

The Pharmaceutical Sector in Syria in 2017

by

Dr. Habib Abboud

Deputy Minister of Health for pharmaceutical Affairs

SECOND RUSSIAN GMP CONFERENCE 2017

18TH , 19TH and 20th of September 2017, Gelendzhik

Grate Thanks

- A Grate Thanks to the Russian Federation Government for its support to my country Syria in many aspects, mostly the political, military , economical and technical support without them the country could have been destroyed.
- We are here to extend this cooperation to the Health and Pharmaceutical Sectors.

The cost of external encountered problems to the country

- All External Financial Facilities had been blocked.
- Most of the sea lines and all airlines had stopped .
- All the land borders with Iraq , Jordan and Turkey ,has been closed

The internal consequences of the crisis

- The devaluation of the local currency for ten time less.
- The cost increase of power supply and feules more than ten times

The war in Syria affected the pharmaceutical sector and its services causing huge damage to the drug factories which located mostly in Aleppo and in Suburbs of Damascus and Homes and Hama in many forms of ways likes , physical damage to the building , damage to the equipments

thefts, some factories closed because the workers and personnel could not arrive to there working areas, shortages of fuels and electricity all of that caused to the reduction of the percentage coverage from 93% to around 55% of the national needed drugs, as well as the factories affected according to the following schedule.

percentage of the needs نسبة coverages التغطية الدوائية بالمائة	The No. of Damaged factories عدد المعامل المتضررة	المعامل التي تعمل the No. of factories that works	Year العام
93	-	70	2010
55	28	42	2013
65	20	50	2014
70	11	66	2016
80	11	69	2017

The economic sanctions on Syria by the Western Countries as well affected badly the needs of the Syrian people for medicines, and food causing shortage and difficulties to import the raw materials and equipments and its spare parts , and packaging materials

as well as the sanctions of the Syrian Banks which make the processes of purchasing and transporting more difficult and dangerous, since many manufacturers has to transfer there money through a third party and through a third country making the process of transporting longer, causing difficulties for the drugs and vaccines which needs a cooling chain more complicated.

This caused inflation and increase in the prices of the drugs, and missing of many important drugs which could be classified into categories :

- The missing drugs because there production is impossible because of shortage of raw material or because its prices not economical any more.
- Continue to produce non profitable drug , the production continues until finishing the stock of API

In spite of all the above mentioned difficulties the Syrian Ministry of Health continues in 2016 & 2017 to solve many problems which encounter the pharmaceutical industry through encouraging the manufacturers to transfer to the safe areas, and produce by contract manufacturing at the same time keeping the pharmaceutical industry under close supervision and quality control to produce under GMP roles,

The Pharmaceutical Sector in Syria in 2017

- Provided as follows:
 1. From local medicinal production:
 - The No. of licensed drug factories is 80 distributed in all counties .
 - The No. of factories which is still out of service is 11
 - The No. factories which working now is 69
 - The No. of pharmaceutical formulations in the market is 7500 product, consisting or 1180 drug compound.
 - The No. of missing or little available drugs because of sanctions of importations of API, or because of difficulties is 150 pharmaceutical formulations.

a- Local Production Strategy

- The MOH strategy is to license 7 factories to manufacture the same composition for the POM and 10 factories for the OTC .
- The local industry encouraged to manufacture all the current imported drugs which cost the government a lot of hard currencies like the kidney drugs and the immunosuppressant and insulin and the antineoplastic drugs, biological products, blood derivatives and pharmaceutical ingredients (API's)

b- Pharmaceutical Importation Strategy

- The specific pharmaceutical products like vaccines which are not produced locally , they are imported by the Syrian Pharmaceutical Importing Agency(GFTO, General Foreign Trade Organization) .
- The annual estimated needs of the imported pharmaceuticals is set by all related Ministries and those needs sent to the MOH where it will be checked and filtered and summed and send to the Ministry of Economy and Foreign Trade(GFTO) in order to make the suitable tenders .

b- Pharmaceutical Importation Strategy

- We turned to the friendly countries (Russia, Iran, China, Belarus, India, Cuba , ..) to fill the gap of the needed and imported drugs in which some of the Western Pharmaceutical Companies stopped to export to Syria because of the financial economical sanctions although the Western Sanctions exclude food and medicine.
- Three Mutual recognition agreements have been signed between the Ministries of Health of Iran, Cuba, Belarus where most of pharmaceutical importation has been done.
- A similar suggested mutual recognition agreement has been sent through the diplomatic channel to the Russian MOH.

