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А.Р. ШОПАБАЕВА, А.Е. РАМАЗАНОВА, Г.А. ДЮСЕМБИНОВА, М.А. КАНУШИНА
*С.Ж. Асфендияров атындағы Қазақ Ұлттық медицина университеті,
 Фармацевтикалық пәндер кафедрасы. «Фармация басқаруы мен экономика және
 клиникалық фармация» курс бөлімі.*

ТИІСТІ ДӘРІХАНАЛЫҚ ПРАКТИКА (GPP) СТАНДАРТЫ БОЙЫНША ДӘРІХАНАЛЫҚ ҰЙЫМЫНЫҢ ДҰРЫС БАСҚАРУЫ: ТАРИХЫ МЕН ҚАЗІРГІ ЖАҒДАЙЫ

Түйін: GPP стандарты бойынша дәріханалық ұйымының дұрыс басқаруын қалыптастыруында барлық қажетті операциялардың істеуін растайтын құжаттаманы тиісті жүргізуі, сондай-ақ операциялардың талаптарға сәйкестігін бағалау үшін тұрақты мониторинг өткізуі маңызды рөл алады. Дәріхана бөліктерінің үйлесімді жұмысын тиісті деңгейде ұйымдастыру үшін стандартты операциялық рәсімдерді - белгілі бір функцияларды қалай, қашан және кім қамтамасыз ететін алгоритмдерді әзірлеу және енгізу қажет.

Түйінді сөздер: дәріханалық ұйым, GPP, стандартты операциялық рәсімдер, ұйымдық менеджмент

A.R. SHOPABAIEVA, A.E. RAMAZANOVA, G.A. DYUSEMBINOVA, M.A. KANUSHINA
*Kazakh National Medical University named after SD Asfendiyarov.
 The department of Pharmaceutical Disciplines, Course Management and Economics
 of Pharmacy and Clinical Pharmacy*

PROPER MANAGEMENT IN THE PHARMACY ACCORDING TO GOOD PHARMACY PRACTICE (GPP) STANDARD: THE HISTORY AND THE CURRENT STATE

Resume: A key role in the formation of effective management in the pharmacy according to standard GPP is proper documentation confirming the functioning of all the necessary operations, and regular monitoring - assessment for compliance with the performance requirements of the operations. Standard operating procedures - algorithms that describe how, when and who to properly carry out each operation, is necessary to develop and implement for organization of coordinated work of all parts of the pharmacy at the proper level.

Keywords: pharmacy, GPP, standard operating procedures, management

E. BEKBOLATOVA, Z. SAKIPOVA, L. IBRAGIMOVA, N. MALIKOVA
*Pharmaceutical and technology of pharmaceutical production faculty,
 Asfendiyarov Kazakh National medical university*

TECHNOLOGY OF HARVESTING, PRIMARY PROCESSING AND STORAGE OF THE HERBAL DRUG CRATAEGUS ALMAATENSIS POJARK FRUITS

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*The paper is dealing with setting up best practices and conditions of collecting, primary processing and storing endemic plant *Crataegus almatensis* Pojark (*C. almatensis*), i.e. fruits in order to ensure the best quality of obtained herbal raw material. The obtained results revealed the best time for harvesting, allowed time for storage between collection and drying, the drying and storing conditions. The work is done as a part of scientific research work on full scale studying the endemic medicinal plant *C. almatensis* as a potential source of medicinal products.*

Keywords: Herbal drug, harvest, storage, processing, drying, Hawthorn, *Crataegus almatensis*, GACP

Introduction.

Herbal drug are being utilized universally for production of traditional as well as modern medicines. Therefore, it is important to establish the most appropriate collection

time, primary processing, drying and storage conditions in order to ensure the quality of herbal raw materials.

Objective of the article is the development of the best practice of collection, processing, drying and storage of the medicinal plant *C. almaatensis*.

