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	DEPARTMENT OF HEA	LTH AND HUMAN S JG ADMINISTRATION	SERVICES	-	
DISTRICT ADDRESS AND PHONE		DO ADMINISTRATION	DATE(S) OF INSPECTION		
1	ce, Suite 5900		03/13/2012 - 03/29/	2012*	
Detroit, MI		22	FEI NUMBER		
) Fax:(313) 393-8139 rmation: www.fda.gov/oc/indu	201 + 1051	1818977	8	
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED	igerà			
	d Ferry Jr., General Manage:				
FIRM NAME	W 72 SEC. 38	STREET ADDRESS	8-804		
JHP Pharmaceut	cicals, LLC	870 Parkdal			
Rochester, MI		Manufacture			
observations, and do no observation, or have in action with the FDA n	This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.				
DURING AN INSPECT	TION OF YOUR FIRM WE OBSERVED:	3			
	Y 20				
OBSERVATION 1	Į.	e na g	g * *		
Written records of i	nvestigations into unexplained discrepan	cies do not always	include the conclusions and for	ollow-up.	
Specifically,	8		* *		
i- Investigation into Deviation PR 2042, initiated in response to incorrect storage conditions (°F) printed on the 25 vial carton label for Pitocin 10 mL, did not address the sterility assurance of the container closure of distributed Pitocin vials that may have been stored incorrectly as a result of this deviation. As filed with the Agency in the Annual Report dated 11/01/10-10/31/11, Pitocin storage conditions should be labeled, "Store between 20° to 25°C (68° to 77°F)". Pitocin 10 mL lot 225867 (artons) and part of Pitocin 10 mL lot 231423 (artons) were packaged, released and distributed in a 25 count carton labeled, "Store between 20° to 25°C (28° to 77°F)". As of 3/26/2012, data had not been provided to support that the integrity of the Pitocin vial container closure system would not be compromised (with respect to sterility) if stored at the lower extreme of the temperature range as listed on the carton label. ii- Open deviation investigation PR 2204, initiated 1/09/2012 had not documented an assessment of marketed lots of Coly-Mycin M, Injectable that may have been impacted by a failed stopper washer cycle requalification, at the time of this observation (3/22/2012). Specifically, the 2011 annual requalification of the stopper washer cycle for endotoxin control of incoming stoppers failed to meet the acceptance criteria of a reduction of endotoxin in 3 of 12 samples submitted for testing. The previous cycle requalification occurred 3/2010. Finished product utilizing stoppers processed under cycle from the time of the last successful requalification to present included 6 lots of Coly M					
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PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES				
DISTRICT ADDRESS AND PHONE		IG ADMINISTRATION	DATE(S) OF INSPECTION	
8	ce, Suite 5900	8	03/13/2012 - 03/29	/2012*
	48207 0 Fax:(313) 393-8139		1818977	
Industry Info	rmation: www.fda.gov/oc/indu	istry	10103//	
NAME AND TITLE OF INDIVIDUAL	TO WHOM REPORT ISSUED			
FIRM NAME	d Ferry Jr., General Manager	STREET ADDRESS		
JHP Pharmaceu		870 Parkda		manus rusines allegaments a russiani
Rochester, MI	48307-1740	Manufacture	er	
Parenteral, ((b)(4)	7-	237535F, ^{(b) (4}		A S
and 1539: failure applicable produ	iii- Corrective Action to the July and August 2011 NVP Environmental Monitoring Deviations (PR 1479 and 1539: failure to initiate NVP monitoring prior to aseptic filling commencement) did not extend to all applicable production departments in that in November 2011 (11/16/11) deviation PR 1995 was initiated for the failure to initiate NVP monitoring prior to aseptic bulk operations for Media Fill lot [5](4)			
OBSERVATION :	2			
The responsibilities	and procedures applicable to the quality	control unit are no	ot in writing and fully followe	d.