b- Pharmaceutical Importation Strategy

The urgent pharmaceutical needs are provided by the International Organisations and Agencies working in Syria like:

- World Health Organisation
- UNICEF
- Syrian Arab Red Crescent
- International Committee Of The Red Cross
- UNDP
- United Nations Population Fund

C- National Drug Quality Control Laboratories

- The National Drug Quality Control and Research Laboratories at the MOH, assured the quality and the efficacy of the pharmaceuticals in the country whether imported or locally produced by using stringent QC. regulations.
- The National QC. Labs. Has been accredited for ISO 17025 from DAKKS, Germany, as well as has been certified for ISO 9001:2015 from SGS, Swisstzerland .

D- Local pharmaceutical Industry

- All pharmaceutical factories has to comply with the national legislation and to work in accordance with the cGMP rules.
- All manufactures has to get GMP& ISO 9001 certifications.
- 8 manufacturers has been certified in accordance with PICs – GMP from Germany.

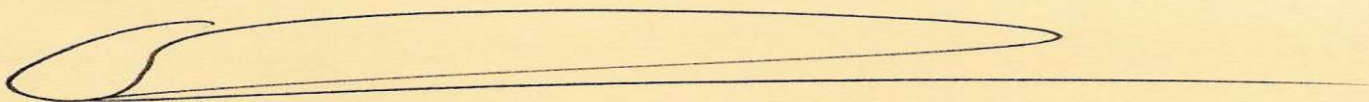
Certificate of participation

Proficiency Testing Round FIP-LMCS 2006

We hereby certify that the Ministry of Health, National Drug Quality Assurances, Syria, has actively participated in the eighth proficiency testing study under Labcode 149. The eighth round has been organised by the Laboratory of the Dutch Pharmacists, a department of the Royal Dutch Association for the Advancement of Pharmacy (= KNMP). It was under the auspices of the Laboratory Medicines Control Section of the International Pharmaceutical Federation (LMCS-FIP).

The Hague, May 2006

Laboratory of the Dutch Pharmacists,



O.S.N.M. Smeets, pharmacist



Implementation of International Quality Management Standards ISO at The Syrian Ministry of Health

Dr. Habib Aboud

Deputy Minister for Medicines & Pharmaceutical Affairs

GOALS

- In accordance with the President's instructions Dr. Bashar ALASSAD in developing the quality of administrative work
- Implementation of ISO 9001-2015 Quality Management System at the Directorates of:
 - Drug Quality Control & research laboratories (DDQCRL)
 - Pharmaceutical Affairs
 - Drugs Inspectorate
 - General Health Laboratories
 - Medical Registry & Licensees
 - Primary Health Care
 - Communicable and chronic diseases

Methodology of work

- Explain all the items of ISO 9001 – 2015- In detail by training all quality teams and all directorates
- A study of the gaps between what each directorate and the requirements in the standard of the quality management system ISO 9001 – 2015
- Benefiting from DDQCRL' documents, such as job descriptions, guidelines, structure and functions of the directorates
- Stimulate quality teams through practical tasks added to training
- Planned follow-up of all works and tasks assigned to each Directorate
- Corresponding to international bodies such as the World Health Organization (WHO) to ensure the requirements of equipment, materials, training programs and certification fees

Foundations of quality system

- Policy and Objectives (_ Minister's Strategy)
- Financial availability
- Responsibilities and authorities
- Staff training
- Business continuity
- evaluations and Tests (Job Performance Measurement)
- continuous improvement
- Customer (Citizen)

work plan

1 - Training phase (8-10) weeks with 2 training hours per week

No	item	time
1	Quality principles & Deming cycle	2 hr
2	Scope – standards references – terms & definitions	2 hr
3	Lead – planning – support	2 hr
4	Operations	2 hr
5	Performance evaluation – improvement	2 hr
6	Practical program	2 hr

