

CiplaR & D Centre
Vikhroli

CONFIDENTIAL		
MANUFACTURING GUIDE		
DOCUMENT NO.: MFG - AFNS	Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray DUONASE	DATE: 01.04.2010
VERSION NO.: 01/A	FOR LOCAL MARKET	PAGE 1 of 5

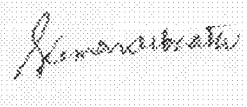
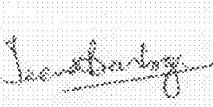
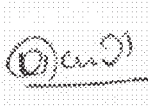
Date of Issue: 1 APR 2010*Supersedes the earlier document***COPIES WITH:**

1. Formulation Development Department - Vikhroli
2. Production Department - Cipla, Sikkim

THERAPEUTIC CATEGORY: ANTHISTAMINIC AND CORTICOSTEROID**NOTE:**

- 1) This guide describes manufacturing formula and process based on the batches manufactured at Formulation development.
- 2) The batch size given here is for 200 Kg (200 Lit) equivalent to 15384 units.
- 3) Based on the performance of this batch, a decision on further batches will be taken by a team of Q A/ Production / Formulation Development.

EXPIRY: This product bears an expiry period of 24 months from the date of manufacture.**CHANGES MADE :** Sucralose added in the manufacturing formula.

PREPARED BY	CHECKED BY	REVIEWED BY	AUTHORISED BY
			
Name: Devendra Jain	Name: Sasapan	Name: Pema May Barbo	Name: Kavindi Gardhi
Date: 01.04.2010	Date: 01/04/2010	Date: 01.04.2010	Date: 01/04/2010

(Azelastine Hydrochloride and Fluticasone Propionate Nasal Spray)

CIP2171
Argentum Pharmaceuticals v. Cipla Ltd.
IPR2017-00807

(FD - 16/P2/1)

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MANUFACTURING FORMULA

Label claim: Each spray delivers:
Azelastine Hydrochloride BP140 mcg
Fluticasone Propionate IP..... 50 mcg

Composition: Azelastine Hydrochloride BP ..
Fluticasone propionate IP.....
Benzalkonium chloride IP.....
Phenyl ethyl alcohol USP.....
(as preservatives)

Batch Size: 200 Kg (200 Lit)

Sr. No.	Ingredients	Qty % w/v	Qty / Batch (kg)
1*	Azelastine Hydrochloride BP		
2*	Fluticasone propionate IP		
3	Glycerin IP		
4	Microcrystalline Cellulose & Carboxymethyl Cellulose Sodium NF (Avicel RC 591)		
5	Polysorbate 80 IP		
6**	Benzalkonium chloride IP as Benzalonium Chloride solution NF 10% w/v		
7	Phenyl ethyl alcohol USP		
8	Sucralose NF		
9	Purified water IP		

Assay Calculation:

* To be dispensed on 100% on as such basis.

** Quantity to be calculated based on 100% assay basis and to be dispensed on weight basis considering the specific gravity.

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MANUFACTURING FORMULA

Source:

RMCA code	Ingredients	Grade	Manufacturer
NB508	Azelastine Hydrochloride	-	Cipla, Patalganga
M58AE	Fluticasone propionate		Cipla, Kurkumbh
N9E25	Benzaloniun Chloride solution	--	Cipla Ltd.
Q5DB8	Microcrystalline Cellulose & Carboxymethyl Cellulose Sodium	Avicel RC 591	FMC Biopolymer
Q703E	Polysobrate 80	--	Seppic
MDE5D/ NF33D	Phenyl ethyl alcohol	--	Penta Manufacturing / Fleurchem Inc- Newyork
--	Sucralose	--	Approved Source

Pack Configuration:

Packing material & Pack size	Grade	Manufacturer
Bottle : 15 ml transparent polypropylene (PP) bottle	-	Kaalmans
Pump : 140mcI crimp on nasal pump	5971 H	Aptar from China
Nasal actuator	5952F With wings	Aptar from China

