

3.2.P.3. Manufacture [Dymista (azelastine hydrochloride and fluticasone propionate) Nasal Spray, 137 mcg/50 mcg]

2. BATCH FORMULA [DYMISTA (AZELASTINE HYDROCHLORIDE AND FLUTICASONE PROPIONATE) NASAL SPRAY, 137 MCG/50 MCG]

The proposed drug product batch size at Cipla's Indore site is 250 kg. The manufacturing batch formula for the Indore site is provided below in Table 1.

Table 1: Dymista Nasal Spray Formula for 250 kg Batch Manufactured at Indore Site

Ingredient	Amount (kg/250 kg/ batch)	Amount (%w/w)	Function
Drug Substances:			
Azelastine Hydrochloride			
Fluticasone Propionate USP			
Excipients:			
Glycerin USP			
Microcrystalline Cellulose and Carboxymethylcellulose Sodium NF (Avicel CL-611)			
Polysorbate 80 NF			
Edetate Disodium USP			
Benzalkonium Chloride NF ^a			
Phenylethyl Alcohol USP			
Purified Water USP			
Nitrogen NF ^b			

