

Dakin's Opened Bottle Study

Objective: To examine the length of time Dakin's products are stable once the bottle is opened and is left opened.

Test Products:

Dakin's Full Strength (0.5 % Sodium Hypochlorite w/v Solutions)

Dakin's Half Strength (0.25 % Sodium Hypochlorite w/v Solutions)

Dakin's Quarter Strength (0.125 % Sodium Hypochlorite w/v Solutions)

Di-Dak-Sol (0.0125 % Sodium Hypochlorite w/v Solutions)

Procedure: Century tested one lot of each strength of Dakin's products, until its expiration date. An opened bottle sample was compared to a non-opened bottle of the same lot. (The non-opened bottle was only opened for the time necessary to retrieve a sample for testing, and served as a control.) The opened bottle sample and control bottle were stored side by side in a cardboard box at 20°C to 25°C (68°F to 77°F). At each test point, the intent was to compare the assay potency and the appearance of each opened bottle to the control (non-opened) bottle.

Summary: At the expiration date (12 months for Dakin's Full Strength and 14 months for all other Dakin's products), the appearance (color) of all the Dakin's opened bottle samples remained the same as the controls. However, there was much less solution left in the Dakin's opened bottle samples when compared to the controls, due to evaporation. Therefore, an assay on the opened bottles at their expiration date could not be performed at that time.

From the data set obtained at 2-3 weeks, 1 month, and the 2-3 month intervals, the potency of all the Dakin's products in the opened bottles was not significantly different from that of the products in the non-opened bottles. In all cases during this study, the product in both the opened bottles and the controlled bottles passed all specifications. The potency of all bottles tested is listed in Table 1.

This study provides a high degree of assurance that once any Dakin's product is opened it can be kept open for at least 2-3 months and still maintain its stability. However, the bottle must be kept free of contamination while open, and must be stored at room temperature and protected from light, as stated on the label.

Table 1: Comparison of the test results of Dakin’s opened bottles with Dakin’s non-opened bottles (served as control).

Sample	Sample Type	% Assay			
		2-3 weeks	1 month	2-3 months	On expiration
Dakin’s Full Mfg # 090601 Lot # 3031 Expiration=12 months	Non-opened Bottle Stability	117.7	117.2	115.0	106.7
	Opened Bottle Stability	117.7	116.9	113.2	N/A*
Dakin’s Half Mfg # 080627 Lot # 3030 Expiration=14 months	Non-opened Bottle Stability	116.1	115.9	115.9	111.9
	Opened Bottle Stability	116.1	115.9	116.9	N/A*
Dakin’s Quarter Mfg # 090604 Lot # 3035 Expiration=14 months	Non-opened Bottle Stability	116.7	116.5	116.5	113.3
	Opened Bottle Stability	116.7	116.5	118.1	N/A*
Di-Dak-Sol Mfg # 090602 Lot # 3032 Expiration=14 months	Non-opened Bottle Stability	117.5	116.9	116.2	110.2
	Opened Bottle Stability	115.6	113.4	107.5	N/A*

* At its expiration date, only a small amount of product was left in the opened bottle stability samples, due to evaporation. Therefore an assay on those bottles could not be performed at that time (only a color comparison could be done).