C. almaatensis is an endemic plant of Rosaceae family, native to the Ile-Alatau mountain region of the Republic of Kazakhstan. The plant present in sufficient industrial scales, therefore drawing attention as a potential source of developing new pharmaceutical preparations on its basis.

G. almaatensis is a tree growing up to 3-4 m tall, with cherry colored branches, with small quantity of thorns of 1-2 cm. Leaves are elliptical-obovoid, sharp, lacinated at a bottom part with a length 4-10 cm, width 4-5 cm. Fruits are dark-purple colored, with a juicy reddish pulp, 10-15 cm in size. It has triangle shaped 3-5 seeds [1,2].

Materials and methods.

The gathering of the *G. almaatensis* fruits was carried out in accordance to WHO guidelines on good agricultural and collection practices (GACP) for medicinal plants in three different stages: the beginning of fruiting (August), when the fruits are ripened (September) and over ripened, i.e. when they are dark, chewy (late October) [3]. Berries were collected in the mountain region of Medeu and gorge Almaarassan, Almatynskaya oblast, Kazakhstan. Fruits were harvested in the dry weather, in three different time frames 9.00am-12.00pm, 14.00pm-16.00pm and 17.00pm-19.00pm.

Berries were harvested manually, avoiding impurities and other herbal substances. Fruits were placed each 8 to 10 kg into special boxes. Each box was labeled with following indications: Latin and official name of the herbal drug, parts of the plant, date and time of collection, the place of collection, name of the harvester, weight.

Harvested material was cleaned from foreign matters like soil, dirt, damaged plants, damaged plant parts, insects. It was then dried under two different temperatures

60±10°C and 75±5°C within 6±1 hours in a drying oven SHS-80-01SPU at the manufacturing site LLP "FitOleum". The drying was carried out not later than 24 hours after harvesting. The raw material was spread in a thin layer of 1.5-2 cm on a special frame and was systematically turned upside down every 30 minutes during drying procedure. The end of drying was determined by absence of adhesion[4].

After drying the herbal material was brought to the condition corresponding to the requirements of the State Pharmacopoeia of the Republic of Kazakhstan [5,6]. The optimal conditions for the harvest, processing and drying were determined due to the content of main active substances, extractive substances and by the output of the raw material.

Main biological active substance procyanidin (expressed as cyanidin chloride) was estimated based on the procedure described in the State Pharmacopoeia Republic of Kazakhstan *Hawthorn fruits*. The data was used for the determination the best collection period for the berries.

Extractive matter content was determined by general method *Determination of extractive matter*. It was the base for proposing the optimal drying temperature conditions.

The timing between collection and drying was proposed due to the loss of the product due to shrinkage, being spoilt, i.e. output of the product.

Assays were carried out in triplicate. The results were expressed as mean value and standard deviation (SD).

Results and discussions.

Collected fruits were identified at the RSE "Institute of botany and phytointroduction" SC MoS Republic of Kazakhstan (reference №01-04/456 from 10th November 2015).

The results of the procyanidin composition obtained for the *C. almaatensis* fruits are shown in Table 1.

Table 1 - Content of procyanidin, expressed as cyaniding chloride, of the *C. almaatensis*

№	Harvesting dates	Stages of fruiting	Analysis date	Content of procyanidins, %
1	20.08.2015	Beginning of fruiting	20.12.2015	1,03±0,04
2	21.09.2015	Ripened fruits	20.12.2015	1,02±0,56
3	25.10.2015	Over ripened fruits	20.12.2015	0,50±0,11

The fruits at the beginning of fruiting and when ripened have the highest content of procyanidin flavonoid (1.02-1.03%), while unripened ones contain two fold less procyanidin (0.5%). It was noted that the optimal time for the harvesting of herbal material is from 9.00am till 16.00pm, after evaporation of the morning dew and before appearance of the evening dew.

Extractive matter content (Table 2) revealed optimal temperature conditions for the drying of the *C. almaatensis* fruits. In order to determine influence of the temperature the ripened berries were subjected to two different temperatures.

