MEDA	Investigation report: Dymista 6.4 g Nasal Spray Stability results	Code: CQA-UB-0039/01

		Department
Author:	Galler, 04.05.2015 Stefan Galler/ Date	CQA
Reviewed:	Hofmann 04052015 Dr. Dietmar Hofmann/ Date	CQA
Released :	Hofmann 04052015 Dr. Dietmar Hofmann / Date	CQA

Valid from: 04.05.2015 Galler
date/name

Supersedes: first edition

Original document archived: CQA archive

PLAINTIFFS' TRIAL EXHIBIT PTX0141 exhibitsticker.com

CIP2173
Argentum Pharmaceuticals v. Cipla Ltd.
IPR2017-00807

Table of Contents

1. Description of Incident

Observations during stability studies:

[redacted]

Specifications of parameters, where oos results have been observed:

Parameter	Specification	
Assay Azelastine HCl	[redacted]	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

[redacted]

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.

Product: Dymista Nasal Spray 6.4g

Bulk batch and manufacturing date	Finished Product batch	Countries
FC2100 06/2012	FC2100	[redacted]
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

[redacted]

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	Fluticasone	
		24 m	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	[redacted]													
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. [redacted]

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 Benzalkoniumchloride 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	[redacted]				

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

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.