Saudi Drug Registration (SDR) system

The Saudi Drug Registration (SDR) System is an electronic system which aims to facilitate the registration of medicinal, herbal and health products for both Human & Veterinary use. The SDR will allow the registered establishments in Drug Establishment National Registry (DENR) to use the system in new application, renewal and variation of their products.

الدليل الإرشادي لاستخدام نظام سدر

تسجيل الأدوية السعودية (سدر)

يعتبر نظام تسجيل الأدوية السعودي (سدر) نظاماً إلكترونياً يهدف إلى تسهيل عملية تسجيل المستحضرات الدوائية والعشبية المخصصة للاستخدام البشري والحيواني. ويمكن استخدام هذا النظام بعد تسجيل المنشآت في نظام السجل الوطني للمنشآت الصيدلانية (سجل) وذلك لتسجيل وتجديد المستحضرات الصيدلانية. كما يمكن متابعة المعاملات والتواصل مع قطاع الدواء عن طريق (سدر).
Guidance to use SDR system

Log in to the web site:

http://sdr.sfda.gov.sa

Click on:

Create New Applications

Choose the application according to the type of drug:

a. Human Drugs
b. Veterinary Drugs
c. Herbal & Health Product

http://sdr.sfda.gov.sa

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1-Type of Application:
Select the type of application:
1. New Drug
2. Generic
3. Biological
4. Radiopharmaceutical

Then complete the required information as shown in the screen.

After you complete the required information Click on save icon.

In filling out the application form it is not required to be in order.
2-Application Details:


- **Active Substance:**
  - Fill in the fields and then click on add icon.

- **Excipient:**
  - Fill in the fields and then click on add icon.

- **ATC Code:**
  - Click on: [ATC Lookup]
  - And search for the drug.

After you complete the required information, click on save icon.

Guidance to use SDR system

<table>
<thead>
<tr>
<th>Type of Application</th>
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</thead>
<tbody>
<tr>
<td>Application Details</td>
</tr>
<tr>
<td>Name(s) and ATC code</td>
</tr>
<tr>
<td>Proposed trade name</td>
</tr>
<tr>
<td>List the active substance(s):</td>
</tr>
<tr>
<td>Type of the active substance(s):</td>
</tr>
<tr>
<td>Single active substance</td>
</tr>
<tr>
<td>Multiple active substances</td>
</tr>
<tr>
<td>Name of active substance(s):</td>
</tr>
<tr>
<td>Quantity:</td>
</tr>
<tr>
<td>Unit:</td>
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<tr>
<td>Reference/Monograph standard</td>
</tr>
<tr>
<td>Add Active Substance</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity</td>
</tr>
<tr>
<td>Unit</td>
</tr>
<tr>
<td>Reference</td>
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</table>

| List the excipient(s): |
| Name of excipient(s): |
| Quantity: |
| Unit: |
| Reference/Monograph standard: |
| Add Excipient |

<table>
<thead>
<tr>
<th>Excipient Name</th>
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<tbody>
<tr>
<td>Quantity</td>
</tr>
<tr>
<td>Unit</td>
</tr>
<tr>
<td>Reference</td>
</tr>
</tbody>
</table>

**Pharmacotherapeutic group: (Please use current ATC code):**

- No ATC code has been assigned: [ATC Lookup]

**ATC Code**

**ATC Group**

- [Save]
2- Application Details:

2.B: Product Information:

After you complete the required information, click on save icon.

Save
2. Application Details:

2.C: Contact Information:

Please fill in the four sections as shown in the image opposite, then click on save icon.
2- Application Details:

2.D: Manufacturers:

Please fill in the three sections as shown in the image opposite, then click on save icon.
2- Application Details:

2.E: Certificate of a pharmaceutical Product:

Answer the question then click on save icon.
2. Application Details:

2.F: Animal Source Material:

If any component of the product contains any animal source material, then check the box and complete the required information, then click save icon.

Otherwise, skip this section.

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الدليل الإرشادي لاستخدام نظام سدر

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الإصدار رقم 1.0 13/12/1431 هـ
3- Scientific Advice:

Complete the required information then click on save icon.

Was there any formal scientific advice given by the SFDA for this medicinal product?

- Yes
- No

Date: 

Reference number of the scientific letter:

Save
4- Pediatric Development Program:

Complete the required information then click on save icon.

Save
5 Application Status:

Select the application status, then complete the required information then click on save icon.
6- Fee Due Statement:

Please refer to the circular No. 3993 dated 15/10/1430 H regarding the service fees which is available in the link below:


Please refer to the circular No. 3993 dated 15/10/1430 H regarding the service fees which is available in the link below:

**Guidance to use SDR system**

**7- Scheduling:**

After choose the meeting from the schedule the time of the meeting it will appear in the bottom of this page, click twice on the time then click on print icon.

![Scheduling Diagram]

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**Calendar Legends:**
- **Busy Day**
- **Week End**
- **Holiday**
- **Available Day**

**Booked appointment details:**
- **Appointment is not yet scheduled**

**Note:** Once appointment is scheduled the application details cannot be changed.
7- Scheduling:

After the click on print icon this window will appear choose from Drop-down list select Acrobat (PDF) file.

Then, click on Export to save the file in computer then print the application form.

Then, Close this window for continue.

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Guidance to use SDR system

dليل الإرشادي لاستخدام نظام سدر

المواعيد: بعد الضغط على ايقونة الطباعة تظهر هذه النافذة اختر من القائمة المنسدلة Acrobat (PDF) file

Export ثم اضغط على لحفظها على الجهاز ثم اطبعها.

ثم اغلق هذه النافذة لإكمال التقديم.
7- Scheduling:

After printing click on scheduling icon for confirm the meeting.

Guidance to use SDR system

المواعد:

بعد الانتهاء من الطباعة
اضغط على أيقونة جدول
المواعد لتأكيد الموعد

المواعد
8- Inquiries:

This section is specific to the application in which any questions or inquiries from SFDA, the applicant will receive and answer here.

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<td>Names and ATC Code</td>
<td>No Records Found</td>
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<tr>
<td>Product Information</td>
<td>Inquiry Title</td>
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<td>Contact Information</td>
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<td>Manufacturers</td>
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<td>Animal Source Material</td>
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<td>Scientific Advice</td>
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