

Determination of the content of residual pesticides in medicinal
vegetable raw materials

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Determination of pesticide residues in raw medicinal plant material
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SUMMARY

Medicinal plants in conditions of increased technogenic pollution of the environment are capable of accumulating various toxicants, including pesticides. In the light of modern requirements for the quality of herbal preparations, the pharmacopoeias of leading foreign countries regulate the content of residual pesticides in the General Pharmacopoeia Monograph. Based on experimental studies, comparative analysis of modern approaches to the quality of medicinal plant materials in domestic and foreign literature, a draft General Pharmacopoeia Article "Determination of the content of residual pesticides in medicinal plant raw materials" was prepared for the XII edition of the State Pharmacopoeia of the Russian Federation. This project was developed with the aim of increasing quality requirements and establishing uniform levels of permissible residual pesticide content in medicinal plant materials.

Key words: medicinal plant raw materials, residual pesticides, methods of analysis.

RESUME

Medicinal plants in conditions of increased technogenic pollution can accumulate a variety of toxicants, including pesticides. In the light of modern requirements to the quality of herbal products, pharmacopoeia of leading foreign countries regulate the content of pesticide residues in the FFS. Basing on experimental studies, comparative analysis of current approaches to the quality of medicinal plants in the domestic and foreign literature, a draft general pharmacopoeial article "Determination of pesticide residues in raw medicinal plant material" for the XIIth edition of the State Pharmacopoeia of the Russian Federation was prepared. This project is intended for enhancing the quality requirements and establishing uniform levels of acceptable content of pesticide residues in raw medicinal plant material.

Keywords: raw medicinal plant materials, residual pesticides, methods of analysis.

The widespread use of plant protection chemicals and foreign substances in various sectors of the national economy inevitably leads to their entry into the environment and their accumulation in all links of the biosphere [1]. Medicinal plants in conditions of increased technogenic pollution of the environment are also capable of accumulating various kinds of toxicants, including pesticides. Based on experimental studies, a comparative analysis of modern approaches to the quality of medicinal plant materials in domestic and foreign literature, safety requirements for food raw materials and food products [5, 7-10], a draft General Pharmacopoeia article "Determination of the content of residual pesticides in medicinal vegetable raw materials "(hereinafter OFS) for the XII edition of the State Pharmacopoeia of the Russian Federation. This project was developed with the aim of increasing quality requirements and establishing uniform levels of permissible content of residual pesticides in medicinal plant raw materials produced by enterprises of various forms of ownership on the territory of the Russian Federation and imported into the territory of the Russian Federation. The OFS is introduced for the first time due to the need to harmonize with the requirements of leading foreign pharmacopoeias: European Pharmacopoeia, British Pharmacopoeia, US Pharmacopoeia, etc. [3, 4, 12, 14, 18]. In the light of modern requirements for the quality of herbal preparations, the pharmacopoeias of leading foreign countries regulate the content of residual pesticides in the General Pharmacopoeia Monograph. produced by enterprises of various forms of ownership on the territory of the Russian Federation and imported into the territory of the Russian Federation. The OFS is introduced for the first time due to the need to harmonize with the requirements of leading foreign pharmacopoeias: European Pharmacopoeia, British Pharmacopoeia, US Pharmacopoeia, etc. [3, 4, 12, 14, 18]. In the light of modern requirements for the quality of herbal preparations, the pharmacopoeias of leading foreign countries regulate the content of residual pesticides in the General Pharmacopoeia Monograph. produced by enterprises of various forms of ownership on the territory of the Russian Federation and imported into the territory of the Russian Federation. The OFS is introduced for the first time due to the need to harmonize with the requirements of leading foreign pharmacopoeias: European Pharmacopoeia, British Pharmacopoeia, US Pharmacopoeia, etc. [3, 4, 12, 14, 18]. In the light of modern requirements for the quality of herbal preparations, the pharmacopoeias of leading foreign countries regulate the content of residual pesticides in the General Pharmacopoeia Monograph.

The requirements of this General Pharmacopoeia Monograph apply to medicinal plant raw materials, regardless of the form of release at the stages of development and introduction into production of new types of drugs, during their processing, storage, transportation, purchase, import into the country, certification and sale.

The CFS uses the following definitions:

Residual pesticides are substances that include residualthe amount of pesticides and any derivatives of pesticides (products of conversions, reactions, metabolites, impurities).

