Stability Study File Contents in case of: Human Drug Product (OLD SYSTEM) &Food Supplement & Vet. Products:

1-Covering letter of the file contents on company paper.

2-Three copies of summary Sheet of stability file on the company(applicant) paper (stamped& signed).

3- Three copies of composition (stamped & on company (applicant) paper.

4-Copy of certificate of analysis from NODCAR.

5- Copy of certificate of analysis from the manufacturer.

6-Complete stability study with tables for 3 different batches (accelerated &or long term) which signed & stamped from the company which perform the stability study.

7-Original Chromatograms of HPLC (of all data) analysis of each time interval for all batches (standard & test for each time interval).

8- Method of analysis for the finished products (if not HPLC submit a reference).

9- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.

10- خطاب التحويل من الإدارة المختصة

11- صورة من موافقة اللجنة الفرعية لتسجيل الادوية على السير في إجراءات التسجيل للمستحضرات البشرية

12- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

13- إقرار بأن الاسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

14- شهادة من المصنع بأنه مسئول عن الدراسة المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

15- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

Add the following items:

In Case of Re- registration:

صورة من إخطار التسجيل في حالة إعادة التسجيل-

- Ongoing stability study for at least three batches each batch /year for surveillance period (shelf period).

- Original pack with the shelf life& storage conditions.

In Case of Imported Products:

- Copy from the CPP confirms the Shelf life & storage conditions (shelf life in the country of origin...) if not present in CPP submit authorized letter from the country of origin containing shelf life & storage conditions .

- Original pack with the shelf life & storage conditions.

ملحوظة:

في حالة عدم عمل دراسة ثبات في مكان غير مصنع:

يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of :
Human Drug Product (NEW SYSTEM)

1-Covering letter of the file contents on company paper.
2- Three copies of summary sheet of stability file on the company (applicant) paper (stamped & signed).
3- Three copies of composition (stamped & on company(applicant) paper).
4- Copy of certificate of analysis from the manufacturer.
5-Original Chromatograms of HPLC(of all data) analysis of each time interval & if not HPLC submit reference (standard & test for each time interval).
6- Method of analysis for the finished products.
7- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.
8- اصل موافقة اللجنة الفنية لمراقبة الادوية على السير في إجراءات التسجيل للإطلاع وصورة منها .
٩- (CD) إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات
١٠- إقرار بان الاسطوانة المدمجة مطابقة للنسخة الورقية المقدمة
١١- أو شهادة من المصنع بأنه مسئول عن الدراسة المقدمة وتكون مختومة بختم بارز ذات علامة مائية بحيث لا يمكن تزويره.
12-Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

Add the following items:

In case of local Products:

1- Complete accelerated stability study with tables on one (R&D batch) at least for four time intervals is required.

In case of imported products:

1- Complete stability study with tables for 3 different batches (accelerated &or long term).
2- Copy from the CPP confirms the Shelf life & storage conditions (shelf life in the country of origin...).

N.B: NODACR is not required.

ملحوظة:

في حالة عدم عمل دراسة ثبات في مكان غير مصنع:

يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of :
NEW SYSTEM (Production Batches 1st, 2nd , or 3rd):

1-Covering letter of the file contents on company paper.

2- Three copies of Summary sheet of stability file on the company (applicant) paper (stamped& signed).

3- Three copies of composition (stamped & signed) on company (applicant) paper the same as the composition approved in license of registration .

4- Copy of certificate of analysis from the manufacturer.

5- Copy of certificate of analysis from NODCAR for the three production batches .

6-Accelerated stability study with tables for (Production batches)at least for four time intervals then Complete long term stability study with tables for (Production batches).

7-Original Chromatograms of HPLC (of all data) analysis of each time interval (standard & test for each time interval).

8- Method of analysis for the finished products.

9- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.

10- صورة من الإخطار المؤقت

11-صورة من محضر التفتيش وسحب العينات

12- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

13-إقرار بأن الإسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

14- شهادة من المصنع بأنه مسئول عن الدراسة المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

15- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

ملحوظة:
في حالة عدم عمل دراسة ثبات في مكان غير مصنع:
يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of :
CHANGE OF COMPOSITION:

1- Three copies of the summary sheet of stability file on the company (applicant) paper (stamped & signed).

2-Three Copies of new composition (stamped & on company (applicant) paper).

