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STUDY OF THE SUPPOSITORY BASIS USING STEREOSPECIFIC ANALYSIS

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Annotation

The safety and quality of medi cines depend on the quality of the ingredients used in pharmaceutical production, both the main active substance and the auxiliary one, in particular, suppository bases (SPOs) come out on top. Physicochemical, biological, and pharmaceutical parameters of VSS, such as absorption, indifference depend on fatty acid and triglyceride compositions, distribution of acyls in triacylglycerides and stereospecific structure of triacylglycerols.

The sequence of the stereospecific analysis is schematically illustrated. The obtained Sn -1,2 (2,3) - diacylglycerols consists of several stages. The distribution of fatty acid acyls in the TAG of cottonseed oil and their dislocation in the product of its processing of SPO was estimated by the method of stereospecific analysis. The results of the determination of the fatty acid composition of the products of the stereospecific analysis of SPO are presented.

Based on the data, the acyl content in three positions of cottonseed oil TAG and SPO was calculated, as well as the results of the structural analysis of fatty acids. The analysis of the SPO showed that the redistribution of fatty acids in the TAG proceeds within quite noticeable limits. So, 0.3% of the C 14: 0 acid from the Sn-1-position passes to Sn-3, and the content of C 16: 0 in the Sn-2-position decreases by 0.8%, and in the Sn-1 - position by 6, 2%. The greatest migration of fatty acids in triacylglycerols is observed in the SPO. Stereospecific data allow to determine the content of acids in the molecule of triacylglycerols in Sn -1, Sn -2, Sn-3 positions. The proposed formula can be used to characterize the degree of transesterification of acids located in any of the three positions of the TAG molecule, regardless of their quantitative content.

The calculation of the content of glycerides of the SSS, SUS, SSU, SUU, USU, UUU types (saturated (S) and unsaturated (U) acids, respectively) was performed by the formulas.

Based on the given positional distribution of fatty acids, the stereospecific composition of TAGs of linoleic (L), oleic (O), palmitic (P), and stearic (C) acids in cottonseed oil was calculated and, accordingly, the TAG. provisions allow you to evaluate the quality of SPO to oxidation to environmental oxygen in order to increase the shelf life, safety and indifference. Stereospecific analysis of SPO allows to rationally select fat components to obtain stable high-quality bases for the production of suppositories.

Soft medicinal forms are ointments, gels, liniment, plasters, suppositories. All of them have a soft consistency, but they belong to different dispersed systems, in other words, they are drugs with a plastic-elastic-viscous medium.[1] Suppositories are still in demand, and their markets are developing due to the introduction of innovations and expanding the range of applications for these drugs (MP).

All natural fats and oils are triglycerides, that is, esters of the tribasic alcohol of glycerol. In nature, there are no fats and oils in which glycerin would be esterified by only one fatty acid; natural fats are always esters of two or more fatty acids.

All three acids are solid, waxy substances, colorless and odorless. In this form, they are an excellent raw material for the preparation of creams, gels, suppositories and various emulsions.

And of this it follows that the relevant is the question of creation and introduction in the domestic production of suppositories pharmacy, so the first priority is a matter of learning and selection of high-quality suppository bases (ACT) derived from domestic raw materials.

The quality of suppository bases is determined by both physicochemical methods and stereospecific analysis of triacylglycerols. (TAG)

In addition to the acids listed above, natural oils also contain unsaturated fatty acids such as, for example, oleic acid with one double bond, linoleic acid with two double bonds and linolenic acid with three double bonds. Unsaturated fatty acids and their esters are liquid at room temperature. Due to the presence of double bonds in them, they are very sensitive to decomposition reactions, for example, to the action of microbes, and easily decompose into smaller molecules. Thus, they deteriorate quickly. Therefore, they are usually hydrogenated at the double bonds, and stearic acid is formed from all three of the above-mentioned unsaturated fatty acids; at the same time they all become solid, which is why this method is called fat hardening i.e. obtaining special-purpose high-hard fats.[2,3,4]

