

Technical and economic justification for biomass production *Lactobacillus rhamnosus* GG for the production of the drug «Acidolac»

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There are several pharmaceutical companies in the world that produce probiotics based on the *Lactobacillus rhamnosus* GG bacteria, such as "Polpharma", "Chr. Hansen", "NORD FARM", etc. In Ukraine, products based on this strain are also produced by JSC "Farmak" ("Lactiale GG") and "Acino Ukraine" ("DermaPro"), but they are manufactured by foreign enterprises.

In our country, "Acidolac" is also not produced, but imported from Poland, so the development of a domestic enterprise for the production of a monostrain drug with a full production cycle would be relevant. "Acidolac" is used for the treatment and prevention of dysbiosis, intestinal infections, and also contributes to the normalization of intestinal microflora during antibiotic therapy. Research has shown that *Lactobacillus* GG is the only scientifically proven strain of lactobacilli that reduces the course of rotavirus infection. Therefore, to calculate the annual demand, statistics on patients with rotavirus and the number of patients who received antibiotic therapy were analyzed.

According to statistics, about 7,000 people in Ukraine contracted rotavirus enteritis in 2022. The course of treatment with this drug for infants from 1 month and children up to 3 years old is 1 sachet per day, and for children over 3 years old and adults, it is 1-2 sachets per day. The course of treatment is 10-14 days. Since the exact age range of patients was not provided, we will take the average dosage values. $1.5 \text{ sachets} * 12 \text{ days} = 18 \text{ sachets}$. The required number of sachets per year for the treatment of rotavirus infection is: $18 \text{ sachets} \times 7,000 \text{ people} = 126,000 \text{ sachets/year}$.

Also, for correct calculation of production capacity, it is necessary to take into account the number of patients taking antibiotics. According to the official statistics of the WHO in Ukraine for 2020, the level of antibiotic consumption was 26.1 units

per 1000 people per day. Taking into account the above information, it can be concluded that out of 1000 people, 26 took antibiotics, or 2.6%. Considering that the permanent population of Ukraine is 40.9 million people (data for 2021), we get the following total number of all patients who took antibiotics: $40,997,699 * 0.026 = 1,065,940$ people.

The total duration of antibiotic treatment is 5-7 days. "Acidolac" is recommended to be taken during antibiotic therapy and continued for 2 weeks after completion. Conducting calculations, we get the following data: $1.5 \text{ sachets} * 21 \text{ days} = 31.5 \text{ sachets}$. The required number of sachets per year is $31.5 * 1,065,940 \text{ people} = 33,577,110 \text{ sachets/year}$ to meet the need for the treatment of dysbiosis caused by antibiotic therapy.

Let's calculate the total demand: $33,577,110 + 126,000 = 33,703,110$ sachets per year.

Table 1. Calculation of annual demand for "Acidolac"

Categories of the population	Dose of drug per day	Number of doses per day	Duration of treatment, days	The number of patients in Ukraine	The number of patients in Ukraine
<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
Patients with rotavirus	1 sachet – $4 * 10^9$ CUF)	1-2	12	7000	126 000
Take antibiotics	1 sachet – $4 * 10^9$ CUF)	1-2	21	1 065 940	33 577 110
Total					33 703 110

As stated by the manufacturer, each sachet contains 0.04 g of biomass. Therefore, it is necessary to obtain $0.04 * 33,703,110 = 1,348,124 \text{ g} \approx 1,348 \text{ kg}$ of biomass. Taking into account the huge number of competitors on the Ukrainian market, including imported probiotics and domestically produced drugs such as "Linex", "Nifuroxazide", "Lactiale", "Bifiform", "Normospectrum", "Florin", "Imoflora", "Primadophilus", etc., it is economically feasible and justified by marketing research to produce only 5% of the calculated amount, which is $1,348 * 0.05 = 67.4 \text{ kg}$ per year.