

MANUFACTURING GUIDE FOR
Azelastine Hydrochloride and Fluticasone Propionate Aqueous Nasal Spray
DUONASE

LABEL CLAIM:

Each spray delivers :

Fluticasone propionate BP.....50 mcg

Azelastine Hydrochloride BP140 mcg

Composition :

Fluticasone propionate BP.....

Azelastine Hydrochloride BP

Benzalkonium chloride NF.....

(as preservative)

Phenyl ethyl alcohol USP.....

(as preservative)

BATCH SIZE : 100 KGS.

S.NO.	NAME OF INGREDIENTS	QUANTITY % w/v	QUANTITY/ BATCH (kgs)
1.	* Fluticasone propionate BP		
2.	** Azelastine Hydrochloride BP		
3.	Glycerin IP		
4.	Microcrystalline cellulose & carboxymethyl cellulose sodium USNF (Avicel RC-591)		
5.	Polysorbate 80 IP		
6.	Benzalkonium chloride NF		
7.	Phenyl ethyl alcohol USP		
8.	Purified water IP q.s.		
9.	140 mcl nasal pumps (Pfeiffer) code no. 44534		
10.	Nasal actuator code no. 47523		
11.	10 ml white opaque HDPE vial (Supplied by Kalmanns)		

Material to be taken on 100 % assay on as such basis.

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** Source: Daito

PLAINTIFFS'
TRIAL EXHIBIT
PTX0135

Material to be taken on 100 % assay on as such basis.