Specifically,	Specifically,			
i-As of the time of this Observation, the duties and responsibilities of the Quality Unit were not clearly defined in written procedures. For example and pertaining to a "label error" with respect to Pitocin 10 mL cartoned product, lots 231423 and 225867 as reported to the Agency under Field Alert Report 12/07/2011:				
a- Written procedure CQP-GEN-00020, Critical Action Committee, indicates that, "[6](4)				
Critical Action Committee met on 12/06/2011 to address the aforementioned label error and a decision was made to submit a Field Alert Report.				
b- Written proce	b- Written procedure SOP-QLA-MQA-03309-RO, Field Alert and Recall Procedure, indicates that			
(b) (4) (b) (4)	(b) (4)			
aforementioned label error pertaining to Pitocin 10 mL cartons.				
				- A
ii- Written procedure SOP-QLA-MQA-03437-RO, Deviation/Investigation Management, was not				
followed in that it states, "(b)(4)				
following deviations were not initiated within one business day of event recognition, and no justification				
		business day o	of event recognition, and r	io justification
was documented:				
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INS	PECTIONAL OBSE	RVATIONS	PAGE 2 OF 6 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRÉSS AND PHON	ENUMBER	O ADMINISTRATION	DATE(S) OF INSPECTION	
	ace, Suite 5900		03/13/2012 - 03/29/	2012*
	troít, MI 48207 13) 393-8100 Fax:(313) 393-8139		1818977	
Industry Info	Industry Information: www.fda.gov/oc/industry			
B	ltownowreportissues ld Ferry Jr., General Manager	•		
FIRM NAME	ta refly bit, deficial manages	STREET ADDRESS		
JHP Pharmaceu	ceuticals, LLC 870 Parkdale Rd COUNTRY TYPE ESTABLISHMENT INSPECTED			
Rochester, MI		Manufacture		
		8	©1	
	(b) (4)		753.743	
a- Deviation 220				and a contract of the contract
Requalification;	date of recognition 12/22/11, date	of deviation ini	itiation $01/09/12$. Coly M	Aycin M Lot
	sted in this Deviation Investigation.		52 80 80 8000 5350	
	48 - Water leak discovered from ce			
4	of deviation initiation 03/01/12. Th	rombin lot 2338	859 was manufactured in	this room on
2/27/2012.	66 - Water leak in Manufacturing S	nito (b)	data of recomition 02/27	1/12 data of
deviation initiat	ion 03/02/12. Dantrium lot (b)(4)		ctured in Suite both on 2/27/	
doridion miliat	ion obvozi iz. Dantitum lot	was manuac	ruiod ni Suite a on 2/2//	den V & draw o
iii- There are no	written specifications established f	or the receipt o	f goggles used as part of	the gown
donned by perso	onnel entering the aseptic processin	g core. Use of	these goggles was observ	ed worn by
	sonnel during the manufacture and	filling of Ketal	ar 100 mg/mL, 5mL, lot	on on
3/21/2012.	(b) (4)			50 Tak 1000
Though observed goggles, lot # were received with a Sterility Report and a Certificate of				
Processing, SOP-QLA-SQC-03389-RO, Incoming Quality Inspection for Components, section WI-QLA-SQC-03389.4-RO, MRO Components and Supplies does not list or require written specifications				
				becifications
to compare the	supplier provided reports and certif	icates against to	or this gown component.	