Table 2 - The influence of the temperature on the content of extractive matter in the *C. almaatensis* fruits

№	Date of harvest	Drying temperature	Output of extractive matter
1	21.09.2015	60±10°C	50,13±3,15
2	21.09.2015	75±5°C	48,02±2,08

Temperatures below 50°C were not considered as it took more than 10 hours for the drying of fruits. Although the drying time was 5±1 hour when using the 75±5°C, the content of the extractive substances were less by 2%, in comparison to drying at 60±10°C. Moreover, it was noticed that fruits get burned at 75±5°C, which results in the loss of product outcome.

The studies of the period between collection and drying revealed that the best time is not more than 24 hours. The longer time leads to the loss of the product due to spoilage, shrinkage and higher possibility of mould growing (Diagram 1).

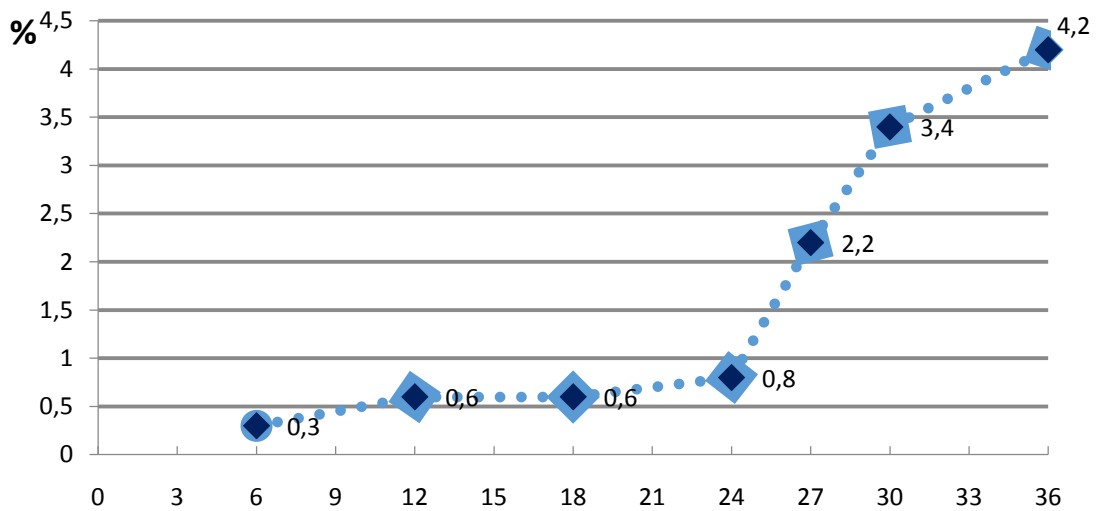


Diagram 1 - Loss of the product (%) versus time (hours)

The output of the product, taking into consideration mechanical loss, loss on drying and content of moisture was 41.8%.

The technological process describing all steps of collecting and primary processing of the *C. almaatensis* berries is shown in Picture 1.

Ingredients	Stage	Check points in the process of manufacture
Harvested raw material	Harvest Primary processing: - purification from impurities (leaves, branches, organic impurities)	Pharmacognostic features according to SPh RK
Purified raw material	Drying Special frame Processing: - purification from impurities (fruit stems)	- temperature; - humidity; - stirring period; - loss on drying; - drying duration
Whole dried raw material	Packaging into kraft boxes and labeling Manually Quarantine	- weight; - labeling; - completeness; - control in accordance to specification for the intermediate product
Packed whole dried raw material	Warehouse	- temperature; - humidity; - microbial contamination; - control in accordance to specification for the finished product

Picture 1 - Technological chart of preparing *G. almaatensis* Pojark

The dried fruits have to be stored in the conditions ensuring prevention from moisture and direct sunlight in the interval of 18-25°C with relative humidity not high than 65 percent in accordance to the requirements of Order of the Minister of national economy Republic of Kazakhstan from 19th March 2015 №232 “On approval of Sanitary rules “Sanitary-epidemiological requirements for the objects in the field of medicines, medical devices and equipment circulation” and Order of the Ministry of Health and social development Republic of Kazakhstan from 24th April 2015 №262 “On approval of Rules on storage and transportation of medicines medical devices and equipment”.

