

GCC Central Registration

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The Gulf Co-operative Council (GCC)

- Saudi Arabia, Kuwait, Oman United Arab Emirates, Bahrain Qatar and Yemen.
- Total population estimated at **45** million inhabitants.
- The GCC is a co-operation organ in different domains including health.
- The various councils of ministers of the participating countries meet twice a year to discuss existing and new co-operation issues.

The Gulf Co-operative Council For Health Ministers

- Coordinating and ensuring communication with and between the Ministers of Health of member countries.
- Organizing conferences, seminars, and training courses.
- Conducting field surveys and researches for common interest of Gulf States.
- Procurement of safe and efficient pharmaceutical products, hospital sundries and equipments of high quality.
- Assessment of the existing systems and strategies in the health fields.

The Executive Office

- Established in 1976.
- Executive board chaired by the executive director.
- Health ministers' council.
- Advisory committees.
- Functions:
 - Group purchasing.
 - Central drug registration.
 - Health policies.
 - Medical research.

Gulf Central Committee for Drug Registrations (GCC DR).

- (GCC-DR). approved in may 1999.
- Located in the Executive Office for Health Ministers, Riyadh, Saudi Arabia.
- Two members nominated by each state.
- Two consultants appointed by Executive Director.
- Committee chairman nominated for one year.

GCC - DR

- Meeting can be held with minimum of 4 states.
- Decision must be anonymous.
- Minimum 4 meetings per year.
- Committee decisions are bound to SGH group purchasing program.
- Full time secretary.
- Committee decisions can petitioned to executive director.

GCC – DR Responsibilities

- Registration of pharmaceutical companies.
- Registration of pharmaceutical products.
- Inspection of pharmaceutical companies for GMP compliance.
- Approval of Quality Control Laboratories (QCL).
- Reviewing of Technical and PMS reports.

اجراءات تسجيل سرقة

Company Registration

To: His Excellency the director of executive board of the health minister's council for G.C.C state.

Please find attached the original file with six copies for the registration of:

It contains the following:

1. Index of contents
2. Registration form Pharmaceutical Companies
3. A certificate issued by the health authorities in the country of origin, clearly indicating the following:
 - a) That the company is authorized to manufacture pharmaceutical products in the country of origin (Indicate License Number and date).
 - b) That the company follows Good Manufacturing Practice.
 - c) That the products intended for export to the GCC state will be identical in their composition as those registered and marketed in the country of origin.
4. A list of the products to be registered in the GCC state.

4. A Letter from the company showing in tabular form, the following information about the company's products:
 - a) The trade and/ or the generic name of the product.
 - b) Composition (active ingredients and their quantities).
 - c) Therapeutic category/categories.
 - d) Registration number and date in the country of origin.
 - e) Date of first marketing in the country of origin.
 - f) Names of other countries in which the product is registered and marketed.
5. Research Summary:
 - a) Summary of the company's research activity, indicating the products in various research phases, marketed, products discovered or developed by the company.
 - b) Copies of the patents and/or recognized international scientific publications which support the validity of data indicated above in 5-a.

Scientific officer:

Name:.....

Signature:.....

Tel. No.:.....

EXECUTIVE BOARD OF THE
Health Ministers' Council
FOR GCC STATES
Gulf Central Committee
For Drug Registration



المكتب التنفيذي
للمجلس وزراء الصحة
لدول مجلس التعاون
لدول الخليج العربية
اللجنة الخليجية المركزية للتسجيل الدوائي

GE
D.R.

شهادة تسجيل شركة

يعتمد المكتب التنفيذي لمجلس وزراء الصحة لدول مجلس التعاون لدول الخليج العربية بتسجيل
شركة
برقم
المركزية للتسجيل الدوائي باجتماعها
وتاريخ
وذلك وفقاً لاجتماع اللجنة الخليجية
والذي عقد في

بتاريخ
الموافق

المدير التنفيذي
Executive Director

الختم الرسمي
Stamp

رئيس قسم التسجيل
Registration Department Head

P. O. Box: 7431, Riyadh 11462, Phone: 00966-1-4885270, Ext. 111-112-113, Fax: 00966-1-4885266, E-mail: sgh@sgh.org.sa

Product Registration

To: His excellency the director of executive board of the health minister's council for G.C.C state.

Please find attached the original file with six copies for the registration of: Dosage form.....

