الاشارة / ت.إ- 2019/12

التاريخ / 10/07/2019

تعميم رقم (12) لسنة 2019

السادة / ممثلي شركات ومصانع الأدوية المحترمين

الموضوع: عينات المستحضرات الصيدلانية المقدمة لقسم التسجيل و التسعير الدوائي

تحية طيبة وبعد،،،

بالإشارة الى الموضوع أعلاه، نحيطكم علماً بإصدار تعديلات في عدد ومعايير وإشتراطات تسليم وتحليل عينات المستحضرات الصيدلانية حسب المرفق.

نرجو التكرم بتعميمها علي جميع الشركات التابعة لكم والتقيد بالكميات والشروط الموضحة أثناء تقديم أي ملف لقسم التسجيل علي أن يبدأ العمل بها من تاريخ صدور هذا الخطاب، علماً بأنه لن يتم إستلام أي عينات غير متوافقة مع هذه المعايير بعد تاريخ **2019/9/1**

وتفضلوا بقبول فائق الإحترام والتقدير،،،

مرفق: شروط و متطلبات عينات المستحضرات الصيدلانية المقدمة للتسجيل

10/07/2019

الدكتورة / عائشة إبراهيم الأنصاري

مدير إدارة الصيدلة والرقابة الدوائية

PDCD 002

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Appendix 1. General requirements for analysis of pharmaceutical products

Main documents

The following are the main documents needed for analysis of pharmaceutical products samples that should be submitted within the product file in relevant sections:

1. Softcopy in English language for the product file including as a mandatory the whole content of module 3 and module 1 as optional for guidance and more information.
2. Certificate of analysis in English language including the main data of the sample and the results of analysis according to specifications of the product.
3. Microbial limit test and Bacterial endotoxins test should be supported with a detailed product's specific method of analysis and validation report. A general method and/or general SOP may not be accepted.

Sample requirements and sample size

1. The submitted sample should be packed in its original pack with the artwork which will be registered in Qatar. If not available, a clarification letter should be accompanied with the sample to clarify the brand name, generic name and composition, potency, dosage form, pack content, pack size and storage conditions.
2. It is the responsibility of the applicant to deliver the samples in the proper storage conditions until handling to Pharmacy & Drug Control Department (PDCD), protected from light and/or as described on the pack of the product. PDCD has the right to refuse receiving the samples and request alternative samples in case of suspecting the validity of the submitted sample due to storage conditions.
3. The sample should have at least one year remaining shelf life at the time of submission.
4. The batch/lot number of the submitted sample should be complying with accompanied certificate of analysis.
5. The submitted sample should be with sufficient size to carry out the complete analysis (complete general tests and specific test) as described in the method of analysis of the manufacturer OR refer to the following table for the recommended minimum sample size in case of not determined in the product file.

No.	Dosage form	Sample size
1	Tablets, soft gelatin capsules & hard gelatin capsules	Minimum 100 tablets/caps
2	Semisolid preparations (ointments, creams & gels)	Minimum 10 tubes
3	Sachets	Minimum 70 sachets
4	Syrups, oral suspensions & oral drops	Minimum 10 bottles
5	Powders for reconstitution (oral suspension)	Minimum 10 bottles
6	Eye drops (solutions or suspensions), otic drops & nasal drops	
6.1	Eye drops (solutions or suspensions), otic drops & nasal drops of sample size ≥ 5ml	Minimum 20 bottles
6.2	Eye drops (solutions or suspensions), otic drops & nasal drops of sample size 1ml – 2.5 ml	Minimum 40 bottles
6.3	Eye drops (0.5 ml minims)	Minimum 10 boxes
7	Ophthalmic ointments	Minimum 5 tubes
8	Rectal & vaginal suppositories	Minimum 50 suppositories
9	Transdermal patches	Minimum 20 patches
10	Aerosols & inhalers	Minimum 10 canisters
11	Vials containing powder for reconstitution (injection)	Minimum 40 vials
12	Solution for injection in vials or ampoules	
12.1	Solution for injection in vials or ampoules < 5 ml	Minimum 50 amp/vials
12.2	Solution for injection in vials or ampoules ≥ 5 ml	Minimum 30 amp/vials
13	Large volume parental (for LVP more than 100ml)	Minimum 3 packs
14	Small volume parental (50 ml & 100 ml)	Minimum 5 packs
15	Topical solution (Shampoo- Lotion- antiseptic solution)	Minimum 5 packs
16	Prefilled Syringes	
16.1	Prefilled Syringes - single dose	Minimum 20 syringes
16.1	Prefilled Syringes - multiple dose	Minimum 10 syringes
17	Haemodialysis & irrigation solution	Minimum 2 packs

6. The applicant should provide additional 2 packs of the finished product in the final packaging (plus PIL) for the pricing and registration purposes.

<u>Reference/working standard requirements</u>

1. Reference/working standard should be submitted for the active pharmaceutical ingredient/s which exists in the submitted sample.
2. If the product contains preservatives, the reference/working standard for these preservatives should be submitted.

3. **The reference/working standard should have at least 6 months remaining shelf life at the time of submission.**
4. **The reference/working standard should be in a quantity not less than 500mg for each, stored in proper storage conditions, in a light and humidity protected, well-sealed container.**
5. **It is the responsibility of the applicant to deliver the reference/working standards in the proper storage conditions until handling to Pharmacy & Drug Control Department (PDCD), protected from light and/or as described on the pack of the product. PDCD has the right to refuse receiving the samples and request alternative samples in case of suspecting the validity of the submitted sample due to storage conditions.**
6. **The reference/working standard should come with a clear, well written, with non-erasable typing in English language printed label include the following :**

- **The name of material clearly written, not a code for the material**
- **The batch/lot number**
- **Validity date**
- **Storage conditions**
- **Potency**
- **Water content / loss on drying, if present**

7. **The certificate of analysis in English language that states clearly the potency of the reference/working standard should be submitted for the same batch/lot number.**
8. **PDCD has the right to ask for primary reference standard if needed.**