

E-file: B2329, FCE-2014 09 10

DEPARTMENT OF ENVIRONMENTAL QUALITY

AIR QUALITY DIVISION

FCE Summary Report

FY 2014 FCE

Facility : Par Sterile Products LLC	SRN : B2329
Location : 870 PARKDALE RD	District : Southeast Michigan
	County : OAKLAND
City : ROCHESTER State: MI Zip Code : 48307	Compliance Status : Compliance
Source Class : MAJOR	Staff : Iranna Konanahalli
FCE Begin Date : 9/22/2012	FCE Completion Date : 9/10/2014
Comments : I did not find violation of RO permit conditions during the inspection. Par is NOT subject to NESHAP / MACT O and but subject to RICE MACT 4Z. Par is also subject to NSPS GG	

List of Partial Compliance Evaluations :

Activity Date	Activity Type	Compliance Status	Comments
09/09/2014	Scheduled Inspection	Compliance	FY 2014 level-2 scheduled annual inspection of Par Sterile Products, LLC. ("Par")
07/25/2014	Stack Test Observation	Compliance	February 20, 2013, CoGen stack test - MI-ROP-B2329-2012
04/10/2014	ROP Annual Cert	Compliance	Par Sterile Products (fka JHP Pharm). B2329: CY 2013 Annual, Jul-Dec 2013 Semi, Annual, MAERS-2013 Cert. received 03/05/2013 - Timely. Zero deviation. EO sterilizers and freeze dryers are removed.
04/10/2014	MAERS	Compliance	MAERS Certification  Par Sterile Products (fka JHP Pharm). B2329: CY 2013 Annual, Jul-Dec 2013 Semi, Annual, MAERS-2013 Cert. received 03/05/2013 - Timely. Zero deviation. EO sterilizers and freeze dryers are removed.
04/17/2013	ROP Other	Compliance	MAERS 3. JHP Pharm. B2329: CY 2012 Jul-Dec 2012 Semi Annual, Annual, MAERS-2012 Cert. received 03/13/2013 - Timely. Zero deviation for Semi-2 Jul-Dec 2012. EO sterilizers and freeze dryers are removed.

Activity Date	Activity Type	Compliance Status	Comments
04/17/2013	ROP SEMI 2 CERT	Compliance	JHP Pharm. B2329: CY 2012 Jul-Dec 2012 Semi Annual, Annual, MAERS-2012 Cert. received 03/13/2013 – Timely. Zero deviation for Semi-2 Jul-Dec 2012. EO sterilizers and freeze dryers are removed.
04/17/2013	ROP Annual Cert	Compliance	3. JHP Pharm. B2329: CY 2012 Jul-Dec 2012 Semi Annual, Annual, MAERS-2012 Cert. received 03/13/2013 – Timely. Zero deviation for Semi-2 Jul-Dec 2012. EO sterilizers and freeze dryers are removed.
10/04/2012	ROP Semi 1 Cert	Compliance	JHP Pharm. B2329: CY 2012 Jan-Jun 2012 Semi Annual Cert. received 09/13/2012 – Timely. Zero deviation for Semi-1 Jan-Jun 2012. EO sterilizers and freeze dryers are removed.

Name: Shelley Vanaball Date: 09/10/2014 Supervisor:

CTE