

F1 Difference & F2 Similarity Factor Calculator for Dissolution

- Instructions:**
1. Prepare the dissolution time points used in Column B.
 2. Prepare the dissolution profiles (as desired) for the reference and test batches at each time point (i) for up to 12 replicates in Columns C to P.
- Notes:**
- Mean and FSD values at each time point will be calculated for up to 12 replicates.
 - If you have the mean dissolution value instead of the raw data you can enter use the first column (Column B).
 - Use FSD value that exceeds the greatest of 0.1 or 1.0.

Dissolution Profile: Reference (percentage)														Mean	SD	F ₁
Time	1	2	3	4	5	6	7	8	9	10	11	12				
1	20.0	20.1	20.7	21.1	20.9	21.3	21.7	22.1	21.1	20.4	20.9	20.9		21	1.0	1.0
2	20.0	20.1	20.7	20.8	20.5	20.4	20.7	20.7	20.5	20.7	20.5	20.8		20	1.0	1.0
3	20.7	20.4	20.7	20.8	20.2	21.0	21.0	21.0	21.1	20.8	20.7	20.5		21	1.0	1.0
4	20.0	20.1	20.2	20.9	20.8	20.8	20.8	20.1	20.5	20.8	20.1	20.8		20	1.0	1.0
5	20.4	20.4	20.1	20.1	20.4	20.1	21.1	20.1	20.4	20.4	20.1	20.1		20	1.0	1.0
6	21.1	21.0	20.2	20.4	20.8	20.8	20.1	20.2	20.8	20.8	20.1	20.1		21	1.0	1.0

Dissolution Profile: Test (percentage)														Mean	SD	F ₂
Time	1	2	3	4	5	6	7	8	9	10	11	12				
1	21.0	21.1	20.8	21.7	20.4	20.9	20.1	20.1	20.9	20.1	20.1	20.9		21	0.9	1.0
2	20.1	20.8	20.3	20.8	20.5	20.1	20.1	20.1	20.8	20.8	20.1	20.4		20	1.0	1.0
3	20.7	20.3	20.0	20.8	20.1	21.1	21.0	20.0	20.0	20.4	20.1	20.0		21	0.9	1.0
4	20.0	20.1	20.0	20.1	20.0	20.0	20.0	20.0	20.1	20.1	20.1	20.0		20	1.0	1.0
5	20.4	20.4	20.0	20.4	20.4	20.1	20.1	20.4	20.1	20.1	20.1	20.1		20	1.0	1.0
6	21.1	21.0	21.1	21.0	20.7	20.2	20.2	21.1	20.7	20.8	21.0	20.1		21	1.0	1.0

Dissolution Factor, F₁ = 1.01 ✔

Similarity factor, F₂ = 11.01 ✔

Legend:

- 1 = mean dissolution value of the reference (percentage) batch at time t
- 2 = mean dissolution value of the test (percentage) batch at time t
- 3 = number of time points/replicates included

- Other Guidelines:**
- Most suitable for dissolution profile comparison when three or more dissolution time points are available.
 - Dissolution time points for both profiles should be the same.
 - Only one measurement should be considered after 10% dissolution of both the products.
 - To allow use of mean data, the FSD of the earlier time points in 10 min should not be more than 10%, and all other time points should not be more than 10%.
 - For cases to be considered similar, F₁ value should be between 0.50 and 1.5, which should be between 50-150.

Dissolution tolerance limit: ↕

1



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