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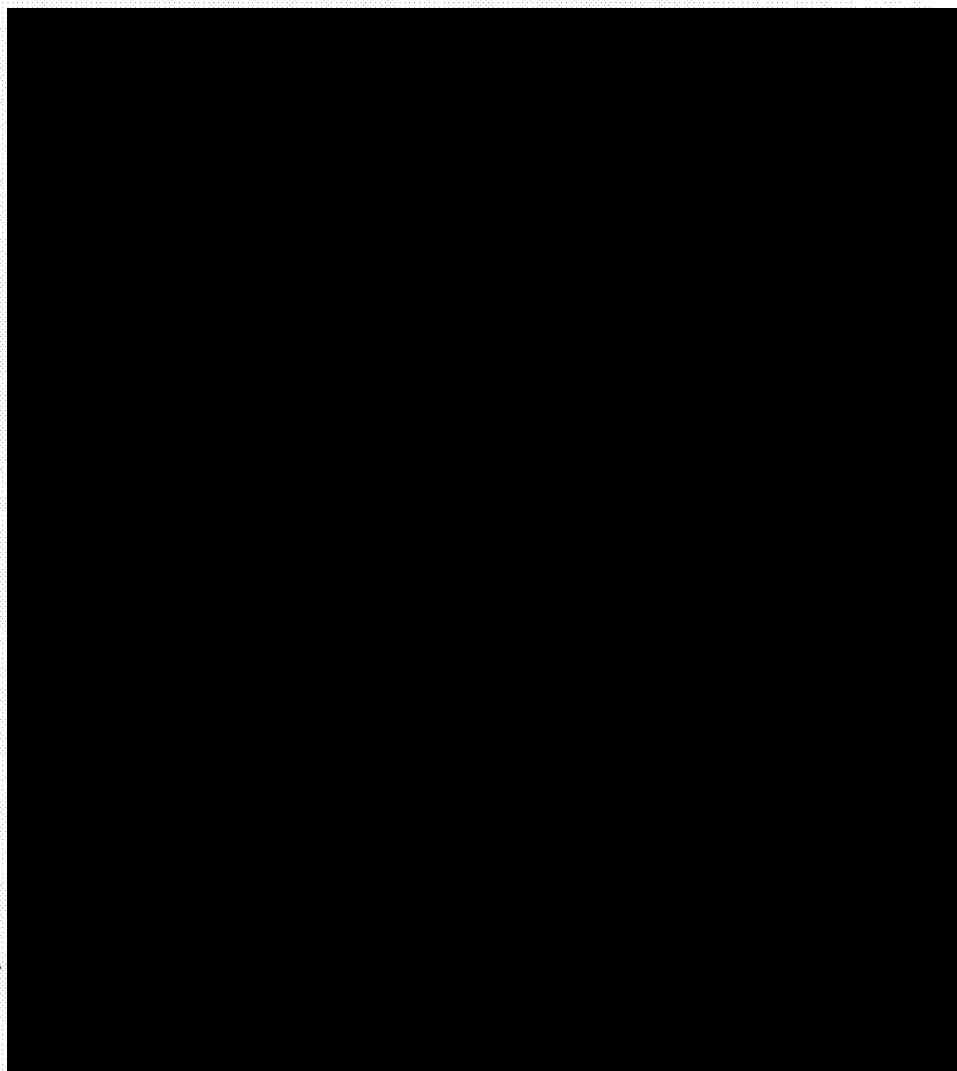
MANUFACTURING METHOD

SPECIAL INSTRUCTIONS

1. All manufacturing operations should be conducted as per existing SOP's.

Batch size: 200 Kg (200 Lit)

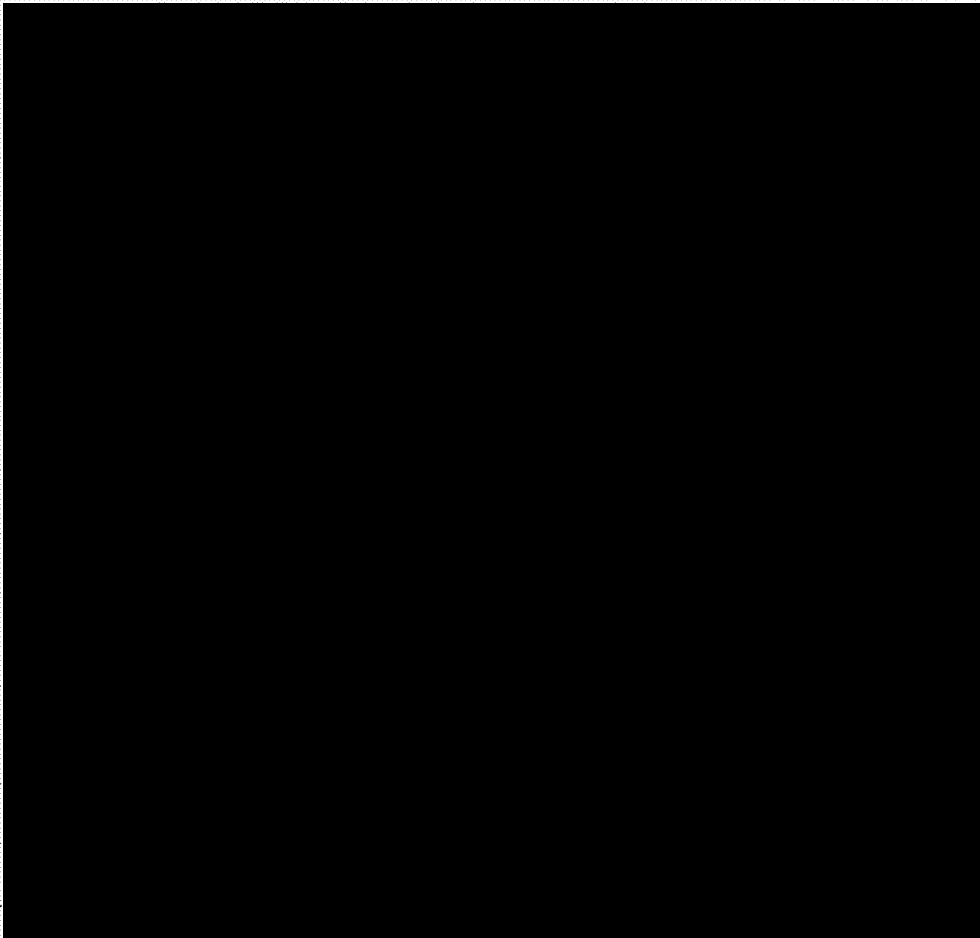
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MANUFACTURING METHOD

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Storage condition: Store in a cool place. Do not freeze or refrigerate.

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