STATE INSTITUTE FOR DRUG CONTROL

Šrobárova 48
100 41 Praha 10

Tel.: +420 272 185 111
Fax: +420 271 732 377

E-mail: posta@sukl.cz
Web: www.sukl.cz

RECEIVER
DYNTEC spol. s r. o.
Pražská 328
411 55 Terezín

File No.
sukls28B6S2/2023
Ref. No.
sukl12506/2024

Transact/line
Ing. Machutková

Date
16.01.2024

DECISION

The State Institute for Drug Control, based in Prague 10, Šrobárova 48 (hereinafter as "Institute"), as the authority responsible for the decision pursuant to § 13 paragraph 2 letter a) point 2 of Act No. 378/2007 Coll., on pharmaceuticals and on amendments to certain related laws Act on Pharmaceuticals, as amended (hereinafter as "Act on Pharmaceuticals"), decided in accordance with the provisions of § 67 of Act No. 500 /2004 Coll., administrative regulations, as amended (hereinafter referred to as "administrative regulations") in the procedure for an application to change a permit for the production of medicinal products delivered on 30 November 2023.

t h u s:

The Institute, in accordance with § 63, paragraph 6 of the Act on Pharmaceuticals and in accordance with Article 61 of Regulation (EU) No. 536/2014 of the European Parliament and of the Council, on clinical evaluations of medicinal products for human use and on the repeal of Directive 2001/20/EC, amends the authorization **decision for the production of medicinal products**, reference No. 7590/INS/00 dated 18 May 2000, as amended, as follows:

- The type and scope of permitted production of human evaluated medicinal products is changed so that in section **1.6 Quality control** points **1.6.1 Microbiological: test for sterility** and **1.6.4 Biological**

and DYNTEC spol. s r. o., based in Pražská 328, 411 55 Terezín, Company ID 475 48 002

is permitted to manufacture medicinal products

in following extent:

Addresses of all production sites	Pražská 328, 411 55 Terezín
Addresses of all places of quality control	Pražská 328, 411 55 Terezín
Type and extent of authorized production	See Annex No. 1 (1 page in total)
	See Annex No. 2 (1 page in total)
Addresses of contract manufacturing sites	See Annex No. 3 ----------
Addresses of contract sites of quality control	See Annex No. 4 ----------
Names and surnames of qualified persons	See Annex No. 5 (1 page in total)

The annexes to this Decision are numbered according to the document „Union Basic Format for Manufacturers Authorization“ as applicable from 2 January 2013, which is part of the Compilation of Community Procedures on Inspections and Exchange of Information.

R e a s o n i n g

In accordance with § 68, paragraph 4 of the Administrative Code, the justification is not provided, as the request to change the authorization for the production of medicinal products was fully granted.

A d v i c e

It is possible to appeal against this decision in accordance with the provisions of § 81 and subsequent of the Administrative Code at the Appeals Institute, **within 15 days** from the date of its delivery. The Ministry of Health of the Czech Republic decides on the appeal.

Official stamp

Ing. Eva Niklíčková
director of the inspection department

Annex No. 1 to decision file No. sukls288652/2023 dated 16.01.2024

Type and extent of authorized production of human medicinal products

Name and address of production site:
DYNTEC spol. s r. o., Pražská 328, 411 55 Terezín

Part 1 – Production operations	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (manufacturing operations for the following pharmaceutical forms)
	1.2.1.17 Other non-sterile medicinal products — single-dose lyophilizates for preparation of peroral suspension
	1.2.2 Batch certification
1.3	**Biological medicinal products**
	1.3.1 Biological medicinal products (types of products)
	1.3.1.8 Other biological medicinal products — single-dose lyophilizates for preparation of peroral suspension
	1.3.2 Batch certification (types of products)
	1.3.2.8 Other biological products - single-dose lyophilizates for preparation of peroral suspension
1.5	**Packaging**
	1.5.1 Primary packaging
	1.5.1.17 Other non-sterile medicinal products — single-dose lyophilizates for preparation of peroral suspension
	1.5.2 Secondary packaging
1.6	**Quality control**
	1.6.1 Microbiological: sterility test
	1.6.2 Microbiological: microbiological safety
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifications related to the scope of manufacturing operations: ----------

Official stamp

Ing. Eva Niklíčková
director of the inspection department

----------end of annex 1----------

Annex No. 2 to decision file No. sukls288652/2023 dated 16.01.2024

Type and extent of authorized production of human evaluated medicinal

products

Name and address of production site:
DYNTEC spol. s r. o., Pražská 328, 411 55 Terezín

Part 1 – Production operations	
1.2	**Non-sterile evaluated medicinal products**
	1.2.1 Non-sterile products (manufacturing operations for the following pharmaceutical forms)
	1.2.1.15 Other non-sterile medicinal products — single-dose lyophilizates for preparation of peroral suspension
1.3	**Biological evaluated medicinal products**
	1.3.1Biological medicinal products (types of products)
	1.3.1.8 Other biological medicinal products — single-dose lyophilizates for preparation of peroral suspension
1.5	**Packaging**
	1.5.1 Primary packaging
	1.5.1.15 Other non-sterile medicinal products — single-dose lyophilizates for preparation of peroral suspension
1.6	**Quality control**
	1.6.1 Microbiological: sterility test
	1.6.2 Microbiological: microbiological safety
	1.6.3 Chemical/Physical
	1.6.4 Biological

Any restrictions or clarifications related to the scope of manufacturing operations: ----------

Official stamp

Ing. Eva Niklíčková
director of the inspection
department

---------- end of annex 2 ----------

Annex No. 5 to decision file No. sukIs288652/2023 dated 16.01.2024

Names and surnames of qualified persons

MVDr. Mgr. Ladislav **Pažout**
Ing. Pavla **Žáková**

Official stamp

Ing. Eva Niklíčková
director of the
inspection department

---------- end of annex 5 ----------