Units of measurement - mg / kg - amount of pesticide mg in 1 kg of medicinal plant materials.

Measuring Instruments - Required to Determine Pesticide Contentinstrument (gas chromatography-mass spectrometer) and methods of performing measurements on it, methods of sample preparation of raw materials for analysis. Sample for determination of residualpesticides - a certain amount of a sample isolated by quartering fromthe combined sample. The mass of a sample of raw materials for the determination of residual pesticides is at least 20.0 g.

Pesticide Residual Control - Definitioncompliance of the investigated objects with the requirements of hygienic safety standards. This General Pharmacopoeia Monograph is devoted to the consideration of the issues of the quantitative determination of residual pesticides and the assessment of the quality of batches of medicinal plant materials.

Received in the middle of the last century in Germany, the first

objective data on the accumulation of pesticides in medicinal plants and phytopreparations served as the beginning of their study as objects of environmental monitoring [1, 16].

The lack of data on the accumulation of pesticides in medicinal plants was a prerequisite for conducting relevant studies in a number of regions of the CIS. Studies have shown that the observed high concentrations of pesticides in plants can be the result of changes in sanitary and hygienic conditions and biological characteristics of species, which differ in different regions [6, 13, 15, 19]. Analysis of the literature data revealed differences in the content of various pesticides in medicinal plants and raw materials procured in a number of European and Asian countries (in ng / g): γ -hexachlorocyclohexane (γ -HCCH) 10-700, dichlorodiphenyltrichloromethylmethane (DDT) 10-1100, dichlorodiphenylchloroethylene (DDE) 20–80, hexachlorobenzene (HCB) 10–100 [17]. These differences are due, in part, to the individual biological characteristics of the species, but mainly, pollution of the natural environment with these toxicants. Highly efficient agriculture is impossible without the use of pesticides that can accumulate in plants. Therefore, medicinal plant raw materials and dosage forms from it are contaminated with various pesticides. Pesticides are found in various types of medicinal plant materials. The most persistent are organochlorine pesticides, which can be detected unchanged even 50 years after application. Derivatives of urea decompose most rapidly. The maximum concentrations of pesticides in wild medicinal plants (stinging nettle, calamus, marsh plantain, St. John's wort, etc.) reached: HCCH - 0.46 mg / kg, lindane - 0.6 mg / kg, fosalon - 0.5 mg / kg, karbofos - 0.75 mg / kg, polychlorocamphene - 0.92 mg / kg. The most heavily contaminated raw material is blue cornflower, which grows together with agricultural crops. In the raw materials of cultivated medicinal plants (ginseng roots, seeds of anise, fennel, coriander, etc.), the following were found in maximum quantities: pirimicarb - 0.5 mg / kg, chlorpyrifos - 31 mg / kg, dimethoate - 0.32 mg / kg, profenofos - 24 mg / kg. The most heavily contaminated fruits are ordinary anise.

As shown by the studies [5], organochlorine pesticides were found in almost all studied collections and dietary supplements sold through the pharmacy network in concentrations (in ng / g): α -HCH - 0–4.2; γ -HCCH - 0-2.6; DDT - 0-2.2; DDE - 0-7.8; HCB - 0-7.4. Despite the ban on the use of DDT since the mid-70s, this pesticide was detected in more than 20% of samples, at concentrations up to 2.2 ng / g. Its metabolite, DDE, is found in almost all studied samples.

The content of pesticides in phytopreparations to a certain extent depends on the type of solvent used. It was found that no more than 4% DDT, 8 - 68% α -HCH, 15–56%, γ -HCH passes into infusions [11, 17]. Experimental studies have shown that the absolute content of most pesticides in phytopreparations decreased in the following order: infusions and decoctions → thick and dry extracts → liquid tinctures and extracts [5]. The average transition values of toxicants in most cases did not exceed 10%, and only in some thick extracts

reached 20-25%. The concentration of pesticides in dosage forms differed: in infusions and decoctions, HCH was found in the greatest quantities, in thick and dry extracts - HCB, in tinctures and liquid extracts - DDT.

Concentrations of organophosphate pesticides and derivatives of sym-triazines in raw materials and phytopreparations, as a rule, are much lower than in chlorine-containing pesticides. In the pharmacopoeias of leading foreign countries, the nomenclature of standardized pesticides differs and includes 34–70 names of compounds of various classes. However, organochlorine pesticides, as one of the most dangerous toxicants, are a mandatory indicator for standardization in all pharmacopoeias (Table 1). Their content is determined by gas chromatography.