3-صورة من إخطار التسجيل

4- صورة من الموافقة على تغيير بيان التركيب مرفق بها بيان التركيب الجديد والقديم

5- Copy of certificate of analysis from the manufacturer.

6- Complete accelerated stability study with tables for 1 batch for 3 months.

7- Original Chromatograms of HPLC (of full data) analysis of each time interval(standard & test for each time interval).

8- Method of analysis for the finished product.

9- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.

10- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

11-إقرار بأن الإسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

12 - شهادة من المصنع بأنه مسئول عن دراسة الثبات المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

13- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

ملحوظة:

في حالة عدم عمل دراسة ثبات في مكان غير مصنع:

يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of :

CHANGING SITE OF MANUFACTURE:

1- Three copies of summary of stability file on the company (applicant) paper (stamped & signed).

2-Three Copies of composition (stamped & on company(applicant) paper).

3- صورة من إخطار التسجيل (مذكور فيه الموافقة على نقل مكان التصنيع ومذكور فيه نوع الدراسة المطلوبه.

4- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.

5- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

6-إقرار بأن الإسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

7- شهادة من المصنع بأنه مسئول عن [دراسة الثبات المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

8- دراسة الثبات المطلوبه من قبل لجنة المتغيرات+chromatograms (of full data) analysis of each time interval(standard & test for each time interval).

9-Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

10-certificate of analysis of the finished product

11-Method of analysis

ملحوظة:

في حالة عدم عمل دراسة ثبات في مكان غير مصنع:

يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of :
SHELF LIFE EXTENSION of Registered Pharmaceutical Products:

1-Covering letter explains the reason on company paper.

2-Three copies of the summary sheet of stability file on the company paper (stamped & signed).

3-Three Copies of composition (stamped & on company (applicant) paper).

4-صورة من إخطار التسجيل

5-Complete stability study with tables for 3 different batches for the required shelf life.

6-Chromatograms of HPLC analysis (of full data) analysis of each time interval(standard & test for each time interval).

7- Method of analysis for the finished products.

8- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter.

9-The original pack and a copy of CPP (Certificate of Pharmaceutical Product) confirms the required shelf life & storage conditions (in case of imported).

10- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة من ملف دراسة الثبات (CD)

11-إقرار بأن الإسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

12- شهادة من المصنع بأنه مسئول عن الدراسة المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

14- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

15-certificate of analysis of the finished product

16-Composition.

17- شيك بألف جنيه

ملحوظة:
في حالة عدم عمل دراسة ثبات في مكان غير مصنع:
يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of : CHANGE OF STORAGE CONDITIONS:

1-Covering letter explains the reason on company paper.

2- Three copies of the summary sheet of stability file on the company (applicant) paper (stamped & signed).

3-Three Copies of composition (stamped & on company (applicant) paper).

4-صورة من إخطار التسجيل

5-Complete stability study with tables for 3 different batches with chromatograms of HPLC analysis (of full data) analysis of each time interval(standard & test for each time interval).

6-Method of analysis for stability for finished product.

7-The original pack and a copy of CPP (Certificate of Pharmaceutical Product) confirms the required storage conditions (in case of imported).

8- أسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

9-إقرار بأن الأسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

10- شهادة من المصنع بأنه مسئول عن دراسة الثبات المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

11- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

12-Certificate of analysis

13-Validation

شيك بألف جنية-14

ملحوظة:
في حالة عدم عمل دراسة ثبات في مكان غير مصنع:
يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين:

Stability Study File Contents in case of : CHANGE OF THE PACK:

1-Covering letter explains the reason on company paper .

2-Threecopiesof the summary sheet of stability file on the company (applicant) paper (stamped & signed).

3-Three Copies of composition(stamped & on company (applicant) paper).

4-صورة من إخطار التسجيل

5-Complete accelerated &\ or Long term stability study with tables for 3 different batches.

6-Chromatograms of HPLC analysis (of full data) analysis of each time interval(standard & test for each time interval) of at least the end of Shelf life.

of at least the end of Shelf life.

7-Method of analysis for stability for finished product.

8- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms for each parameter

9-The original pack and a copy of CPP confirms the required pack (in case of imported).

10- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

11-إقرار بأن الإسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

12- شهادة من المصنع بأنه مسئول عن الدراسة المقدمة وتكون مختومة بختم بارز أو ذات علامة مائية بحيث لا يمكن تزويره.