work plan

2 - Executing the procedures through 6 months

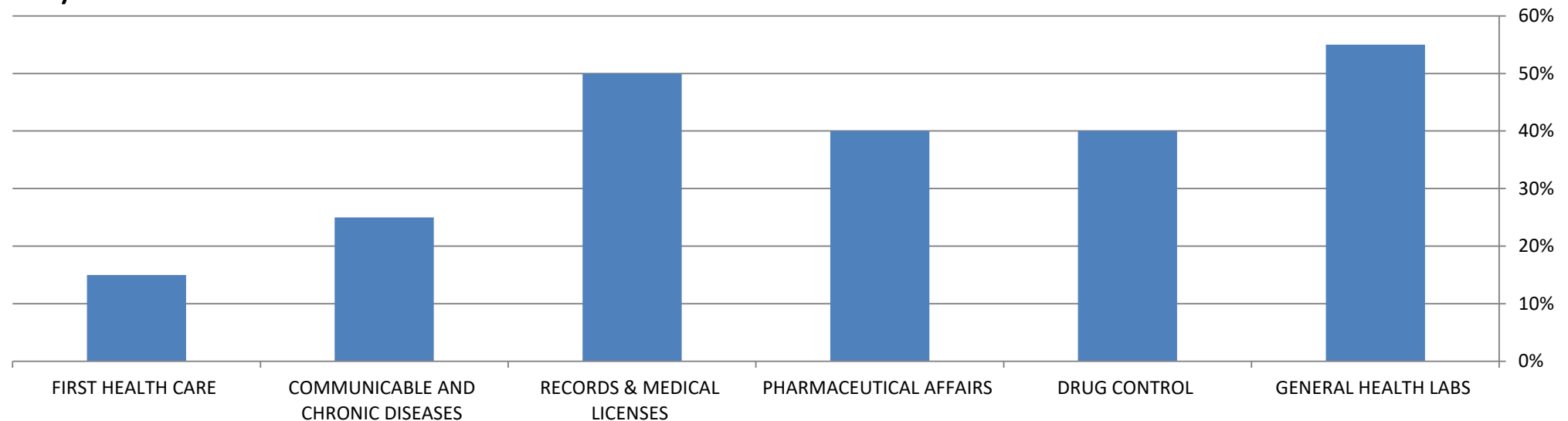
No	procedure	time	notes
1	Quality Manual	2 months	
2	Job description	2 months	
3	Quality policy	1 week	
4	Quality objectives	1 week	
5	Employees	1 month	
6	Equipment & infrastructure	2 weeks	
7	Internal audit	1 week	

Certifications settings

- Ensure that all the provisions of the standard are implemented
- The Minister's approval of the fees
- Communicating with Syrian donors
- Identify the time and agenda of grants in coordination with the responsible directorates

DIRECTORATES ACHIVEMENTS

- General Health Labs: 65%
- Drugs Inspectorate: 40 %
- Pharmaceutical Affairs : 40 %
- Medical Registry& Licensees: 50%
- Communicable and chronic diseases: 25%
- Primary Health Care : 15%



DIRECTORAT OF DRUG QUALITY CONTROL AND RESEARCH LABORATORIES

DDQCRL

The Directorate was established in accordance with the regulatory decision No. **57 of 1993**.

The Directorate is a leading national and international Reference in the field of pharmaceutical control.

The laboratories are equipped with specialized automated equipment developed to improve the quality of medicines available in imported and locally manufactured medicines.

DDQCRL is committed to applying the good laboratory practices at all stages of its work, & always seeking to develop in line with the latest international developments in this field

DDQCRL PROVIDES SERVICES TO OTHER DIRECTORATES OF MEDICINE AND TO SYRIAN UNIVERSITIES

- 1- Specialized training seminars in the field of good international laboratory practices
- 2 - Specialized courses for the directorates of medicine in the field of application of quality systems and to obtain the ISO certificate the new version of the specification **ISO 9001/2015**
- 3 - Study and conformity of certificates of analysis and specifications and pharmaceutical studies.
 - 4- mutual research with all Syrian universities and provide the necessary support for the success and implementation of such research, which include:
 - ✓ Reference Standard
 - ✓ Analysis plans
 - ✓ Scientific references
 - ✓ Technical expertise for high technology equipment
- 5- Implementing the supervision and pharmaceutical industry for pharmacists, which is conducted in the Directorate of Laboratories for Drug Control and Research in cooperation with the Faculty of Pharmacy, University of Damascus to cover the theoretical part.