Strength

Manufacture by

It contains the following:

1. Table of contents.
2. Completed registration form should be attached.
3. Full specifications and methods of analysis of the product including stability data and storage conditions.
4. A certificate of analysis for the samples submitted for registration, issued by the company's.
5. A certificate issued by the health authorities indicating the free sale of the product in the country of origin.
6. A letter from the company indicating the animal sources (specifying the animal), if the product contains any ingredients of animal origin.
7. Percentage of alcohol in the finished product, if present, and justifying that percentage.

8. A letter from the company indicating that the enclosed package insert or applicable labeling is the same as that approved and currently used in the country of origin.
9. The package insert should be Arabic and/or English. The company pledges to add and/or omit any information required for handling the product in the GCC state and to translate the package insert into Arabic language as determined by the committee.
10. The product's label.
11. Fifteen samples of the product including samples of the outer carton and container label.
12. A list of names of the other countries in which the product is registered and currently marketed.
13. Abstracts from independent international scientific references and publications about the efficacy and safety of the product.
14. Summary of pharmacological, toxicological, and clinical studies as well as post marketing surveillance for products requiring such documents.
15. Studies of bioavailability and bioequivalency.
16. Any additional comments or documents, the company wishes to attach.

Scientific officer:

Name:

Signature:

Tel. No.:



G.C.C.
D.R.

شهادة تسجيل مستحضر صيدلاني

REGISTRATION CERTIFICATE FOR PHARMACEUTICAL PRODUCT

يعتمد المكتب التنفيذي لمجلس وزراء الصحة لدول مجلس التعاون لدول الخليج العربية تسجيل المستحضر الصيدلاني التالي وذلك وفقا لاجتماع اللجنة الخليجية المركزية للتسجيل الدوائي باجتماعها والذي عقد في

الموافق

بتاريخ

والذي عقد في

The Executive Board of the Health Ministers' Council for G.C.C. States approved the registration of the following pharmaceutical product according to the Gulf Central Registration Committee meeting held in _____ on _____

Manufacturer Name, Origin	الشركة المصنعة واسم بلد المنشأ
Company Registration No.	رقم تسجيل الشركة
Brand Name	الاسم التجاري
Generic Name	الاسم العلمي
Pharmaceutical Form and Concentration	شكل المستحضر الصيدلاني وتركيبه
Pack Size	حجم العبوة
Shelf Life	مدة الصلاحية
Storage Conditions	شروط التخزين
Prescribing Instructions	طريقة الصرف
CIF Price	سعر التصدير
Remarks	ملاحظات

Product Registration Number
Date

رقم تسجيل المستحضر
تاريخ

المدير التنفيذي
Executive Director

الختم
Stamp

رئيس قسم التسجيل
Registration Department Head

GCC-DR Achievements

- **20** Meeting to date.
- Registration of **96** pharmaceutical companies.
- Registration of **533** products.
- Preparation of technical guidelines for:
 - GMP standard.
 - Bioequivalence guidelines.
 - Stability guidelines.
 - GLP guidelines.
 - PMS guidelines.

The most Frequently asked questions

- Submission of new product File centrally or nationally.
- Re-Registration of products registered in some & not all other Gulf markets.
- Legalization? Embassies.
- Co-Marketing, Co-manufacturing.
- CPP/which country.

- Authenticated from the relevant authorities.
 - Certificate of analysis.
 - Package insert.
 - Animal source.
 - Site change.
- Old products which already registered in all state.

Resolution No. 11-Z

56 Conference – Doha, 5 – 6 January 2004

The committee should start the pricing of the new products registered centrally from the beginning of 2004 and CIF price in single international currency.

Executive Board Meeting

60th meeting of

Riyadh – 12 – 14 April 2004

Recommendation:

The members were asked not to register the company which produce generic products until it is registered centrally.

Pharmaceutical SGH Tenders:

Bids presented for (sensitive) drugs with uncontrollable effectiveness, must be centrally registered; e.g:

- a.** Generic drugs for which bioequivalence studies cannot be done, e.g. inhalable medicines and some nasal inhalers.
- b.** Drugs supported by biotechnology for which bioequivalence studies cannot be done and which require clinical or pharmacodynamic studies.
- c.** Drugs with narrow therapeutic spectrum, which are administered orally.

Pharmaceutical SGH Tenders:

The registered items to participate with in the SGH tenders are those which are provided by the member GCC countries having reference laboratories or being centrally registered. However, the Executive Board Office should receive the lists including such items, one month prior to opening envelopes date.

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Thank You