FACILITIES & EQUIPMENT SYSTEM				
OBSERVATION	3			
Written procedures	s are not established and followed for the o	leaning and maint	enance of equipment, including	g utensils, used
	, processing, packing or holding of a drug		1 1	,
c 'c 11				
Specifically,				
i- Filter integrity testing of the HEPA filters in the of the Line Depyrogenation Tunnel is not				
performed as specified under SOP-ENG-MNT-03137-RO, V.12.0, Test, Repair & Replacement of				
Environmental Air & Laminar Filters. Specifically, no Filter Integrity Testing is performed for these				
specific (b)(4) HEPA filters. Records indicated the subject HEPA filter within a hank of HEPA				
filters in this had been installed in July of 2006. The scientific rationale for not performing the				
Filter Integrity Testing was not supported when a single filter from this same Line Depyrogenation				
	EMPLOYEE(S) SIGNATURE			DATE ISSUED
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OF THIS PAGE	Sarah M. Napier, Investigat	or 3/	U)	03/29/2012
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INST	ECTIONAL OBSER	VATIONS	PAGE 3 OF 6 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION		/2022*		
	River Place, Suite 5900 Dit, MI 48207		03/13/2012 - 03/29/ FEINUMBER	74012*
	(313) 393-8100 Fax: (313) 393-8139		1818977	
NAME AND TITLE OF INDIVIDUAL T	mation: www.fda.gov/oc/indu	stry		
TO: J. Donald	d Ferry Jr., General Manager	STREET ADDRESS		
JHP Pharmaceut		870 Parkda		
CITY, STATE, ZIP CODE, COUNTRY Rochester, MI		TYPE ESTABLISHMENT IN Manufacture		
non-routine main could not be spectesting. [b](4) ots are listed	non-routine maintenance to the line on 1/03/2012. The point in time at which the damage occurred could not be specifically pinpointed with data from current filter monitoring including NVP			
Brevital 500 mg, injectable, lot 190031 exp. 11/14 Coly Mycin M, injectable, lot 224668 exp. 05/14 Ketalar 100 mg/mL, 5mL, injectable, lot 220961 exp. 07/14 Pitocin 10 mL, injectable, lot 231423 exp. 02/13 Tigan 100mg/mL, 20 mL, injectable, lot 148665 exp. 12/13				
ii-Written procedure SOP-ENG-MNT-03097-RO, Maintenance of Critical Equipment, section 6.3.8 requires that "[6](4) [b](4) [c)(4) [c)				
a- Suite HEPA- during Filter Integrity Testing, documented under Deviation 1580. Exception Report approved by QA on 8/16/2011 b- Suite HEPA- PM due 7/08/2011 completed 8/14/2011 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 1581. Exception Report approved by QA on 8/16/2011 c- Suite HEPA PM due 7/08/2011 completed 8/14/2011 resulting in low air volumes during Filter Integrity Testing, documented under Deviation 1583. Exception Report approved by QA on 8/16/2011 d- Suite HEPA PM due 7/08/2011 completed 8/14/2011 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 1583. Exception Report approved by QA on 8/16/2011 d- Suite HEPA PM due 7/08/2011 completed 8/14/2011 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 1584. Exception Report approved by QA on 8/16/2011				
	EMPLOYEE(S) SIGNATURE Rebecca E. Dombrowski, Inve	and and an	20	DATE ISSUED
SEE REVERSE OF THIS PAGE	Sarah M. Napier, Investigat			03/29/2012

200 River Place, Suits 5300 Detroit, MI 48207 1313 393-8135 Industry Information: www.fda.gov/oc/industry Industry Information: www.fda.gov/oc/industry To: J. Donald Ferry JT., General Manager To: J. Donald Ferry JT., General Manager To: Jr. Donald Serry JT., General Manager To:	DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
Industry Information: www.fda.gov/co/industry Industry Information: www.fda.gov/co/industry TO: J. Donald Perry Jr., General Manager To: J. Donald Retry		NUMBER			(00004
Internation when the same to make the same to the same	THE STATE OF THE S		294		/2012*
The Pharmaceuticals, LLC The Pharmaceuticals and the street of the street shows	(313) 393-8100 Fax: (313) 393-8139		1818977		
JEP Pharmaceuticals, LLC Gradult aroos cooling The cochester, MI 48307-1740 The completed testing date (8/14/2011) including: Teleased by QA on 8/26/2011 and shipped on 8/26/2011. Treleased by QA on 8/26/2011 and shipped on 9/16/2011. Treleased by QA on 9/13/2011 and shipped on 9/16/2011. Additionally, the following 2 more recent Filter Integrity Testing deviation investigations pertaining to leaks detected in the HEPA filters in the Grade space of Suite were also found overdue and without supporting QA Exception Reports filed: e- Suite HEPA. PM due 1/15/2012 performed 2/10/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 F- Suite HEPA. PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. This parts washer had been used on the day observed (3/13/2012) in washing of containers used for the production of the production	Industry info	rmation: www.fda.gov/oc/indu TOWHOM REPORT ISSUED	ıstry		
