



GMP in HACCP

S skrbno izbranimi dobavitelji z dolgoletnimi izkušnjami na farmacevtskem trgu in na trgu s kozmetiko se lahko izvor vseh izdelkov ESSENS ponaša z mednarodno priznanim certifikatom GMP. Vsi dobavitelji so tudi imetniki certifikata HACCP. Globalni trg, mednarodna proizvodnja, oskrba s surovinami in aktivne farmacevtske sestavine povečujejo kompleksnost dobavnih verig, zato GMP zagotavlja najvišjo možno kakovost in enoten globalni pristop. Seznaniti vas želimo z informacijami o GMP in certifikatu HACCP ter vam pojasniti kaj pomeni certificiranje.

GMP (po slovensko DPP) je angleška kratica za »dobro proizvodno prakso« (Good Manufacture Practice)

Predstavlja sistem, ki si prizadeva za izboljšavo varnosti zdravil, hrane, kozmetike, krme za živali, itd.

GMP določa pravila delovanja, da bi se izognili nevarnosti (npr. pojavu nevarne hrane) in da zakonodaja ne bo kršena. Po izpolnitvi strogih pravil in standardov v skladu s pravili mednarodne uredbe proizvajalec, pridelovalec ali rejec prejme potrdilo, ki ga je potrebno redno obnavljati.

Certificiranje GMP deluje pod okriljem Svetovne zdravstvene organizacije (WHO- World Health Organisation)

Razlog za pričetek je bil na globalni ravni zagotoviti neškodljiva zdravila. Slaba kakovost zdravil ne predstavlja le tveganja za zdravje, ampak je tudi zapravljanje sredstev in ne le za potrošnike, temveč tudi za nacionalne vlade. Slabo ravnanje z zdravili lahko vodi do toksičnosti snovi, ali nasprotno, terapevtske sestavine se pojavljajo v neustreznih količinah, ki ne dosežejo terapevtskega učinka. Med proizvodnim procesom mora biti zagotovljena kakovost. Različne faze proizvodnje so pod nadzorom. Ni dovolj, da se testira samo končni izdelek. Cilj je, da države sprejmejo le uvoz in prodajo zdravil, ki so proizvedena v skladu z dobro proizvodno prakso.

Glavna tveganja ne-certificiranih podjetij so:

- Kontaminacija proizvoda - lahko povzroči neželene učinke za zdravje ali celo smrt
- Nepravilno označevanje embalaže - nevarnost zlorabe
- Premalo ali preveč aktivna sestavina - neučinkovitost ali stranski učinki

Pogoji poteka in certificiranja GMP:

- Vsi vidiki proizvodnje so pod nadzorom – uporaba prostora, surovine, izobraževanje, osebna higiena zaposlenih
- Za posamezne postopke so razvili potrebne podrobne pisne postopke, ki bi lahko imeli določen vpliv za kakovost končnega izdelka.
- Vsak posamezen proces v proizvodnem procesu mora biti dokumentiran z dokazi o pravilnem postopku za vsak izdelek
- Svetovna zdravstvena organizacija (WHO) je določila podrobne smernice dobre proizvodne prakse (GMP), ki se lahko v vsaki državi razlikujejo in so lahko formulirani v skladu z lastnimi zahtevami, vendar morajo biti vedno v skladu WHO in GMP

HACCP je angleška kratica za »analizo tveganj in kritičnih kontrolnih točk« (Hazard Analysis and Critical Control Points)

Je sistem za vsa podjetja za proizvodnjo živil, predelavo in distribucijo hrane. Sistem je tudi za podjetja, ki spadajo v prehrabetno verigo (kmetijstvo, proizvajalci embalažnih materialov, itd.) Glavni cilj HACCP so zdrava živila. Sistem HACCP je bil ustvarjen in vpisan v bazo predpisov Evropskega parlamenta in Sveta leta 2004. Zahteve sistema HACCP v Češki republiki so urejene v biltenu Ministrstva za kmetijstvo CZ 2/2010.



SGS

Certificate TR22/81875350

The management system of

ERTE KOZMETİK SAN. TİC. A.Ş.

ÇİHANGİR MAH., GÜVERCİN CAD., NO: 5/1 C BLOK
AVCILAR, İSTANBUL, TURKEY

has been assessed and certified as meeting the requirements of

ISO 22716



Cosmetics – Guidelines on Good Manufacturing Practices (GMP)

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 January 2022 until 11 January 2025
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before
Issue 1. Certified since 12/01/2022

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

Pieter Weterings
Certification Manager

SGS Belgium NV

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ERTE KOZMETİK SAN. TİC. A.Ş.

