Check List for Stability Study of Imported Human drug product submitted according to 820/2016 decree (CTD)

Product Name:	**Company Name:**
Date:	**Revised By: (Full Name):**

Module 1
(1.8- stability part)

		Check	Notes
1.8.1	Sample		
1.8.2	Summary sheet of stability file		
1.8.3	CD commitment, CD		
1.8.4	Storage conditions commitment		
1.8.5	Composition		
1.8.6	Copy of CPP, Covering letter from license holder illustrate shelf life, storage conditions, pack in detail if not mentioned in CPP		
1.8.7	Finished Product Specifications		
1.8.8	Covering letter of manufacturer of drug substances		

Module 3(stability part)

Prepare the dossier as follow: Copy of		Check	Notes
3.2.P.1	Description and composition of drug product		
3.2.P.5.1	Specification		

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Website: www.eda.mohp.gov.eg Email: stability@eda.moheatlh.gov.eg

3.2.P.5.2	**Analytical procedure** **-Method of analysis for** **1-Assay** **2-Related substance (If present)** **3-preservatives and antioxidant (If present)** **-<u>If method of analysis is compendial submit copy of reference for method of analysis :</u>** **<u>- If method of analysis is not HPLC ,in this case submit (last time interval with HPLC& specificity with TLC or HPLC):</u>**		
3.2.P.5.3	**Validation of analytical procedure** **-Validation protocol & report of method of analysis and chromatograms for** **1-Assay** **2--Related substance (If present)** **-For Non official (full validation is required)** **Specificity-Accuracy-Precision – linearity(regression equation &calibration curve)-Ruggedness** **For official (Specificity-Accuracy-Precision)**		
3.2.P.5.4	**Batch analysis (certificate of analysis)**		
3.2.P.7	**Full description of container closure system**		
3.2.P.8	**stability**		

<u>(stability summary and conclusion)</u> <u>3.2.P.8.1 for drug product</u>	
1-product name, strength, dosage form	
2- manufacturing site	
3- manufacturing date, Expire date	
4- packaging site	
5- stability performed by	
7- Batch Number ,Batch size	
8- batch type (production or pilot)	

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9- No of batch	
10--type of study(accelerated or long term or intermediate …)	
11-- date of starting of stability	
12-- stability conditions	
13- propsed shelf life and storage conditions	
14- storage conditions and shelf life of in use stability(if present ,)	
15- storage conditions and shelf life after reconstitution and infusion (If present)	
16- container closure system	
17-Batch Number of Drug substances	

3.2.P.8.2 for drug product
(post approval stability protocol and stability commitment)

Stability commitment such as:
1-The company committed to carry out ongoing stability study

3.2.P.8.3 for drug Product
(Stability data)

	Stability Tables
1-Physical analysis :	
2-Chemical analysis:	
3-Microbiological analysis or sterility in case of (injection):	
4-Biological analysis(in case of cream& eye drops):	
5- pack in details:	
6-Stability conditions	
7-Batch number	
8-Manuf date,Expire date	
9-Name of product	

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Other notes in stability table:

Side stability studies (If present):

-After opening (In-use):

-After reconstitution:

-After dilution:

-Stability of solvent:

Assay chromatograms for each time interval (in case of long term stability study):

0	1	3	6	9	12	18	24	36	48

Assay chromatograms for each time interval (in case of accelerated stability study):

0	1	3	6

(يتم وضع الأصول الأتية داخل plastic jacket فى الملف مع الأحتفاظ بصورة منها داخل الملف)

Archive: 1-Check list
2-Stability tables
4-Summary sheet& Composition
5-Certificate of analysis
6-Method of analysis
7- C.P.P& covering letter illustrate shelf life, storage condition& pack (if not mentioned in C.P.P)
8-اى اوراق حاصة بحالة معينة للمستحضر

"Final decision"			
استكمال		استقبال مرة أخرى	

ملحوظة :-
الـ checklist خاضعه للتحديث المستمر من قبل اللجنه وتبعا الى الـ WHO guideline والـ ICH guideline

Date: **Dr. Signature**

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