Analysis of permissible levels of pesticides has shown that the most strictly regulated content of pesticides in food in Russia (Hygienic standards GN 1.2.1323-03) (Table 2) [2]. In Russia, at present, the content of organochlorine pesticides is standardized only in food products and biologically active additives (BAA) based on medicinal plant materials (Table 3). However, at the level of modern requirements, it is necessary to assess and standardize the content of pesticides in medicinal plant raw materials that are used to obtain phytopreparations.

Table 1

The nomenclature of pesticides, the content of which is standardized in medicinal products and in food in most countries

Пестицид	Лекарственное растительное сырье				Пищевые продукты	
	BP	EP	USP	ГФРБ	ГСА	ГН
Алахлор	+	+	+	+	-	+
Алдрин и Диалдрин (сумма)	+	+	+	+	+	+
ДДТ (сумма ДДЕ, ДДТ и ТДЕ)	+	+	+	+	+	+
Дихлорфос	+	+	+	+	+	+
Гептахлор	+	+	+	+	+	+
Гексахлорбензол	+	+	+	+	+	+
Гексахлорцикло-гексан	+	+	+	+	+	+
Линдан (γ -гексохлороциклогексан)	+	+	+	+	+	+

Примечания: BP – Британская фармакопея; EP – Европейская фармакопея 6.2; USP – Американская фармакопея; ГФРБ – Фармакопея Республики Беларусь, ГСА – Государственный Стандарт Австралии, ГН – Гигиенические Нормативы Российской Федерации ГН 1.2.1323-03; «+» обозначает, что содержание пестицида нормируется данным документом; прочерк обозначает, что содержание пестицида не нормируется данным документом.

table 2

Permissible norms for the content of residual pesticides in the medicinal vegetable raw materials and food products (in mg / kg)

Наименование пестицида	Лекарственное растительное сырье				Пищевые продукты	
	BP	EP	USP	ГФРБ	ГСА	ГН
Алахлор	0,02	0,05	0,02	0,02	–	0,02
Алдрин и Диалдрин (сумма)	0,05	0,05	0,05	0,05	0,01–0,2	нд
ДДТ (сумма ДДЕ, ДДТ и ТДЕ)	1,0	1,0	1,0	1,0	0,1–5,0	0,05–0,1
Гептахлор	0,05	0,05	0,05	0,05	0,01–0,2	нд
Гексахлорбензол	0,1	0,1	0,1	0,1	0,05–0,1	0,01
Гексахлорцикло-гексан	0,3	0,3	0,3	0,3	–	0,1
Линдан (γ -гексохлороциклогексан)	0,6	0,6	0,6	0,6	–	0,1

Примечание: BP – Британская фармакопея; EP – Европейская фармакопея 6.2; USP – Американская фармакопея; ГФРБ – Фармакопея Республики Беларусь, ГСА – Государственный Стандарт Австралии, ГН – Гигиенические Нормативы Российской Федерации ГН 1.2.1323-03; нд – не допускается, прочерк означает, что данные отсутствуют.

Table 3

Acceptable levels of pesticides in dietary supplements based on plant raw materials

(according to SanPin 2.3.2.1078-01)

Пестициды	Допустимые уровни, не более, мг/кг
ГХЦГ и его изомеры	0,1
ДДТ и его метаболиты	0,1
Гептахлор	Не допускается
Алдрин	Не допускается

The draft General Pharmacopoeia Monograph "Determination of the content of residual pesticides in medicinal plant raw materials" for the XII edition of the State Pharmacopoeia of the Russian Federation includes:

- procedure for taking samples for analysis - describes how to take samples from lots and lots of medicinal plant materials, rules for taking analytical samples based on regulatory documents adopted in Russia;
- the necessary requirements for the analysis (description instruments, reagents, utensils) - describes the rules for preparing samples for analysis and conditions for conducting gas chromatographic analysis with a gas chromatographic and mass spectrometric end (in accordance with the instrumental capabilities of domestic control and analytical laboratories);
- processing of the results obtained - calculation formulas are given the content of residual pesticides in medicinal plant materials (in mg / kg);

● determination of compliance with the safety requirements of the medicinal vegetable raw materials - the values of the limits of the permissible content are presented residual pesticides, which are recommended for the assessment of pesticide contamination of medicinal plant materials.

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