13- خطاب التحويل من الإدارة المختصة

14- - Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

15-certificate of analysis

ملحوظة:
في حالة عدم عمل دراسة ثبات في مكان غير مصنع:
يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of : Pharmaceutical Products of different concentrations:

*** في حالة الرغبة في تسجيل مستحضر صيدلي بأكثر من تركيز أو أن يكون معبأ في عبوات بأحجام مختلفة يمكن إجراء دراسة الثبات على كل من المستحضر الأعلى تركيزا والمستحضر الأقل تركيزاً (وذلك على أن يكون بيان التركيب وطريقة التصنيع متماثلة) و تستثنى التركيزات المتوسطة وتتبع نفس الطريقة مع أحجام العبوات:**

File contents in this case of the concentration inbetween the higher &lower concentration:

1-Covering letter of the file contents on company paper .

2-Three copies of Summary sheet of stability file on the company (applicant) paper (stamped & signed).

3- Three copies of composition(stamped & signed on company (applicant) paper).

4- Method of analysis for the finished products.

5- Test method validation of assay of active ingredient in finished product provided by HPLC chromatograms (of full data) analysis of each time interval(standard & test for each time interval) for each parameter.

6-صورة من الموافقة على السير في إجراءات التسجيل.

7-خطاب من الشركة تتعهد فيه بأن طريقة التصنيع وبيان التركيب هي نفسها لكل التركيزات

8-خطاب التحويل من الإدارة المختصة

9- Sample with labeling (product name ,manufacturing date, expiration date& batch number ''as the same as C.O.A or stability tables '')

ملحوظة:
في حالة عدم عمل دراسة ثبات في مكان غير مصنع:
يتم إرفاق اصل العقد مع المكان الذي يتم عمل دراسة الثبات فيه و صورة من رخصة هذا المكان وصورة من السجل التجارى للشركتين والبطاقة الضريبية للشركتين.

Stability Study File Contents in case of:
Biologial Product:

١- في حالة تسجيل مستحضر حيوى مستورد جديد :-

1-Covering letter of the file contents on company paper.

2- 3 Copies of summary sheet of stability file on the company paper (stamped and signed).

3- 3 Copies of composition (stamped and signed on company paper) identical to the attached one in transfer letter.

4-Copy of certificate of analysis from NORCB

5- Copy of certificate of analysis from the manufacturer of finished &raw material of active ingredient (s).

6-Copy of certificate of analysis from the manufacturer of the pack (containing mainly toxicity test)

7-Complete stability study with tables stamped from the site at which the stability was performed for 3 different batches (commercial batches) (long term) &stability protocol.

8-Chromatograms of assay analysis of each time interval for all batches.

9- Method of analysis for the finished products.

10- Test method validation of assay of active ingredient in finished product provided by assay chromatograms for each parameter.

11-Transfer letter from department of biological products registration with attached certified composition from biological containing the following items:- Product name ,Generic name &strength ,Dosage form ,Route of administration , Applicant ,Marketing authorization holder , Manufacturer of the active substance ,Manufacturer of finished product ,Manufacturer of the diluent ,Manufacturer responsible for batch release ,Packager(primary &secondary) , Pack , Source of the packaging material and type of registration.

12-CD identical to the paper copy submitted in the stability study files.

13-Commitment that the CD matching to the paper copy submitted in the stability study files.

14- Sample of original pack with the shelf life & storage conditions (or outer carton box)

15-Pack specifications in details.

16-Copy from the CPP confirms the shelf life & storage conditions (shelf life in the country of origin...) and in case of absence of shelf life in CPP, submit us with authorized letter from the country outside clarify the shelf life and storage conditions.

٢- في حالة تسجيل مستحضر حيوى محلى جديد(سيتم إستيراد المادة الفعالة من الخارج) أو (سيقوم المصنع المحلى بإنتاج المادة الفعالة):-

1-Covering letter of the file contents on company paper.

2- Copies of summary sheet of stability file on the company paper (stamped and signed).

3- Copies of composition (stamped and signed on company paper).

4-Copy of certificate of analysis from NORCB.

5- Copy of certificate of analysis from the manufacturer of finished &raw material of active ingredient (s).

6-Copy of certificate of analysis from the manufacturer of the pack (containing mainly toxicity test).

7-Complete stability study with tables stamped from the site at which the stability was performed for 3 different batches (Pilot batches) (long term) &stability protocol.

8-Chromatograms of assay analysis of each time interval for all batches.

9- Method of analysis for the finished products.