ISO 22716



**Cosmetics – Guidelines on
Good Manufacturing Practices (GMP)**

Issue 1

Detailed scope

**Manufacturing of Perfumes and Fragrances Alcoholic, Manufacturing
of Body Care, Manufacturing of Bath Care, Manufacturing of Skin Care,
Manufacturing of Hair Care, Manufacturing of Sun Care**

Additional facilities

**CİHANGİR MAH., GÜVERCİN CAD., NO: 1 A BLOK
AVCILAR, İSTANBUL, TURKEY**



CERTIFICATE

Certification Body for certification of management systems
accredited by ČIA according to ČSN EN ISO/IEC 17021-1:2016

CERT QUALITY SYSTEM s.r.o.

certifying the Management Systems
confirms that the Company

K2pharm s.r.o.
Ratibořská 1651/177a, Kateřinky
CZ – 747 05 Opava

for fields of activities:

**Research, development and manufacturing of food
supplements.**

**Research, development and manufacturing of
cosmetics.**

has established and applies an Management Systems
in accordance with fulfilment

**general requirements for the system of critical points according to
the bulletin of the Ministry of Agriculture no. 2/2010 – HACCP, head
1-4 and good manufacturing practices and hygiene in compliance
with the regulation (EC) n°852/2004**



Certificate validity till: 20.10.2025

Certificate No: F20221012



21.10.2022

.....
Date of the certificate
issue



.....
Head of Certification Body
CERT QUALITY SYSTEM s.r.o.



CERTIFICATE

Certification Body for certification of management systems
accredited by ČIA according to ČSN EN ISO/IEC 17021-1:2016

CERT QUALITY SYSTEM s.r.o.

confirms that the Company

K2pharm s.r.o.

Ratibořská 1651/177a, Kateřinky

CZ – 747 05 Opava

for fields of activities:

**Research, development and manufacturing
of food supplements.**

**Research, development and manufacturing
of cosmetics.**

has established and applies an Quality Management Systems
in accordance with the standard

ČSN EN ISO 9001:2016



Certificate validity till: 20.10.2025

Certificate No: Q20221013



21.10.2022

.....
Date of the certificate
issue



.....
Head of Certification Body
CERT QUALITY SYSTEM s.r.o.



Czech

CERTIFICATE

Certification Body

TÜV SÜD Czech s.r.o.

being an accredited certification body for IFS certification and having signed an agreement with the IFS owner, confirms that the processing activities of



K2pharm s.r.o.

**Ratibořská 1651/177a, 747 05 Opava, Czech Republic
COID 65706**

for the audit scope:

Production of food supplements (homogenization, sieving, granulation, pelletizing, drying, tableting, coating, capsule filling, banding) packed into plastic and aluminum packaging (doses, blisters) or in bulk.

Product scope(s): 10 - Dry products, other ingredients and supplements

Technology scope(s): C, D, E, F

meet the requirements set out in the

**IFS Food
Version 6.1, November 2017**
and other associated normative documents
at Foundation level



Audit date: 2019-04-09 - 2019-04-10

Register number of certificate: 12.257.719

Next audit to be performed within the time period:

Date of issue of certificate: 2019-06-04

2020-02-14 - 2020-04-24
or unannounced

Certificate valid until: 2020-06-04



Milan Kroutil
Head of certification body
Prague, 2019-06-04



Deutsche
Akkreditierungsstelle
D-ZE-19697-01-00



CERTIFICATE

Certificate no. 12879

ERTE KOZMETİK SANAYİ VE TİCARET A.Ş.

Beysan San. Sit. Dereboyu Cad. No:4
TR- Beylikdüzü İSTANBUL

QS Zürich AG certifies that the Management System of the above mentioned company has been evaluated and meets the requirements established by the following rules:

GMP - ISO 22716: 2007

The management system includes:

**Production, Sales and Marketing of Perfumes and
Fragrances Alcoholic Products , Body Care Products, Bath
Care Products, Skin Care Products, Hair Care Products**

Certificates will be renewed every year along 3 years. The certificates which exceed the expiration date are not valid. During the period of validity of this certificate, the management system of the company must always comply with the requirements of the certified standards.

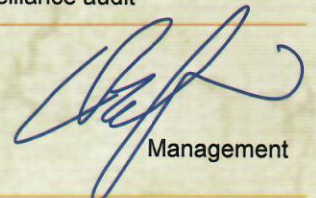
For updated amendments within the scope
of certification of the present certificate,
please refer to
<http://www.quality-service.ch/>



Audit date: 10.11.2016
Date of issue: 02.12.2019
Expiration date: 09.11.2020
Subject to successful surveillance audit

QS ZÜRICH AG
P.O. Box 6335
CH-8050 Zürich
info@quality-service.ch




Management