However, it should be noted that the safety and quality of products used for pharmaceuticals, in particular suppository bases, comes first. Physicochemical (hardness, melting point, fatty acid composition, etc.), biological and pharmaceutical indicators such as absorption, indifference depend on fatty acid, triglyceride composition, acyl distribution in triacylglycerides and stereospecific structure of triacylglycerols. it follows that the quality depends on the quality suppository suppository bases used when manufactured uu such dosage form.[5, 6]

Suppository (Suppositorium) is a dosage form that is solid at room temperature and melts or dissolves at the temperature of the human body, intended for injection into natural and pathological openings and cavities of the body.[7,8]

... In connection with the general deterioration of the ecological situation, there is an increase in dermatological, gynecological diseases, malignant skin tumors, etc., in the treatment of which soft dosage forms are most often used.

The intensification of demand and the lagging behind it of the industry led to an increase in the number of names and the volume of soft dosage forms for which the demand of the population is not satisfied. In recent years, the industrial production and range of suppositories has increased in the world, which tends to be used more widely in medical practice.[9]

Suppositories are used to achieve both local and resorptive action of the drugs included in their composition. They play an important role in pediatric and geriatric practice, when problems arise with the assimilation and delivery of drugs by other routes of administration.

There are countries where suppositories are in great demand, and their markets are developing through the introduction of innovations and expanding the range of applications of these drugs. We can say that in many respects the state of the suppository market is determined by the traditions of their medical use in each specific country, including within the framework of self-medication.

Due to the fact that suppositories continue to be widely used in Uzbekistan, their market can be considered as one of the promising directions for the development of domestic production.

Currently, 720 trade names of soft drugs are registered in the Republic of Uzbekistan, taking into account various dosage forms, dosages and packaging. The results of the structured analysis show that the pharmaceutical market of the Republic of Uzbekistan is dominated by imported soft drugs (51%), the results are presented in Table 1.

Table 1: Analysis of the soft drugs market by country for 2019-2020.

No.	Soft LF	Uzbekistan		CIS		Abroad	
		Qty	%	Qty	%	Qty	%
1.	Mr. spruce	7	4.97%	25	11.74%	132	36.06%
2.	M az	85	60.28%	76	35.68%	84	22.95%
3 .	From the suppository	36	25.53%	84	39.44%	47	12.84%
4.	P asta	one	0.7%	2	0.93 %	2	0.55%
5 .	L iniment	eight	5.68%	eleven	5.16%	0	0%
6 .	To rem	4	2.84%	fifteen	7.05%	101	27.6%

From the analysis of the market for soft drugs, it was revealed that the main type of dosage form for this group is ointments. On average, ointments make up 40% of soft DF, and 30% suppositories are listed in the State Register.[10]

In accordance with the State Register of Medicines and the results of the analysis of the range of suppositories, rectal suppositories currently prevail (58.%) (Table 2).

Table 2

No.	Suppositories	Uzbekistan		CIS		Abroad	
		Qty	%	Qty	%	Qty	%
one.	P ektalnye	29	80.55%	47	55.96%	18	38.3%
2.	Into aginal	7	19.45%	31	36.9%	24	51.06%
3 .	Both rectally and vaginally	0	0%	6	7.14%	five	10.64%

This is also evidenced by the data for the countries in Figure 1. a B C.

Figure 1.(a): The ratio of the prevalence of suppositories in RUz.

Figure 1.(b)

Figure 1.(c).

As can be seen from Figures 1 a, b, c, the use of suppositories for rectal and vaginal administration is significantly predominant. The republic uses mainly foreign production and the CIS countries.

So the above indicates the relevance of the issue of creating suppositories in the depths of domestic industrial pharmacy, which means that the primary task is to study and select high-quality suppository bases obtained from domestic raw materials.

Experimental Part

Quality suppository bases define op redelyayutsya like physicochemical met odes so stereospecific analysis TAG.

Stereospecific analysis of the TAG structure is based on the hydrolytic stereospecificity of phospholipase A with respect to synthetic phospholipids obtained from natural TAGs taken for analysis.[11,12] TAG analysis consists of three groups:

1. Obtaining from TAG the sum of isomeric diacylglycerols under conditions excluding acyl migration (representative diacylglycerols);
2. Phosphorylation of diacylglycerols in order to obtain phospholipids;
3. Hydrolysis of phospholipids by phospholipase A.