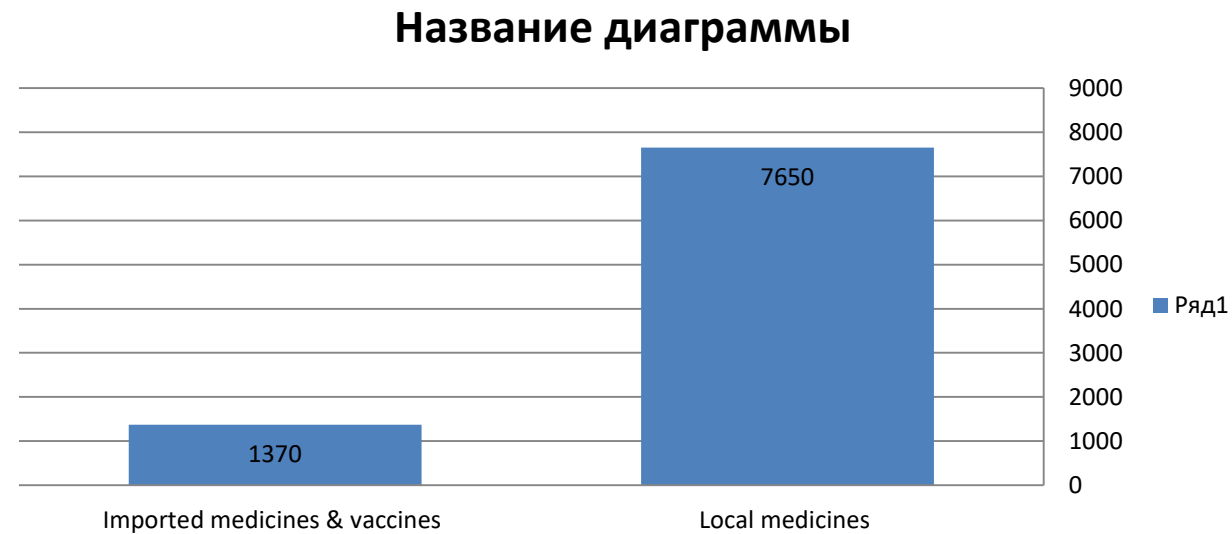
DRUG QUALITY CONTROL AND RESEARCH LABS STATISTICS FIRST HALF 2017

- Total reports : 6440
- Non compliance reports : 52
- Accepted with minor notes : 59

Directorate of Pharmaceutical Affairs

statistics 2017

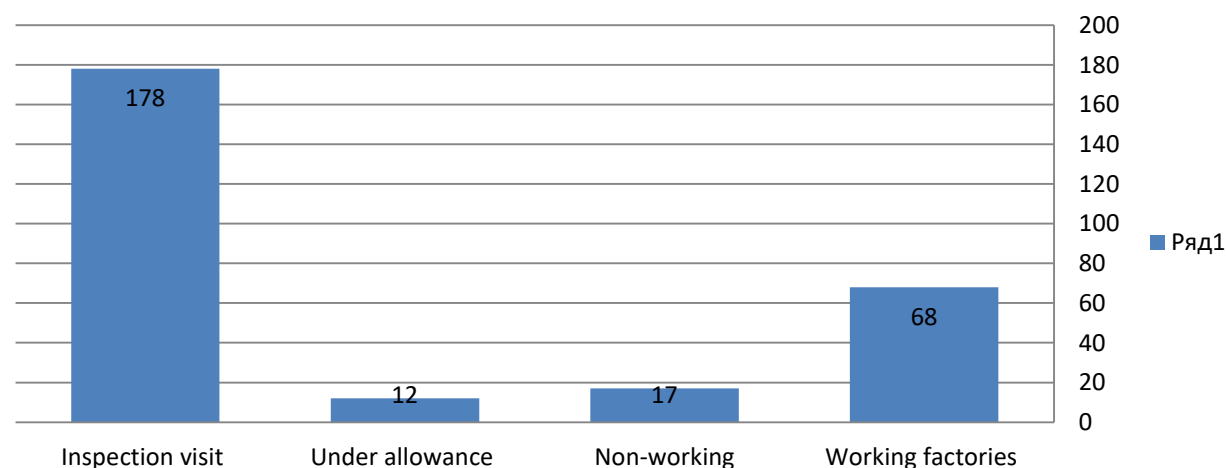
- Total manufactured medicines : 7650
- Imported medicines & vaccines : 1370



Drug Inspectorate Directorate statistics 2017

- Working factories : 68
- Non-working : 17
- Licensing stage: 12
- Inspection visits Conducted locally :178

