Serial: 00000/YYYY

Format and Content of Comparative In Vitro Dissolution Study Report to be Submitted to the Central Administration of Pharmaceutical Affairs (CAPA)

1.	**Title page**	
1.1	**Study title**	
1.2	**Name of the test drug & dosage form**	
1.3	**Name of active ingredient(s) & conc.**	
1.4	**Name of sponsor & manufacturer**	
1.5	**Name of the reference drug & dosage form**	
1.6	**Name of active ingredient(s) & conc.**	
1.7	**Name of manufacturer, sponsor & country of origin**	
1.8	**Name and address of bioequivalence center / company**	
1.9	**Name, affiliation and signature of: (dated)**	
1.9.1	**Chairman of the board (center)**	
1.9.2	**Center manager (center)**	
1.9.3	**Technical manager (center)**	
1.9.4	**Chief analyst (center)**	
1.9.5	**Quality assurance manager (center)**	
1.9.6	**Registration manager (company)**	
1.9.6	**Other responsible members in the company**	

2.	**Reason for dissolution submission (CAPA approval is to be submitted)**	
2.1	**Bio-waiver of one strength based on approved bioequivalence study of other strength**	
2.2	**Bio-waived active ingredient**	
2.3	**Variation in :**	
2.3.1	**Change in inactive ingredients**	
2.3.2	**Change in raw materials' suppliers**	
2.4	**Re-registration**	

تليفون: ٢٣٦٤٨٠٤٦ - ٢٠٢ + ٢٣٦٤٨٧٦٩ -٢٠٢+ داخلي: ١٨٠٦ فاكس : ٢٣٦٨٤١٩٤-٢٠٢+
العنوان : ٢٢ شارع الاخشيد – منيل الروضة – القاهرة
رقم الحجرة : ٨١٣
Website: www.eda.mohp.gov.eg
Email : bioequivalence@eda.mohealth.gov.eg

3.	**Original certificate of sameness or equivalence including: (dated & signed)**	
3.1	**Test product (as stated in registration documents)**	
3.1.1	**Trade name**	
3.1.2	**Dosage form**	
3.1.3	**Strength**	
3.1.4	**Manufacturer, sponsor**	
3.1.5	**Batch number**	
3.1.6	**Manufacture date & expiry date**	
3.2	**Reference product (as on the pack)**	
3.2.1	**Trade name**	
3.2.2	**Dosage form**	
3.2.3	**Strength**	
3.2.4	**Manufacturer & sponsor & country of origin**	
3.2.5	**Batch number**	
3.2.6	**Manufacture date & expiry date**	
3.3	**Conclusion (similarity factor "f_2") for all pH**	

4.	**Dates of:**	
4.1	**Contract with sponsor**	
4.2	**Start of analysis**	
4.3	**End of analysis**	
4.4	**Report issue**	

5.	**Product Information (presented as follows)**	
Item	**Test Product**	**Reference Product**
1.Product name		
2. API$_{(S)}$		
3.Molecular & structural formula		
4.Dosage form		
5.Type of the product (Immediate or modified release)		
6.Dosage regimen		
7.Strength		
8.Batch number		
9.Manufacture date		

تليفون: ٢٣٦٤٨٠٤٦ - ٢٠٢ + ٢٣٦٤٨٧٦٩ -٢٠٢+ داخلي: ١٨٠٦ فاكس : ٢٣٦٨٤١٩٤-٢٠٢+
العنوان : ٢٢ شارع الاخشيد – منيل الروضة – القاهرة
رقم الحجرة : ٨١٣
Website: www.eda.mohp.gov.eg
Email : bioequivalence@eda.mohealth.gov.eg

10.Expiry date		
11.Storage conditions		

6.	**Potency determination (done for both test and reference products, on at least ten dosage forms and taking three determinations then statistically analyzed)**	
6.1	**Assay methodology**	
6.2	**Tabulated results & acceptance values**	
6.3	**HPLC chromatograms or UV charts (dated)**	
6.4	**Assay method validation in term of calibration curve**	

7.	**Uniformity of dosage unit (weight variation and / or content uniformity) "according to the official compendia" (Reference is to be attached)**	
7.1	**Description of method used**	
7.2	**Tabulated results & acceptance values**	
7.3	**HPLC chromatograms or UV charts (dated)**	

8.	**Dissolution testing "on 12 dosage units"**	
8.1	**Dissolution testing method (with reference attached)**	
8.2	**Dissolution media used**	
8.2.1	**pH 1.2**	
8.2.2	**pH 4.5**	
8.2.3	**pH 6.8**	
8.2.4	**The most suitable medium (done only if there is a reference method in FDA or USP)**	
8.3	**Equations & tabulated results including (mean - SD - CV% "RSD"….) for the 12 dosage units (peak areas or UV absorbance values and % dissolved) for all pH**	
8.4	**Tabulated similarity factor "f2" calculation for each pH**	
8.5	**Tabulated dissimilarity factor "f1" calculation for each pH**	
8.6	**Comparative dissolution profile for each pH**	
8.7	**HPLC chromatograms or UV charts (dated)**	

تليفون: ٢٣٦٤٨٠٤٦ - ٢٠٢ + ٢٣٦٤٨٧٦٩ -٢٠٢+ داخلي: ١٨٠٦ فاكس : ٢٣٦٨٤١٩٤-٢٠٢+
العنوان : ٢٢ شارع الاخشيد – منيل الروضة – القاهرة
رقم الحجرة : ٨١٣
Website: www.eda.mohp.gov.eg
Email : bioequivalence@eda.mohealth.gov.eg

9.	**Dissolution method validation**	
9.1	**Full validation report for the most suitable medium (if there is no reference for the most suitable medium, full validation will be done for only one of the three media "1.2, 4.5, 6.8" at which the drug is most soluble) as follows:**	
9.1.1	**Calibration curve (with regression equation)**	
9.1.2	**Linearity**	
9.1.3	**Selectivity**	
9.1.4	**Accuracy**	
9.1.5	**Precision (interday and intraday)**	
9.1.6	**Recovery**	
9.2	**Verification report for the other media as follows:**	
9.2.1	**Accuracy**	
9.2.2	**Precision**	
9.3	**Data of the previously mentioned parameters**	
9.4	**Represented HPLC chromatograms or UV charts (dated)**	

10.	**Extra items can be submitted (if any)**

11.	**References**

<u>The study report should be submitted as follows</u>:

1. According to the above mentioned sequence.

2. On the official papers of the bioequivalence center / company.

3. All the pages should be numbered.

4. Containing an index (a table of contents).

5. Separators should be used between each of the previously mentioned items.

Date: / /

تليفون: ٢٣٦٤٨٠٤٦ - ٢٠٢ + ٢٣٦٤٨٧٦٩ -٢٠٢+ داخلي: ١٨٠٦ فاكس : ٢٣٦٨٤١٩٤-٢٠٢+
العنوان : ٢٢ شارع الاخشيد – منيل الروضة – القاهرة
رقم الحجرة : ٨١٣
Website: www.eda.mohp.gov.eg
Email : bioequivalence@eda.mohealth.gov.eg