The sequence of analysis is schematically illustrated in Fig. 2.3. As can be seen from the diagram, the obtained Sn -1,2 (2,3) - diacylglycerols consists of the following steps:

One
2 1,2,3-triacyl - A – glycerin
3 (S_n - glycerin)
1 TAG
FFA 2 2 2 non-cleavage
3 last
1,2 diacyl- 2,3 diacyl-monacyl-
S_n - glycerin S_n - glycerin glycerin
Hydrolysis of KOH
Phosphorylation Fatty acids
S_n - 2 - positions
1 P · P_h O
2 + 2 + P · P_h - P - O - C_6 H_5
R · R_h 3 OH
1-2 diacyl - 3 - phenyl 1 - phenyl phosphate
Phosphate glycerin - 2,3-diacylglycerol

(S_n - glycerin (S_n - glycerin
3 - phosphate) 1 - phosphate)
Phospholipolysis Phospholipase A (gyurza poison)
1 P · P_h
+ 2 + FFA
R · R_h 3
1-acyl - 3 - phenylphas- 1- phenylphasphate · 2,3 -
phat S_n - glycerin diacyl - S_n – glycerin
(lysophosphatidylphenol) (D-phosphatidylphenol)

Fatty acid
S_n - 1 - positions

Fig. 2: Schematic sequence of stereoanalysis.

1. Hydrolysis of fat by pancreatic lipase;
2. Separation of lipase hydrolysis products by preparative thin-word chromatography on silica gel plates;

Phosphorylation of Sn -1,2 (2,3) -diacylglycerols consists of the following processes:
1. Synthesis of phenyldichlorophosphate;
2. Isolation of L and D -phosphotidylphenols.
3. Purification of L and D - phosphotidylphenols.

Phospholipolysis of L and D - phosphotylphenols is carried out in 2 stages:
1. Phospholipolysis of L and D - phosphotidylphenols;
2. Isolation of phospholipolysis products.

The composition of free fatty acids obtained by the cleavage of lysophosphotidylphenols should not differ from the composition of the Sn -2 acids of monoacylglycerols obtained by lipolytic hydrolysis. The coincidence of the compositions confirms the absence of isomerization during the isolation of Sn -1, 2 (2,3) - diacylglycerols and, therefore, their representativeness.

The content of Sn -3- position is obtained by calculation by two methods:
First - Sn -3 = 3 (starting TAG) - (lysophosphatides) - (2-mono-acylglycerols);
The second is Sn -3 = 2 x (D - phosphodiphenols) - (2-monoacylglycerols).

The closeness of the results of the two calculations shows the reliability of the stereospecific TAG analysis. When comparing THICK about - acid compositions of individual positions or reactions allowed discrepancy in content of basic 2-4%.

On the basis of the use of stereospecific analysis, the initial hydrogenated cottonseed oil and the product of its hydrogenation - salomas-1, obtained on a nickel catalyst, with a preliminary oxidized surface, were investigated.

Hydrogenation of cottonseed oil, physical and chemical indicators are given in table. 1., was carried out at a temperature of 200 ^{0}C, the pressure in the volumetric hydrogen transmission rate is 2 kPa. At the same time, the volumetric oil supply rate was varied (from 1.5 to 2.0 h^{-1}) to obtain RVO with practically the same iodine numbers (eg, about 78% J_2).

Table 1: Physical and chemical indicators of cottonseed oil and SPO.

Samples	**Iodine number,% J2**	**K.ch. %, KOH**	**Fat-acid composition**			**Selectivity,%**
			US.	**Ol.**	**Lin.**	
Cottonseed oil	113.2	0.3	25.0	17.9	53 , 1	-
SPO	77.9	0.6	34.2	45.2	20.6	81.0
Salomas - SPO	77.5	0.5	32.1	49.9	18.0	88.0

X) - SPO obtained on a nickel-copper-molybdenum-aluminum catalyst without an oxidized surface;
XX) - SPO obtained on a nickel catalyst with an oxidized surface.