Название диаграммы



- **BEST WISHES & SUCCESS**

DIRECTORAT OF DRUG QUALITY CONTROL AND RESEARCH LABORATORIES

- DDQCRL has obtained.
- ✓ **CERTIFICATE ISO 9002/1994 in 1999**
- ✓ **CERTIFICATE ISO 9001/2000 in 2001**
- ✓ **CERTIFICATE ISO 14001: 1996 in 2003**
- ✓ **Laboratory accreditation (ISO/IEC 17025) in 2010**
- ✓ **CERTIFICATE ISO 9001/2008 in 18 January 2014**
- ✓ **CERTIFICATE ISO 9001/2015 in 18 January 2017 (during war period)**



**SGS Yarsley
International Certification Services Limited**

Certificate Number

Q16614

**This is to certify that the
Quality Management systems of**

***DIRECTORATE OF THE NATIONAL DRUG QUALITY
ASSURANCE AND RESEARCH LABORATORIES
(N.D.Q.A.R.L.)
SYRIAN ARAB REPUBLIC - MINISTRY OF HEALTH***

**have been assessed and registered as meeting the
requirements of ISO 9002**

The scope of registration is detailed on the Assessment
Schedule bearing this certificate number.

SGS Yarsley International Certification Services Ltd
Signed by

W Cheng
26 August 1999

This certificate remains valid subject to
satisfactory maintenance of the system.



**Registered Office:
SGS Yarsley
International Certification Services Limited
SGS House, 217/221 London Road,
Camberley, Surrey GU15 3EY, United Kingdom.**

Whilst all due care and skill was exercised in carrying out this assessment,
SGS Yarsley ICS accepts responsibility only for proven gross negligence.
This is not a legal document and cannot be used as such. The use of the
Accreditation mark shown on this certificate indicates accreditation in the
respect of those activities covered by that Accreditation Authority. This certificate
remains the property of SGS Yarsley ICS to whom it must be returned on request.





SGS United Kingdom Ltd
Yarsley International Certification Services

Certificate Number

Q16614

This is to certify that the
Quality Management systems of

Directorate of the National Drug Quality
Assurance and Research Laboratories
(N.D.Q.A.R.L.)

Syrian Arab Republic – Ministry of Health

have been assessed and registered as meeting the
requirements of ISO 9001

The scope of registration is detailed on the Assessment
Schedule bearing this certificate number.

SGS Yarsley International Certification Services
Signed by

26 August 1999

11 October 2001

Original registration date

Certificate issue date

This certificate remains valid subject to satisfactory
maintenance of the system for 4 years from the above
certificate issue date.

SGS Yarsley International Certification Services
is a division of SGS United Kingdom Ltd.
Registered in England No. 1193985
Registered Office:
SGS House, 217/221 London Road,
Camberley, Surrey GU15 3EY, United Kingdom.

Whilst all due care and skill was exercised in carrying out this assessment,
SGS Yarsley ICS accepts responsibility only for proven gross negligence.
This is not a legal document and cannot be used as such. The use of the
Accreditation mark shown on this certificate indicates accreditation in the
respect of those activities covered by that Accreditation Authority. This certificate
is an accredited certificate issued under the accredited scope granted to
SGS Yarsley ICS by UKAS, Registration No.005. This certificate remains the
property of SGS Yarsley ICS to whom it must be returned on request.



005

Certificate BE03/3280EM

SGS

The management system of

**Directorate of the Drug Quality
Assurance and Research
Laboratories (D.Q.A.R.L.)**

Ministry of Health
Syrian Arab Republic

has been assessed and certified as meeting the requirements of

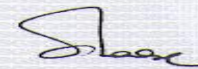
ISO 14001:1996

For the following activities

**The management and c-ordination of Directorate
of drug Quality Assurance Research including
analysis and approval of samples.**

This certificate is valid from 09 October 2003 until 08 October 2006
Issue 1.

Authorised by



SGS International Certification Services EESV
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

Page 1 of 1



Accreditation Number
024 EMS



DAkkS | Deutsche Akkreditierungsstelle GmbH
Spittelmarkt 10 | 10117 Berlin | Germany

MoH - Ministry of Health
DDQCRL - Directorate of Drug
Quality Control and Research Laboratory
Mr. Dr. Habib Abboud
Al-Adawi, Khateeb Street
Technical Health Institute Building
DAMASCUS, SYRIEN

Deutsche
Akkreditierungsstelle GmbH
(German Accreditation Body)
Office Berlin

Contact:
Volker Briehn
Phone: +49 30 670591-19
Fax: +49 30 670591-25
volker.briehn@dakks.de

19.04.2011

Dear Mr Abboud,

Dispatch of the accreditation certificate

we are pleased to send you your accreditation certificate with the corresponding annex to the certificate.