10- Test method validation of assay of active ingredient in finished product provided by assay chromatograms for each parameter.

11-Transfer letter from department of biological products registration with attached certified composition from biological containing the following items:- Product name ,Generic name &strength ,Dosage form ,Route of administration , Applicant ,Marketing authorization holder , Manufacturer of the active substance ,Manufacturer of finished product ,Manufacturer of the diluent ,Manufacturer responsible for batch release ,Packager(primary &secondary) , Pack , Source of the packaging material and type of registration.

12-CD identical to the paper copy submitted in the stability study files.

13-Commitment that the CD matching to the paper copy submitted in the stability study files.

14- Sample Original pack with the shelf life & storage conditions

15-Pack specifications in details.

16-Certificate of responsibility stamped from the site at which the stability study was performed.

٣-إعادة تسجيل مستحضر حيوى مستورد:-

1-Covering letter of the file contents on company paper.

2- Copies of summary sheet of stability file on the company paper (stamped and signed).

3- Copies of composition (stamped and signed on company paper).

4-Copy of certificate of analysis from NORCB.

5- Copy of certificate of analysis from the manufacturer of finished &raw material of active ingredient (s).

6-Copy of certificate of analysis from the manufacturer of the pack (containing mainly toxicity test).

7-Complete stability study with tables stamped from the site at which the stability was performed for 3 different batches (commercial batches) &stability protocol.

8-Chromatograms of assay analysis of each time interval for all batches.

9- Method of analysis for the finished products.

10- Test method validation of assay of active ingredient in finished product provided by assay chromatograms for each parameter.

11-Transfer letter from department of biological products registration with attached certified composition from biological containing the following items:- Product name ,Generic name &strength ,Dosage form ,Route of administration , Applicant ,Marketing authorization holder , Manufacturer of the active substance ,Manufacturer of finished product ,Manufacturer of the diluent ,Manufacturer responsible for batch release ,Packager(primary &secondary) , Pack , Source of the packaging material and type of registration.

12-CD identical to the paper copy submitted in the stability study files.

13-Commitment that the CD matching to the paper copy submitted in the stability study files.

14- Sample Original pack with the shelf life & storage conditions (or outer carton box)

15-Pack specifications in details.

16-Copy from the CPP confirms the shelf life & storage conditions (shelf life in the country of origin...) and in case of absence of shelf life in CPP submit us with authorized letter from the country outside clarify the shelf life and storage condition.

17- Copy of registration notice in case of re-registration

٣-إعادة تسجيل مستحضر حيوى محلى:-

1-Covering letter of the file contents on company paper.

2- Copies of summary sheet of stability file on the company paper (stamped and signed).

3- Copies of composition (stamped and signed on company paper).

4-Copy of certificate of analysis from NORCB.

5- Copy of certificate of analysis from the manufacturer of finished &raw material of active ingredient (s).

6-Copy of certificate of analysis from the manufacturer of the pack (containing mainly toxicity test).

7-Complete stability study with tables stamped from the site at which the stability was performed for 3 different batches (commercial batches) &stability protocol.

8-Chromatograms of assay analysis of each time interval for all batches.

9- Method of analysis for the finished products.

10- Test method validation of assay of active ingredient in finished product provided by assay chromatograms for each parameter.

11-Transfer letter from department of biological products registration with attached certified composition from biological containing the following items:- Product name ,Generic name &strength ,Dosage form ,Route of administration , Applicant ,Marketing authorization holder , Manufacturer of the active substance ,Manufacturer of finished product ,Manufacturer of the diluent ,Manufacturer responsible for batch release ,Packager(primary &secondary) , Pack , Source of the packaging material and type of registration.

12-CD identical to the paper copy submitted in the stability study files.

13-Commitment that the CD matching to the paper copy submitted in the stability study files. 14- Sample Original pack with the shelf life & storage conditions

14-Pack specifications in details.

15- Copy of registration notice in case of re-registration

16-Certificate of responsibility stamped from the site at which the stability study was performed.

Notice:-

In case of performing the stability study in place rather than the manufacturer:-

-Attach the contract between the applicant and the place at which the stability was performed and a copy of the license of the place at which the stability was performed.

Stability Study File Contents in case of :

Cosmetics :

1-Summary Sheet of stability file on the company paper (stamped and signed).

2- Complete stability study performed on 3 different batches (accelerated &or long term) including viscosity test for non-powder products.

3- Stability study tables should include manufacturing & expiry date for each batch.