The distribution of fatty acid acyls in the TAG of cottonseed oil and their dislocation in the product of its processing of SPO was estimated by the method of stereospecific analysis. Determination results of fatty - acid composition analysis stereospecific products ACT Representat avleny in table 2.

Table 2: Fatty acid composition of cottonseed oil and SPO.

Types of glycerides	Fatty acids, mol,%					
	C14: 0	**C16: 0**	**C16: 1**	**C18: 0**	**C18: 1**	**C18: 2**
HM: *TAG*	1,2	24.8	0.9	2.1	17.9	53.1
2-MAG	-	3.5	-	Sl.	22.1	74.4
D- phosphatildylphenols	0.7	16.8	Sl.	0.2	18.3	64.0
L- lysophosphatides	2.1	40.7	2.6	5.9	17.5	31.2
SPO: *TAG*	1,2	25.9	-	5.0	49.9	18.0
2-MAG	-	2,3	-	5.4	54.9	37.4
D- phosphatildylphenols	0.9	21.6	-	3.8	50.6	23.1
L- lysophosphatides	1.8	34.5	-	7.3	48.6	7.8

Based on the data in Table 2, we calculated the acyl content in three positions of the TAG of cottonseed oil and SPO. Analysis of the data in Table 3 shows that in cottonseed oil palmitic acid content of Sn -2 position is 3.5%. In this position, the largest portion of the fatty acid is linoleic acid (74.4%), and oleic (22.1%). The largest amount of saturated acids ($C_{14:0}$, $C_{16:0}$, $C_{18:0}$) is located in the Sn -1-position, mainly etopalmetic acid (40.7%). In the Sn -3 position, the same as in Sn -2, the largest part is linoleic acid (53.7%). Similar results on the stereospecific analysis of cottonseed oil were obtained by other authors.

STR analysis showed h then at the same catalyst but with the oxidized surface of the redistribution of the fatty acids in triacylglycerols etc. of Tek in a sufficiently perceptible range. So, 0.3% of the $C_{14:0}$ acid from the Sn -1-position passes to Sn -3, and the content of $C_{16:0}$ in the Sn -2-position decreases by 0.8%, and in the Sn -1-position by 6, 2%. Thus, the analysis of the data in Table 3 showed that the greatest migration of fatty acids in triacylglycerols is observed in SPO.

Table 3: Results of structural analysis of fatty acids in cottonseed oil and SPO.

Fatty acid	**Content of acyls in 3 positions, mol,%**					
	Cottonseed oil			**SPO**		
	Sn-1	**Sn-2**	**Sn-3**	**Sn-1**	**Sn-2**	**Sn-3**
C14 : 0	2.1 (58.3)	-	1.5 (41.7)	1.8 (50.1)	-	1.8 (49.9)
C16: 0	40.7 (54.7)	3.5 (4.7)	30.2 (40.6)	34.5 (44.4)	2.3 (3.0)	40.9 (52.6)
C16: 1	2.6 (96.3)	-	0.1 (3.7)	-	-	-
C18: 0	5.9 (93.6)	Sl.	0.4 (6.4)	7.3 (48.8)	5.4 (36.0)	2.3 (15.2)
C18: 1	17.5 (32.6)	22.1 (41.2)	14.1 (26.2)	48.6 (32.5)	54.9 (36.7)	46.2 (30.8)
C18: 2	31.2 (19.6)	74.4 (46.6)	53.7 (33.8)	7.8 (14.4)	37.4 (69.3)	8.8 (16.3)

X) is the proportion of acid in a certain position in% relative to its total content in triacylglycerols.

$$C_n = \frac{Mg_o - MG}{Mg_o - TG} \cdot 100 \ (\%)$$

Where: MG_o and MG - initial and final content of palmitic acid in 2-monoglycerides,%;
TG is the average content of this acid in a mixture of triacylglycerides.

However, this equation, as noted, is suitable only in cases where palmitic acid in 2-monoglycerides is contained in large quantities.