We will perform the next on-site assessment at the latest in January 2012.
With regard to the exact date, we will be contacting you in due time.

We would appreciate if you informed us, according to our contractual provisions, without being asked on all changes relevant to the accreditation.

As your contact partner for accreditation we shall be happy to respond to all questions you may have regarding your accreditation. We look forward to continuing our effective cooperation.

Yours sincerely,

for DAkkS



p. p. Volker Briehn
Customer manager

Enclosures

Case Number:
PL-14296-01

Managing Directors:
Norbert Barz, Dr. Thomas Facklan

Registered Office: Berlin
Local Court Charlottenburg
HRB 122846 B
VAT-ID: DE815123526

Berliner Volksbank
Bank Account: 8841025009
Bank Code No.: 100 900 00

Office Berlin
Spittelmarkt 10
10117 Berlin
Phone: +49 30 670591-0
Fax: +49 30 670591-15

Office Braunschweig
Bundesallee 100
38116 Braunschweig
Phone: +49 531 592-1901
Fax: +49 531 592-1905

Office Frankfurt
Gartenstraße 6
60594 Frankfurt am Main
Phone: +49 69 610943-0
Fax: +49 69 610943-90

PARTICIPATION OF DDQCRL IN THE PROGRAM OF INTERNATIONAL PROFICIENCY TESTS:

The Directorate moved to a new stage in quality control through its participation in **31/5/2001** Proficiency Testing which is organized by the Department of Quality of Official Drug Control Laboratories WINAp
In the FIP



Certificate of participation

Proficiency Testing Round FIP-LMCS 2004

We hereby certify that the Ministry of Health, National Drug Quality Assurances, Syria, has actively participated in the sixth proficiency testing study under Labcode 149. The sixth round has been organised by the Laboratory of the Dutch Pharmacists, a department of the Scientific Institute of the Dutch Pharmacists (= WINAp). It was under the auspices of the Laboratory and Medicines Control Section of the International Pharmaceutical Federation (LMCS-FIP).

The Hague, August, 2004

Laboratory of the Dutch Pharmacists,

A handwritten signature in black ink, appearing to read 'O.S.N.M. Smeets', is written over a horizontal line.

O.S.N.M. Smeets, pharmacist

**Alexanderstraat 11
Postbus 30460
2500 GL The Hague
Holland**

**Telephone +31 70 37 37 143
Telefax +31 70 31 06 530**

e-mail : O.S.N.M.Smeets@WINAp.nl

SGS

Certificate SY11/2126

The management system of

**Directorate of Drug Quality
Control & Research
Laboratories (D.D.Q.C.R.L)**

Al Adawi, Al Khateeb St.,
Damascus - Syria

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Inspection, analysis and testing of Pharmaceutical Products.

Further clarifications regarding the scope of this certificate and the applicability of
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 18 January 2014 until 18 January 2017 and
remains valid subject to satisfactory surveillance audits.
Re certification audit due before 09 December 2016
Issue 2. Certified since 18 January 2005

Authorised by

SGS United Kingdom Ltd. Systems & Services Certification
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0311

Page 1 of 1



005



This document is issued by the Company subject to its General Conditions of
Certification Services accessible at www.sgs.com/terms_and_conditions.htm.
Attention is drawn to the limitations of liability, indemnification and jurisdictional
issues established therein. The authenticity of this document may be verified at
http://www.sgs.com/clients/certified_client.htm. Any unauthorized alteration, forgery
or falsification of the content or appearance of this document is unlawful and
offenders may be prosecuted to the fullest extent of the law

PT

**Directorate of Drug Quality
Control & Research
Laboratories (D.D.Q.C.R.L)**



ISO 9001:2015

Inspection, Analysis and Testing of Pharmaceutical Products

This certificate is valid from 18 January 2017 until 18 January 2020
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 09 December 2019
Issue 3. Certified since 18 January 2005

John

SGS United Kingdom Ltd
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001 2015 0216

Page 1 of 1



S G S S G S S G

This document is issued by the Company subject to its General Conditions of Certification Services accessible at www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitations of liability, indemnification and jurisdictional issues established therein. The authenticity of this document is independently verified at <http://www.sgs.com/certified-clients-and-products/certified-client-ids>. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is strictly prohibited and may result in severe civil or criminal penalties, including damages and imprisonment.