

附件 溶離相似性 (f<sub>2</sub>值) 之計算方式及結果認定

$$f_2 = 50 \cdot \log \left[ \frac{100}{\sqrt{1 + \frac{\sum_{t=1}^{t=n} [\bar{R}(t) - \bar{T}(t)]^2}{n}}} \right]$$

上列公式 f<sub>2</sub> 溶離相似值，n 為溶出之採樣點數， $\bar{R}(t)$  係對照藥品於 t 時間點之平均溶出百分比， $\bar{T}(t)$  係受試藥品於 t 時間點之平均溶出百分比。

In this equation  $f_2$  is the similarity factor, n is the number of time points,  $\bar{R}(t)$  is the mean percent drug dissolved of e.g. a reference product, and  $\bar{T}(t)$  is the mean percent drug dissolved of e.g. a test product.

f<sub>2</sub> 值 ≥ 50，為認定受試藥品及對照藥品溶離曲線比對相似之必要條件。