

Supplementary data

Assay calculations

1. Assay on as such basis = [Assay on anhydrous basis x (100- water content)] /100

2. Qty. to be dispensed = [Standard quantity x 100]/ Assay on as such basis

Fluticasone propionate API assay in terms of anhydrous basis : 99.7 % w/w

Fluticasone propionate API water content : 0.15 % w/w

1. Assay on as such basis = [99.7 (100-0.15)] / 100 = 99.5505 %

2. Molecular conversion (to calculate standard quantity)

Fluticasone propionate =	Fluticasone
500.573 (mol. wt)	444.509 (mol. wt)
‘X’	100 mcg

‘X’ = [500.573*100] / 444.509 = 112.6126 mcg

3. Qty. to be dispensed =

[112.6126*100] / 99.5505 = 113.1211 mcg

[113.1211 mcg ~ 0.1131 mg]

4. Unit dose and batch size calculation

Compositions	* Unit dose calculation (mg)	Batch size calculation (gm)
FP	0.1131	0.0452 (45.2 mg)
Lactose	24.8869	9.9548
Total	25.0000	10.0000

*Dose per capsule (25 mg of each capsule contains 113.1211 mcg of fluticasone propionate means 100 mcg of fluticasone).

Batch no. of all materials

Materials	Batch no.	Company
Lactohale® 200	100NT11	DFE Pharma, Germany
Size 3 HPMC (Vcaps®) capsules	9030024	Capsugel, India
Revolizer® device	38J17059	Cipla, India
Fluticasone propionate	BWC150438	Cipla, India