



Serial: 00000/YYYY

**Format and Content of Dissolution Profile 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 and address of bioequivalence center / company	
1.6	Name, affiliation and signature of: (dated)	
1.6.1	Chairman of the board (center)	
1.6.2	Center manager (center)	
1.6.3	Technical manager (center)	
1.6.4	Chief analyst (center)	
1.6.5	Quality assurance manager (center)	
1.6.6	Registration manager (company)	
1.6.6	Other responsible members in the company	

2.	Reason for dissolution profile submission (CAPA Approval is to be attached)
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3.	Dates of:	
3.1	Contract with sponsor	
3.2	Start of analysis	
3.3	End of analysis	
3.4	Report issue	

4.	Product Information (presented as follows)	
	Item	Test 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	
10.Expiry date	
11.Storage conditions	

5.	Potency determination (done on at least ten dosage forms and taking three determinations then statistically analyzed)	
5.1	Assay methodology	
5.2	Tabulated results & acceptance values	
5.3	HPLC chromatograms or UV charts (dated)	
5.4	Assay method validation in term of calibration curve	

6.	Uniformity of dosage unit (weight variation and / or content uniformity) "according to the official compendia" (Reference is to be attached)	
6.1	Assay methodology	
6.2	Tabulated results & acceptance values	
6.3	HPLC chromatograms or UV charts (dated)	

7.	Dissolution testing "on 12 dosage units"	
7.1	Dissolution testing method (with reference attached)	
7.2	Dissolution media used	
7.2.1	pH 1.2	
7.2.2	pH 4.5	
7.2.3	pH 6.8	
7.2.4	The most suitable medium (done only if there is a reference method in FDA or USP)	



7.3	Equations & tabulated results including (mean - SD - CV% "RSD"....) for the 12 dosage units (peak areas or UV absorbance values and % dissolved) for all pH	
7.6	Dissolution profile for each pH	
7.7	HPLC chromatograms or UV charts (dated)	

8.	Dissolution method validation	
8.1	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:	
8.1.1	Calibration curve (with regression equation)	
8.1.2	Linearity	
8.1.3	Selectivity	
8.1.4	Accuracy	
8.1.5	Precision (interday and intraday)	
8.1.6	Recovery	
8.2	Verification report for the other media as follows:	
8.2.1	Accuracy	
8.2.2	Precision	
8.3	Data of the previously mentioned parameters	
8.4	Represented HPLC chromatograms or UV charts (dated)	

9.	Certificate (dated & signed)	
9.1	Test product (as stated in registration documents)	
9.1.1	Trade name	
9.1.2	Dosage form	
9.1.3	Strength	
9.1.4	Manufacturer, sponsor	
9.1.5	Batch number	
9.1.6	Manufacture date & expiry date	
9.2	Conclusion (mean % dissolved of the drug for each pH meet or dosen't meet the requirements)	



10. Extra items can be submitted (if any)

11. References

When dissolution profile for the reference product is required, the above mentioned requirement should be fulfilled.

The study report should be submitted as follows:

- 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: / /