Therefore, for cottonseed oil, which contains only 3.5% palmitic acid with Sn- 2 monoglycerides, we recommend evaluating the redistribution of fatty acids in triacylglycerols using the following formula:

$$P = \frac{MG}{MG_{about}} \cdot x100;$$

Where: MG_o, MG - the initial and final content of palmitic acid in Sn - 2- monoglycerides;
MG - the absolute difference in the content of palmitic acid in Sn - 2 - monoglycerides, which is determined by the formula:
MG = MGo-MG

Based on the last equation, we calculated the interesterification index (P) for salomas 1 and 11, which is 5.7 and 34%, respectively.

It is known that, in contrast to enzymatic analysis, stereospecific data allow the determination of the acid content in the triacylglycerol molecule at Sn -1, Sn -2, Sn -3 positions. Our proposed formula can be used to characterize the degree of transesterification of acids located in any of the three positions of the triacylglycerol molecule, regardless of their quantitative content.

The calculation of the content of glycerides of the **SSS, SUS, SSU, SUU, USU, UUU types** (saturated **(S)** and unsaturated **(U)** acids, respectively) was carried out according to the following formulas (11, 12):

; (1); (4)
; (2); (5)
; (3). (6)

where *b* is the content of saturated acids in 2-monoglycerides, in mol%;
g is the content of saturated acids in 1,3-diglycerides, in mol%.

(7)

a - the content of saturated acids in the original sample, in mol%.
d - the content of unsaturated acids in 1,3-diglycerides, in mol%.

(8)

e - the content of saturated and unsaturated acids in the 1,3-diglyceride molecule in mol%
e = 100 - (g + d)

(9)

To determine the amount of individual glycerides (taking into account position isomers), the content of fatty acids in 1,3-diglycerides in molar percent **(X) was** calculated using the formula:

(10)

where *h* and *i* are the content of this acid in the original sample and 2-monoglycerides, respectively, in mol%.

Then the content of individual glycerides in molar percent was calculated using the following formulas:

monoacid (11)
two-acid (12)
(13)
tri-acid (14)
(15)
(16)

where A, B, C are molar percentages of fatty acids.

To determine the iodine number of cottonseed oil and hydrogenated fats, the Wijs method was used. The method is based on the use of iodine to completely saturate unsaturated bonds. For quantitative saturation of double bonds, the condition of 100% excess of halogen, strictly limited in time of saturation of double bonds, was observed, and the reaction was carried out in the dark in flasks with ground stoppers. The unattached excess of iodine was titrated with sodium thiosulfate ($Na_2S_2O_6$) after preliminary introduction of a solution of potassium iodide and water into the reaction medium. The introduction of potassium iodide leads to the release of an equivalent amount of iodine to an excess amount of halogen unused for saturation of double bonds.

The fatty acid composition of the feedstock and hydrogenation was adjusted x-liquid romatografiey methyl esters.[11,12] Pozitsionnoe distribution of fatty acid acyl triglyceride molecules in cottonseed oil and the hydrogenation was determined by a modified method stereospecific anali for.[13] Raspredelenie cottonseed oil triglyceride of the position-type CB composition is shown in Table 4.

Table 4: Positional-typical glyceride composition of cottonseed oil sample.

Triacylglyceride group index	Mole fraction,%	
	An experience	calculation[x)]
H_3	28.1-28.3	31.9
H_2P including NNP NPN PNN	48.7-49.0 20.1-22.7 1.7-1.0 26.9-25.3	44.4
MON_2 including NPP Tnp PPN	22.1-22.0 1.2-0.8 19.3-20.4 1.7-0.8	20.5
P_3	1.1-0.7	3.2

x) Provided the statistical distribution of the sum of unsaturated and saturated acids in triglycerides.

The positional distribution of fatty acid acyls in the triglycerides of cottonseed oil is shown in Table 5 using the example of analysis of a sample of cottonseed oil with I.ch. 107.0.

Table 5: Positional distribution of fatty acids in triacylglycerides (TAG[1]) cottonseed oil sample.

