Line 13 of paragraph 2 of C.3 Apparatus 2 for Inhalation Powders—Marple Miller Impactor/C.3.1 Design—Apparatus 2: Change

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration of T seconds as determined during testing for Delivered-Dose Uniformity.

to:

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration such that the total volume sampled is at least 4 L.

AND

Line 3 of paragraph 2 of C.4 Apparatus 3 for Inhalation Powders—Andersen Impactor (with pre-separator)/C.4.1 Design—Apparatus 3: Change

Once the product is positioned, discharge the powder into the apparatus by activating the timer and opening the two-way solenoid valve for the required duration, T ± 5%, as determined during testing for Delivered-Dose Uniformity.

to:

Once the product is positioned, discharge the powder into the apparatus by activating the timer and opening the two-way solenoid valve for the required duration such that the total volume sampled is at least 4 L.

AND

Line 19 of paragraph 2 of C.5 Apparatus 4 for Inhalation Powders—Multistage Liquid Impinger/C.5.1 Design—Apparatus 4: Change

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens the valve for the same duration, T, as used during testing for Delivered-Dose Uniformity.

to:

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration such that the total volume sampled is at least 4 L.

AND

Line 9 of paragraph 4 of C.6 Apparatus 5 for Inhalation Powders—Next Generation Impactor (with pre-separator)/C.6.2 Procedure—Apparatus 5: Change

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens the valve for the same duration, T, as used during testing for Delivered-Dose Uniformity.

to:

Adjust the timer controlling the operation of the two-way solenoid valve so that it opens this valve for a duration such that the total volume sampled is at least 4 L.

Section

C. AERODYNAMIC SIZE DISTRIBUTION—INHALATION AEROSOLS, SPRAYS, AND POWDERS