	Investigation report: Dymista 6.4 g Nasal Spray Stability results	Code: CQA-UB-0039/01
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		Department
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**CIP2173**  
**Argentum Pharmaceuticals v. Cipla Ltd.**  
**IPR2017-00807**





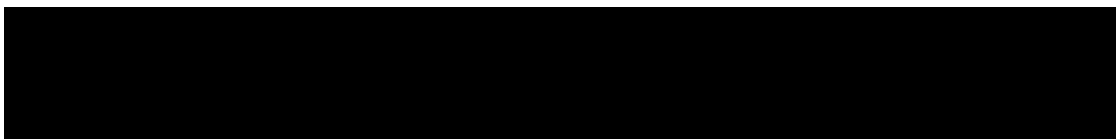
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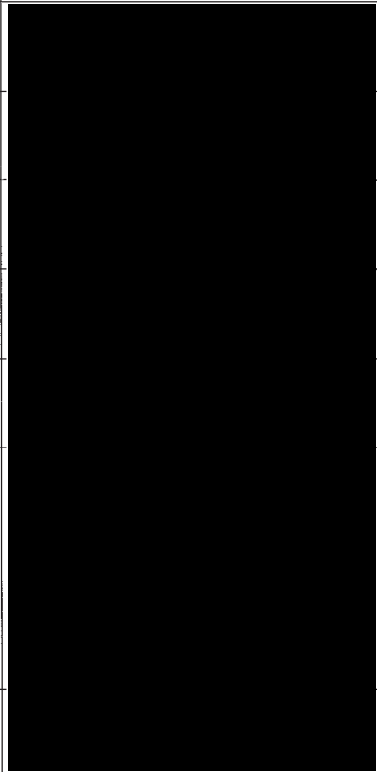
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## 1. Description of Incident

### Observations during stability studies:



### Specifications of parameters, where oos results have been observed:

Parameter	Specification	
Assay Azelastine HCl		release and shelf-life
Assay Fluticasonpropionate		release and shelf-life
Assay Benzalkonium chloride		shelf-life
Assay Phenylethylalcohol		shelf-life
Assay Disodium EDTA		release and shelf-life
Delivered Dose Uniformity		release and shelf-life
Weight loss		shelf-life



All imported batches are undergoing EU-testing and all batches met the release specification and were released to the market.

After the first oos report for the validation batches has been received, batch release for this product and manufacturing has been put on hold.

A shelf life of 36 months is registered for the 6.4g and the 23g form as well.



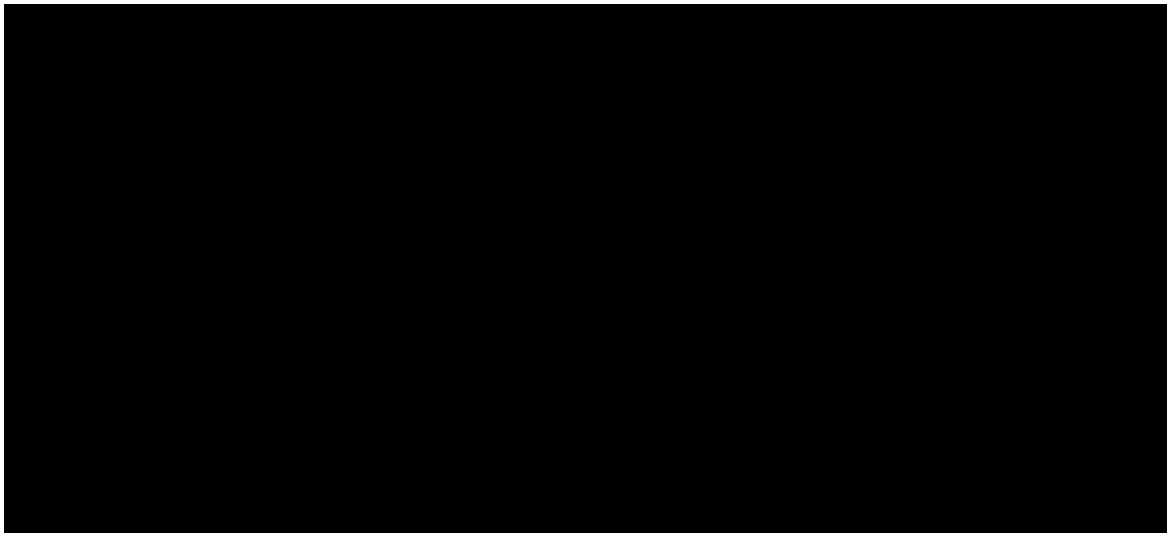
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**Product: Dymista Nasal Spray 6.4g**

Bulk batch and manufacturing date	Finished Product batch	Countries
FC2100 06/2012	FC2100	
FC2102 07/2012	FC2102	
FC2106 07/2012	FC2106	
FC3188 05/2013	FC3188 FC3192 FC3297 FC3458	
FC4001 01/2014	FC4001	

Table 1: Finished product of Dymista 6.4g preparations with running stability studies





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Batch	Condition/ Orientation	Weight loss Max. 2.0%	Assay									Delivered dose uniformity individual values 75-125%		Osmolality mosmol/ kg
			Azelastine (%) 95.0 -105.0%		Fluticasone (%) 95.0 -105.0%		BAC (%) 80.0 -105.0%		PEA (%) 70.0 -105.0%		EDTA (%) 90.0 -110.0%		Azelastine	
			0 m	24 m	0 m	24 m	0 m	24 m	0 m	24 m	0 m	24 m		
FC 2100	25°C/60%RH/ upright													
FC 2100	25°C/60%RH/ horizontal													
FC 2102	25°C/60%RH/ upright													
FC 2102	25°C/60%RH/ horizontal													
FC 2106	25°C/60%RH/ upright													
FC 2106	25°C/60%RH/ horizontal													
FC 2100	30°C/75%RH/ upright													
FC 2100	30°C/75%RH/ horizontal													
FC 2102	30°C/75%RH/ upright													
FC 2102	30°C/75%RH/ horizontal													
FC 2106	30°C/75%RH/ upright													
FC 2106	30°C/75%RH/ horizontal													

Table 2: Summary of results of batches FC2100, FC2102 and FC2106 after 24 months 25°C / 60% r.h. and 30°C / 75% r.h.

Spray is stored in upright and horizontal position.

Attachment 1: Complete stability tables of batches FC2100, FC2102 and FC2106 at 25°C, 60% r.h. up to 24 months

Batch	Condition	Weight loss Limit NMT 2.0%	Assay Azelastine Limit 95.0 – 105.0%	Assay Fluticasone Limit 95.0 – 105.0%	Assay Benzalkoni mchloride Limit 80.0 – 105.0%	Delivered Dose Uniformity Fluticasone Not more than 2 out of 20 determinations are outside 80 - 120% of label claim, none is outside 75 - 125% of label claim for Azelastine HCl and Fluticasonpropionate
FC3188	25°C/ 60%r.h. Upright 18 months					

Table 3: Summary of oos results of batch FC3188 (18 months storage)

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