SÚKL STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48
100 41 Praha 10
Czech Republic
Phone: +420 272 185 111
Fax: +420 271 732 377
E-mail: posta@sukl.cz
Web: www.sukl.cz

Prague, January 20, 2022

Declaration

State Institute for Drug Control
(hereinafter only SUKL)

as a competent authority of the Czech Republic for inspection of persons handling pharmaceuticals and issuing Certificates of Good Manufacturing Practice according to Section 13 of the Act No 378/2007 Coll., on Pharmaceuticals and on Amendments to Some related Acts, as amended,

hereby declares that

FARMAK a.s., manufacturing site: Na vlčinci 16/3, Klášterní Hradisko, 77900 Olomouc, Czech Republic is a manufacturer of active pharmaceutical ingredients:

ADENOSINE, TESTED MICROBIOLOGICALLY AND FOR PYROGENES, CAS 58-61-7
ALFUZOSIN HYDROCHLORIDE, CAS 81403-68-1
BRIMONIDINE TARTRATE, CAS 70359-46-5
BROMFENAC SODIUM SESQUIHYDRATE, CAS 120638-55-3
BUTAMIRATE CITRATE, CAS 18109-81-4
DEFERASIROX, CAS 201530-41-8
DOFETILIDE, CAS 115256-11-6
DOSULEPIN HYDROCHLORIDE, CAS 897-15-4
DOXAZOSIN MESILATE, CAS 77883-43-3
ESZOPICLONE, CAS 138729-47-2
HYMECROMONE, CAS 90-33-5
CHLORPROTHIXENE, CAS 113-59-7
CHLORPROTHIXENE HYDROCHLORIDE, CAS 6469-93-8
KETOROLAC TROMETAMOL, CAS 74103-07-4
MAGNESIUM LACTATE, CAS 18917-93-6
MEPHENOXALONE, CAS 70-07-5
MOXONIDINE, CAS 75438-57-2
N-(3-MORFOLIN-4-YLPROPYL)-4-SULFAMOYLBENZAMIDE HYDROCHLORIDE (MSBA.HCL), CAS 1073637-77-0
REGADENOSON, CAS 313348-27-5
REGADENOSON MONOHYDRATE CAS 875148-45-1
RILUZOLE, CAS 1744-22-5
RIVAROXABAN, CAS 366789-02-8
SACUBITRIL SODIUM SALT, CAS 149690-05-1
SELEGILINE, CAS 14611-51-9
SELEGILINE HYDROCHLORIDE, CAS 14611-52-0
TIZANIDINE BASE, CAS 51322-75-9
TIZANIDINE HYDROCHLORIDE, CAS 64461-82-1
TREAMID (XC268BG)

SÚKL
STATE INSTITUTE FOR DRUG CONTROL
Šrobárova 48
100 41 Praha 10
Czech Republic
Phone: +420 272 185 111
Fax: +420 271 732 377
E-mail: posta@sukl.cz
Web: www.sukl.cz

VALSARTAN DISODIUM SALT, CAS 137862-53-4
WARFARIN SODIUM AMORPHOUS, CAS 129-06-6
WARFARIN SODIUM CLATHRATE, CAS 67430-45-9
XC-8, CAS 1464897-15-1
ZILEUTON, CAS 111406-87-2
ZOLPIDEM TARTRATE, CAS 99294-93-6
ZOPICLONE, CAS 43200-80-2

and a holder of a Certificate of Good Manufacturing Practice issued by SUKL.

According to Section 70 of the Act No 378/2007 Coll. the manufacturer of API is allowed to manufacture and market API if complies with the principles of good manufacturing practice. Compliance with the principles of good manufacturing practice in the manufacture of API is evidenced by the Certificate of Good Manufacturing Practice.

According to law of the Czech Republic no other documents as Manufacturing Licence, Certificate of a pharmaceutical product (CPP) or Free Sale Certificate are issued for manufacturers of API. The product can be sold freely in country of origin and exported to other countries.

Státní ústav pro kontrolu léčiv
Šrobárova 48
100 41 Praha 10
(126)

Eva Niklíčková
Director of the Inspection Section