ملحوظة:

يتم تقديم ملفات دراسات الثبات الخاصة بمستحضرات التجميل وذلك داخليا عن طريق قسم تسجيل مستحضرات التجميل ويتم التعامل داخليا بين ادارة تسجيل مستحضرات التجميل و قسم الثبات فى حالة الموافقة اما فى حالة صدور قرار باستكمال من قبل اللجنة يتم اصدار خطاب للشركة بالمطلوب ويتم استلامه من سكرتارية الثبات والرد يوم الخميس من الساعة ٩,٥ –١١ صباحا .

Stability Study File Contents in case of :

Insecticides & Antiseptics :

1-Covering letter of the file contents on company paper.

2- Summary Sheet of stability file on the company paper (stamped and signed).

3-Copy of composition (stamped & on company paper).

4-Copy of certificate of analysis from NODCAR.

5- Transfer letter from Biocidal Registration Department.

6- Copy of certificate of analysis from the manufacturer.

7-Complete stability study performed on 2 different batches at least (accelerated &or long term).

8-Chromatograms of HPLC analysis at each time interval for all batches.

9- إسطوانة مدمجة مطابقة للنسخة الورقية المقدمة بملف دراسة الثبات (CD)

10-إقرار بأن الاسطوانة المدمجة مطابقة للنسخة الورقية المقدمة

ملحوظة:

للاستفسار عن دراسات الثبات للمبيدات أو المطهرات و لاستقبال الملفات الخاصة بدراسات الثبات للمبيدات أو المطهرات فان ذلك يتم فى يوم الاثنين من كل أسبوع فى الساعة ال ١٢ ظهرا على شباك رقم ٥.

Composition Revision (requirement)

1- Separate the active & inactive ingredient in the composition .

2- Arrange the items of composition as the following :

Ingredient	quantity	Specification	Function

3-Unify the units of ingredient's amount in the composition.

4-Specify the adjusted pH in case of presence of alkalinizer or any other pH adjuster.

5- In case of Film Coated Tablet separate the core & Coat .

6- In case of Capsule separate the cap & body and revise the color of both with sample.

7- In case of presence of pellets write the composition of it .

8-Check spelling of Trade name & Active ingredient according to under registration approval .

9- Write the dosage form as in the under registration approval .

10-The composition must be on Applicant paper (not manufacturer) .

11- Write the ingredient without abbreviations or chemical name.

12- In case of presence of ethyl alcohol write evaporated during manufacturing.

13-Percent of methyl paraben & propyl paraben (Hydroxy benzoate) = 0.1 -0.2 % of the total average weight .

14-Determine the grade of the following ingredient :

Povidone

Hydroxy propyl methyl cellulose (HPMC)(Hypromellose)

Methacrylic acid and any acrylate ester

Methyl cellulose

Hydroxy ethyl cellulose

Microcrystalline cellulose (MCC)

Polyethylene glycol

Poly vinyl pyrrolidine (PVP)

Lactose (monohydrate - anhydrous)

Powdered cellulose

Colloidal silicon dioxide (aerosil)

-incase of presence of any alcohol (only in solid dosage form) write * above it and write under composition evaporated during manufacturing

- incase of presence of mixture of two cellulose write ratio between them beside it

- in case of not writing grade of any type of cellulose and write number should write grade of its viscosity (cps) (ex.2910 , 6000 , Aerosil 200,……..)

-in case of presence amount equivalence should written beside its material not under quantity column

Composition revision in case of:

1- Human pharmaceutical products which follow ministerial decrees 296/2009 .

2- Human pharmaceutical products which follow ministerial decrees 370/2006 when the composition is not attached with under registration approval.

3-In case of transfer letter from any registration department (Human –Veterinary – Food - Biological) which declare that the composition must be revised in the stability department.

4-When the company wants to change composition from that attached with under registration approval , the company must give 3 copies of new & old composition and commitment that the stability study is done on the new composition .

5- In case of addition of equivalence to that mentioned in under registration approval ,The company must give the reference that declare the amount of salt that equivalent to base or reference that declare the molecular weight of salt & base and the calculation .

6-In case of Re-registered product the composition change in done in variation department.

In Case of capsule containing pellets:

1- **capsule containing pellets** **لو الموافقة ٣٧٠ لازم يغيرها ويكتب فيها**
2- **Each hard gelatin capsule containing (sum of active and inactive)or (sum of content))mg of pellets which eq. to (…)mg of active ingredient**