National Centre For Public Health And Pharmacy

CERTIFICATE NUMBER: ***NNGYK/GYSZ/66571-1/2024***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:
The manufacturer: ***Sp Accure Labs Private Limited***
Site address: ***Plot No 12, Biotech Park Phase II, Lalgadi Malakpet, Medchal, 500078, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100033946*** / ***LOC-100053539***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 and Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-03-02***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572. [3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Digitally signed by Chitic Vlad
Date: 2025.07.23 20:39:01 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates Special Requirements 7 Other: Oncology products included(en) 1.1.1.4 Small volume liquids Special Requirements 7 Other: Oncology products included(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell Special Requirements 7 Other: Oncology products included(en) 1.2.1.13 Tablets Special Requirements 7 Other: Oncology products included(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell Special Requirements 7 Other: Oncology products included(en) 1.5.1.13 Tablets Special Requirements 7 Other: Oncology products included(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

This certificate is valid till 31.12.2025

2024-12-18

Name and signature of the authorised person of the Competent Authority of Hungary

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Confidential
National Centre For Public Health And Pharmacy
Tel:***Confidential***
Fax:***Confidential***

Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2023/240***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1,2]

Part 1

Issued following an inspection in accordance with
Art. 111(5) of Directive 2001/83/EC as amended

The competent authority of Bulgaria confirms the following:
The manufacturer: ***Kwality Pharmaceuticals Limited***
Site address: ***I A Industrial Area, Raja Ka Bagh, Tehsil Nurpur Distt, Kangra (H.P.), 176201***
OMS Organisation Id. / OMS Location Id.: ***ORG-100048403*** / ***LOC-100080161***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-04-21***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.[3]

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

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[1] *The certificate referred to in paragraph Art. 111(5) of Directive 2001/83/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: (powder for injection)(en)
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: oral powder in sachet(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.2 Secondary packaging
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: oral powder in sachet(en) 1.5.1.13 Tablets Special Requirements 7 Other: non-coated and film-coated tablets(en)
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Inspection covers manufacturing and testing of medicinal products in Cytotoxic Block and Cephalosporin Block: Cytotoxic Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume liquids (vial) and Lyophilized Injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Tablets: Tablets/Coated tablets. Cephalosporin Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume Aseptic powders for injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Other Solid dosage form - powder for oral suspension in sachets (Oral Dry Syrups); Tablets/Coated tablets. Activities pointed out in p.1.1.1.6, p.1.2.1.8 and p.1.5.1.8 refer only to manufacture of cephalosporin block. It has been distant inspection

2023-06-21

Name and signature of the authorised person of the Competent Authority of Bulgaria

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Confidential
Bulgarian Drug Agency
Tel:***Confidential***
Fax:***Confidential***

Iran Food and Drug Administration

ISLAMIC REPUBLIC OF IRAN

MINISTRY OF HEALTH AND MEDICAL EDUCATION

Ref: **665/74710**
Date: **26/10/2024**
Attach: **No**
Validity Date: Oct. 2025

GMP Certificate

Manufacturer: Varian Pharmed Co.

Address: No. 1534, Golshid 2nd St., Golrokh 2nd St., West Ghazali Blvd., Eshtehard Industrial City, Alborz, I.R. Iran

Production Line: SVP (Ampules) General

This is to certify that above-mentioned production line was duly inspected and approved in accordance with Good Manufacturing Practice Principles for pharmaceutical products which are currently in force in the I.R of Iran.

The manufacturer plant is subject to regular GMP inspections based on PIC/S regulations (at suitable intervals) by the Iranian Food and Drug Administration.

The production line of SVP (Ampules) General ***is in compliance with the cGMP/GMP standards and relevant principles and regulation and complies with the Good Manufacturing Practice requirements of the PIC/S Guidelines.***

The Grade of GMP is "A" for the mentioned production line.

Gh.Hossein Sadeghian, Pharm.D
IFDA Director General for
Drugs and Controlled Materials

Central Building of Iran Food and Drug Administration No.:30,Fakhr Razi St.,Enghelab Ave.,Tehran,Iran Zip Code: 1314715311 Tel:+98 (21) 61927000 Fax:+98 (21) 66405571
https://fda.gov.ir info@fda.gov.ir

DCA
DRUGS CONTROL ADMINISTRATION
TELANGANA

DRUGS CONTROL ADMINISTRATION
GOVERNMENT OF TELANGANA

L.Dis.No. 22156/E(M)/TS/2017 Dt. 8/11/2017

To
M/s. SPAL Private Limited,
Plot No 12, Biotech Park Phase II,
Lalgadi Malakpet, Shameerpet,
Medchal - Malkajgiri District,
Telangana - 500101.

DECLARATION ON COMPANY NAME

This is to declare that the company name (**SP Accure Labs Pvt. Ltd and SPAL Private Limited**) with the residing address (as below) is one and the same.

Manufacturing unit: Plot No.12, Biotech park phase II,
Lalgadi Malakpet, Shameerpet (Mandal),
Medchal – Malkajgiri District,
Telangana-500101.

Also note that the full form of SPAL is SP Accure Labs.

DRUGS CONTROL ADMINISTRATION * HYDERABAD * GOVERNMENT OF TELANGANA

Kailas 8/11/17

T. Kailasam
Joint Director (FAC) & Licensing Authority
DRUGS CONTROL ADMINISTRATION

T. KAILASAM
Joint Director (ENF)
Licensing & Controlling Authority
Drugs Control Administration
Government of Telangana
Hyderabad - 500 038.

GST No. 02AAACK6458M2ZC D.L. No. NNZ/08/40 & BNZ/08/41

KWALITY PHARMACEUTICALS LTD.

Works : 1-A, Industrial Area, Raja Ka Bagh, Tehsil Nurpur, Distt. Kangra - 176201. (HP)

(WHO-cGMP & ISO 9001:2015 & 14001:2015 Certificated Co.)

Plant Head : +91-7696311127
Mobile : +91-9814052314
+91-9815745569

E-mail : sunil@kwalitypharma.com

To WHOM SO EVER IT MAY CONCERN

Date: 18.07.2025

Declaration Letter

We, Kwality Pharmaceuticals LTD, herewith declare that according to valid bilateral agreements, for territory of Republic of Moldova, only ALLGOAL Group Medical Ltd, though its locally registered partner Lismedfarm SRL are authorized to submit and participate in tenders for governmental procurement of Oncology products for needs of IMSP.

Any other companies, submitting offers on behalf of Kwality Pharmaceuticals LTD, are acting without our permission and we are NOT guaranty about origin and quality of products, they supply, also we are NOT responsible, for any obligations, these companies, takes on themselves.

Sincerely,

For Kwality Pharmaceuticals Limited

Name: Aditya Arora
Designation: Director
Date: 18.07.2025