsmol/l.
6. The obtained results point to the possibility of application of the worked out technology in manufacturing oral solid form of a drug – tablets with dry extract from ginger rhizome - and to the possibility of their production on an industrial scale.

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EKSTRAKT Z KŁĄCZA IMBIRU LEKARSKIEGO (*ZINGIBER OFFICINALE* ROSC.) W STAŁEJ DOUSTNEJ POSTACI LEKU

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Streszczenie

Postanowiono zbadać przydatność wybranych polimerów kwasu akrylowego (*Carbopoli*), chitozanu i celulozy mikrokrystalicznej jako dominujących nośników suchego wyciągu z kłącza imbiru lekarskiego (*Zingiber officinale* Rosc.) w stałej, doustnej postaci leku. Celem pracy było otrzymanie tabletek w procesie bezpośredniego tabletkowania oraz ocena wpływu rodzaju użytych substancji pomocniczych na szybkość uwalniania substancji biologicznie czynnych z wytworzonych tabletek. Przeprowadzono badania wytworzonych tabletek, określając ich parametry fizykochemiczne. Najwyższą twardość zmierzono dla tabletek, które w swoim składzie zawierały polimery kwasu akrylowego (*Carbopol* 71 GNF, *Carbopol* 974 PNF). Wykonano badania dostępności farmaceutycznej substancji biologicznie czynnych z tabletek do płynu akceptorowego 0,1 mol/l HCl oraz porównawczo do płynu nawadniającego interwencyjnego hipotonicznego (PNIH) i pediatricznego wyrównawczego (PP). Badania oparto na przepisach ogólnych i szczegółowych monografii Farmakopei Polskiej VII (FP VII). Tabletki zawierające *Carbopol* 71 GNF jako dominujący nośnik ekstraktu oraz *Vivapur* 112 i *Prosolv* HD 90 odznaczały się wysoką dostępnością farmaceutyczną. Wprowadzenie *Prosolv* SMCC 50 obok dominujących nośników ekstraktu wpływa korzystnie na dostępność farmaceutyczną substancji biologicznie czynnych z badanych tabletek. Z przeprowadzonych badań wynika, że rodzaj zastosowanych substancji pomocniczych i zróżnicowana osmolarność modelowych płynów akceptorowych istotnie decydują o dostępności farmaceutycznej hydrofilowych środków leczniczych zawartych w suchym ekstrakcie z kłącza imbiru. Substancje pomocnicze zastosowane w odpowiednich proporcjach okazały się przydatne do wytworzenia tabletek zawierających suchy ekstrakt z kłącza imbiru.

Słowa kluczowe: *Zingiber officinale* Rosc., *Carbopol*, chitozan, mikrokrystaliczna celuloza, bezpośrednie tabletkowanie