Conclusions

On the basis of studies following conclusions were established:

- 1.The best optimal time for harvesting the fruits of the herbal substance *C. almaatensis* Pojark if the beginning of fruiting and when fruits are ripened, i.e. the end of August and September.
- 2.The duration between collection and drying should not exceed 24 hours.
- 3.The recommended temperature interval for drying fruits is 60±10°C in an air-drying oven. The duration of drying is 6±1 hours.
- 4.The dried fruits have to be stored in accordance to the requirements of Order of the Ministry of Health and social development Republic of Kazakhstan from 24th April

2015 №262 "On approval of Rules on storage and transportation of medicines medical devices and equipment".

Herbal substance has undergone quality assessment according to the State Pharmacopoeia of the Republic of Kazakhstan.

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Э.Н. БЕКБОЛАТОВА, З.Б. САКИПОВА, Л.Н. ИБРАГИМОВА, Н.Т. МАЛИКОВА

*Факультет фармации и технологии фармацевтического производства,
Казахский Национальный медицинский университет им. С.Д. Асфендиярова*

ТЕХНОЛОГИЯ СБОРА, ПЕРВИЧНОЙ ОБРАБОТКИ И ХРАНЕНИЯ ЛЕКАРСТВЕННОГО РАСТИТЕЛЬНОГО СЫРЬЯ ПЛОДОВ CRATAEGUS ALMAATENSIS ROJARK

Резюме: В данной статье приведены исследования по разработке надлежащей практики и установлению условий сбора, первичной обработки и хранению плодов боярышника алматинского *Crataegus almatensis* Rojark (*C. almatensis*) с целью обеспечения надлежащего качества получаемого растительного сырья. Полученные результаты помогли установить оптимальный период сбора, время хранения с момента сбора до начала сушки, условия сушки и хранения. Работа выполнена в рамках научно-исследовательской работы по полномасштабному изучению эндемического растительного сырья *C. almatensis* в качестве потенциального источника для получения лекарственных средств.

Ключевые слова: Лекарственное растительное сырье, сбор, хранение, обработка, сушка, боярышник, *Crataegus almatensis*, GACP

Э.Н. БЕКБОЛАТОВА, З.Б. САКИПОВА, Л.Н. ИБРАГИМОВА, Н.Т. МАЛИКОВА

*Фармация және фармацевтикалық өндіріс технологиясы факультеті, С.Ж. Асфендияров атындағы
Қазақ Ұлттық медицина университет*

CRATAEGUS ALMAATENSIS ROJARK ЖЕМІСТЕРІН ЖИНАУ, БАСТАПҚЫ ӨНДЕУ ЖӘНЕ САҚТАУ ТЕХНОЛОГИЯСЫН ӘЗІРЛЕУ

Түйін: Бұл мақалада дәрілік өсімдік шикізатының тиісті сапасын қамтамасыз ету мақсатында эндемикалық дәрілік өсімдік алматылық долана (*Crataegus almaatensis* Rojark) жемістерін жинау, бастапқы өңдеу және сақтау тиісті тәжірибиесі мен жағдайлары сипатталған. Алынған нәтижелер мәліметтері бойынша жинаудың оптималды кезеңі, жемістердің жиналған уақыты мен кептіру аралығындағы уақыт ұзақтығы, кептіру және сақтау жағдайлары анықталды. Бұл жұмыс эндемикалық дәрілік өсімдік шикізатын жан-жақты зерттеу аясындағы ғылыми-зерттеу жұмысының бір бөлімі болып табылады.

Түйінді сөздер. Дәрілік өсімдік шикізаты, жинау, сақтау, өңдеу, кептіру, долана, *Crataegus almatensis*, GACP