Index acids	Mole fraction of fatty acids,%			
	TAG [1]	Sn-1	Sn-2	Sn-3
14: 0	1.1 0.2	1.5 0.2	-	1.8 0.3
16: 0	25.0 0.4	39.7 1.0	1.5 0.6	36.8 1.2
18: 0	2.1 0.2	3.5 0.7	-	2.8 0.8
18: 1	17.8 0.4	16.3 0.6	22.0 0.8	11.5 1.1
18: 2	54.0 0.9	38.4 1.3	76.5 0.2	47.1 1.6

Based on the given positional distribution of fatty acids, the stereospecific composition of TAG[1] of linoleic (L), oleic (O), palmitic (P), and stearic (C) acids in cottonseed oil was calculated.

Table 6 shows only those TAG[1], the content of which in the oil exceeded 0.1 mol%.

Table 6: Basic Triacylglycerides of Cottonseed Oil.

TAG type[1]	TAG type[1]	Mole fraction of TAG,%
H_3	Lll	10.3-11.3
	LLO	2.7-3.0
	LOL	4.0-3.9
	ALL	5.7-5.3
	LOO	1.1-1.0
	OOL	2.2-1.9
	OLO	1.5-1.4
	OOO	0.5-0.6
H_2P	PLL	14.0-13.3
	BOB	8.1-10.2
	OLP	4.5-4.8
	LOP	3.1-3.6
	FLOOR	5.4-4.6
	PLO	3.7-3.5
	OOP	1.7-1.8
	VET	1.4-1.2
P_2N	PLP	11.1-12.1
	POP	4.3-4.2
	Pic	0.4-0.3
	SOP	0.3-0.4
P_3	RFP	0.8-0.6

The content of trans isomers in the obtained modified fats was calculated from the data of IR spectra.[11,12]

The mass content of trans-isomerized fatty acids in hydrogenated fats was determined according to a known method[14] using IR spectroscopy on an IKS-14 device. Determination of the investigated index was carried out at a value of radiation absorption of 968 cm $^{-1}$ (= 10330 nm).

The quantitative content (X,%) of trans-isomerized fatty acids was calculated using the following formula:

$X = 100\ Kg / Km\%$ (17)

where: *Km* is the absorption coefficient of infrared rays of methylelaidates at 968 cm^{-1}:

$Km = D / Cd$ (18)

D is the density (g / l) of a solution of carbon tetrachloride with an absorption spectrum of 968 cm^{-1};

C is an indicator determined experimentally;

d is the thickness of the cuvette of the test solution of carbon tetrachloride, cm;

Kg - absorption coefficient of infrared rays of hydrogenated fat at 968 cm^{-1}:

$Kg = Dg / Cd_k$ (19)

T de : *D* - density (g / L) dissolved hydrogenated fat absorption spectrum at 968 cm^{-1};

C is the indicator determined experimentally for the dissolved hydrogenated fat;

d_{to} - the thickness of the cuvette of dissolved hydrogenated fat, see.

Determination of iodine content was carried out by the Wiiss method[12,14], or it was calculated from the composition of fatty acids. The acid number of modified fats opr edelyali alcohol-ester method[11,12] Melting point and pour point, and hardness were determined fat method to those described in.[15]

CONCLUSIONS

Thus, it can be concluded that cottonseed oil and the obtained SPOs on the stereospecific arrangement of FA acyls have been studied. Stereospecific data allow to determine the content of acids in the molecule of triacylglycerols in Sn -1, Sn -2, Sn -3 positions. Proposed I formula can be used to characterize the degree of transesterification acids located in any of three positions of the TAG molecules, regardless of their quantitative content.

The calculation of the content of glycerides of the **SSS, SUS, SSU, SUU, USU, UUU types** (saturated **(S)** and unsaturated **(U)** acids, respectively) was performed by the formulas.

On the basis of the given positional distribution of fatty acids, the stereospecific composition of TAG of linoleic (L), oleic (O), palmitic (P), and stearic (C) acids in cottonseed oil and, accordingly, SPO was calculated.

1. Quantitative arrangement of FAs in the TAG structure. Knowledge of the location of saturated and unsaturated fatty acids in 3 positions makes it possible to evaluate the SPO to oxidation to ambient oxygen in order to increase the shelf life, safety and indifference.
2. Enables the ability to relocate FA acyls in TAG and develop measures for their directed redistribution.
(3) Stereospecific analysis of SPO allows rationally select fat components to obtain stable high-quality SPOs for the production of suppositories.

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