

ANNOTATION

**of report on Research Practice of a six-year student, group BT-51m
specialty 8.05140101 - Industrial Biotechnology**

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**New recombinant glargine insulin production process using methylotrophic
yeast *Pichia pastoris***

Research report contains 50 pages of printed text. The report consists of an introduction, two chapters, conclusions, references and includes 9 figures and 8 tables. The report from research practices are sections: Chapter 1 Literature review and Chapter 2 Experimental part.

The introduction highlights the relevance of the chosen research, its purpose and tasks, a brief description of the place of scientific research practice.

Research object is focused on recombinant human insulin with prolonged action as well as expression systems based on methylotrophic yeast *Pichia pastoris*.

Materials and methods: genetic analysis of the producer, media preparing and analysis, cultivation process and validation tests at each stage of obtaining API.

The main results: new optimal composition of BMGY media, improved cultivation system using Sensitive Bio™, which guarantee the final increase of the API product up to 6%.

Acknowledgments and conclusions:

1. There were optimized the media compound and culturing techniques for selected transformed strain *Pichia pastoris* X-33 F.
2. Carried out the isolation and purification of glargine API by using new advanced techniques.
3. Developed and get accepted the validation project to prove the reliability and reproducibility of glargine API.
4. The following API has been successfully passed the scalability and replicability testing.