الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority
رقم الصـادر : 26653/ع
وحدة التسجيل : قطاع الدواء
تاريخ الصادر : 02 / 12 / 1432 هـ
جهة الإحالة : تعميم
12-1432-1-26653-51-2

بسم الله الرحمن الرحيم

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
(٢٥٥)
قطاع الدواء

"تعميم"

الموضوع: متطلبات بطاقة و تغليف عينات الأدوية المستخدمة في الدراسات السريرية

رقم التعميم: ٢٦٦٥٣/ع وتاريخ: ٢ / ١٢ / ١٤٣٢هـ

سعادة مدير المكتب العلمي (لجميع الشركات) **الموقر**

السلام عليكم ورحمة الله وبركاته ،،،

استنادا إلى نظام الهيئة العامة للغذاء و الدواء الصادر بالمرسوم الملكي رقم (م/٦) و تاريخ ١٤٢٨/١/٢٥هـ و نظام المنشات و المستحضرات الصيدلانية الصادر بالمرسوم الملكي رقم م/٣١ و تاريخ ١٤٢٥/٦/١ هـ ، نود إفادتكم بما يلي:

أولا: مواصفات البطاقة و التغليف للأدوية المستخدمة في الدراسات السريرية

يجب الالتزام بمواصفات البطاقة و التغليف للأدوية المستخدمة في الدراسات السريرية **Labeling and Packaging for investigational medicinal products (IMP)** وفقا للمرفق (١،٢)

ثانيا: استيراد الأدوية المستخدمة في الدراسات السريرية

يجب تقديم طلب استيراد لعينات الدواء المستخدم في الدراسة السريرية بعد أخذ الموافقة على إجرائها إلى وحدة الفسح المركزي- بقطاع الدواء وفقا لمتطلبات الاستيراد في الهيئة العامة للغذاء و الدواء.

وفي حال وجود أي استفسارات فيمكنكم التواصل عن طريق البريد الالكتروني: CT.Drug@sfda.gov.sa أو الاتصال على هاتف ٢٧٥٩٢٢٢- ٠١ تحويله ٢٣١٨ أو ٢٣٣٩ وحدة الدراسات السريرية.

و تـقبلوا خالـص الـتحية و الـتقدير ،،،

نائب الرئيس لشئون الدواء

أ.د. صالح بن عبدالله باوزير

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مرفق رقم (١)

متطلبات الهيئة العامة للغذاء و الدواء لبطاقة و تغليف عينات الأدوية المستخدمة في الدراسات السريرية

SFDA requirements for Labeling and Packaging for investigational medicinal products (IMP)

Labeling and Packaging Requirements:

I. The following information should be included on labels unless its absence can be justified:

1. Name, address and telephone number of the sponsor, contract research organization or investigator (the main contact for information on the product. clinical trial and emergency unblinding);

    1.1 The address and telephone number of the main contact for information on the product, clinical trial and for emergency unblinding need not appear on the label where the subject has been given a leaflet or card which provides these details and has been instructed to keep this in their possession at all times.

2. Pharmaceutical dosage form, route of administration, quantity of dosage units. And in the case of open trials, the name/identifier and strength/potency;

3. The batch and/or code number to identify the contents and packaging operation;

4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

5. The trial subject identification number/treatment number and where relevant, the visit number;

6. The name of the investigator (if not included in (1) or (1.1);

7. Directions for use (reference may be made to a leaflet or other explanatory document intended for the trial subject or person administering the product);

8. "For clinical trial use only" or similar wording; (Arabic & English)

9. The storage conditions;

10. Period of use (use-by date. expiry date or re-test date as applicable), in month/year format and in a manner that avoids any ambiguity.

11. "Keep out of reach of children" except when the product is for use in trials where the product is not taken home by subjects. (Arabic & English)

o/s

II. When the product is to be provided to the trial subject or the person administering the medication within an immediate container together with outer packaging that is intended to remain together, and the outer packaging carries the information listed in section I, the following information shall be included on the label of the immediate container (or any sealed dosing device that contains the immediate container):

1. Name of sponsor, contract research organization or investigator:

2. Pharmaceutical dosage form, route of administration (may be excluded for oral solid dose forms), quantity of dosage units and in the case of open label trials, the name/identifier and strength/potency:

3. Batch and/or code number to identify the contents and packaging operation;

4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

5. The trial subject identification number/treatment number and where relevant. The visit number.

III. If the immediate container takes the form of blister packs or small units such as ampoules on which the information required in section I cannot be displayed, outer packaging should be provided bearing a label with those information. The immediate container should nevertheless contain the following:

1. Name of sponsor, contract research organization or investigator:

2. Route of administration (may be excluded for oral solid dose forms) and in the case of open label trials, the name/identifier and strength/potency;

3. Batch and/or code number to identify the contents and packaging operation;

4. A trial reference code allowing identification of the trial, site, investigator and sponsor if not given elsewhere;

5. The trial subject identification number/treatment number and where relevant, the visit number.

IV. Symbols or pictograms may be included to clarify certain information mentioned above.

Additional information, warnings and/or handling instructions may be displayed.

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V. During packaging of investigational medicinal products, it may be necessary to handle different products on the same packaging line at the same time. The risk of product mix up must be minimized by using appropriate procedures and/or, specialized equipment as appropriate and relevant staff training.

VI. Packaging and labeling of investigational medicinal products are likely to be more complex and more liable to errors (which are also harder to detect) than for marketed products, particularly when "blinded" products with similar appearance are used. Precautions against mis-labelling such as label reconciliation, line clearance, inprocess control checks by appropriately trained staff should accordingly be intensified.

VII. The packaging must ensure that the investigational medicinal product remains in good condition during transport and storage at intermediate destinations. Any opening or tampering of the outer packaging during transport should be readily discernible.

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مرفق رقم (٢)

متطلبات الهيئة العامة للغذاء و الدواء لبطاقة و تغليف عينات الأدوية المستخدمة في الدراسات السريرية

SFDA requirements for Labeling and Packaging for investigational medicinal products (IMP)

I. Outer Label Text

Clinical Trial No.
Drug Name and Strength
Dosage form
Specific description for syringe content
Route of Administration
Storage condition
Lot No.
Expiry Date
Expiry Date(Arabic)
Use as directed
Warning: For Clinical Trial Use only.
Warning: For Clinical Trial Use only.(Arabic)
Manufacture name , city, country

II. Inner Label Text

CT No. Visit number: Visit Date: dd/mm/yyyy Patient No.:	For Clinical Trial use only Please keep out the reach and sight of Children Drug Name Strength Dosage form, Route of administration Use as directed Investigator/..... Telephone No,/ Do not tore above .....°C(....F) Expire Date: marked on the folding box Lot No./	CT No. For Clinical Trial Use only Visit number: Visit Date: dd/mm/yyyy Patient No.: Drug Name Strength Dosage form, Route of administration

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