JHP Pharmaceuticals, LLC GROUND AND ACT ONE STREET HOST		d Ferry Jr., General Manage			
lots were manufactured in Suite during the time frame between the due date (7/08/2011) and the completed testing date (8/14/2011) including: released by QA on 8/04/2011 and shipped on 8/26/2011. Dantrium lot released by QA on 8/26/2011 and shipped on 9/16/2011. Additionally, the following 2 more recent Filter Integrity Testing deviation investigations pertaining to leaks detected in the HEPA filters in the Grade space of Suite were also found overdue and without supporting QA Exception Reports filed: e- Suite HEPA — PM due 1/15/2012 performed 2/10/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 Found HEPA — PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. iii-According to SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, 100 — (1971) yet connected to the parts washer located in the Suite Production Core of Building 100 — (1971) yet connected to the parts washer located in the Suite Production Core of Building 100 — (1971) yet connected to the parts washer located in the Suite Production Core of Building 100 — (1971) and 1970 — (1971) in washing of 1970 — (1971) — (1971) in washing of 1970 — (1971) — (X	ticals, LLC	870 Parkdal		
lots were manufactured in Suite during the time frame between the due date (7/08/2011) and the completed testing date (8/14/2011) including: released by QA on 8/04/2011 and shipped on 8/16/2011. released by QA on 9/13/2011 and shipped on 9/16/2011. released by QA on 9/13/2011 and shipped on 9/16/2011. Additionally, the following 2 more recent Filter Integrity Testing deviation investigations pertaining to leaks detected in the HEPA filters in the Grade space of Suite were also found overdue and without supporting QA Exception Reports filed: e-Suite HEPA — PM due 1/15/2012 performed 2/10/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 F-Suite HEPA — PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. iii-According to SOP-MAN-PRP-03270-RO. Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, 1019	1222				
Pantrium lot released by QA on 8/26/2011 and shipped on 9/16/2011. Additionally, the following 2 more recent Filter Integrity Testing deviation investigations pertaining to leaks detected in the HEPA filters in the Grade space of Suite were also found overdue and without supporting QA Exception Reports filed: e-Suite HEPA — PM due 1/15/2012 performed 2/10/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 f-Suite HEPA — PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. iii-According to SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, 100 — 10	lots and the complete	lots were manufactured in Suite during the time frame between the due date (7/08/2011) and the completed testing date (8/14/2011) including:			
leaks detected in the HEPA filters in the Grade of space of Suite were also found overdue and without supporting QA Exception Reports filed: e-Suite HEPA - PM due 1/15/2012 performed 2/10/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 f-Suite HEPA PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. iii-According to SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, 1010 was observed labeled as beyond expiration (exp. 2/19/12) yet connected to the parts washer located in the Suite Production Core of Building 100. In parts washer had been used on the day observed (3/13/2012) in washing of 1010 and 1010 in 1010 i	Dantrium lot (b) (4)	released by QA on 8/26/201	11 and shipped	on 9/16/2011.	
during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 f- Suite HEPA HEPA PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA on 3/19/2012 Product impacted under the above late deviations include Brevital lot #182060F, released and shipped for distribution on 3/9/2012. iii-According to SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, "SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, "Integrated detergent lot was observed labeled as beyond expiration (exp. 2/19/12) yet connected to the parts washer located in the Suite Production Core of Building (SOP). This parts washer had been used on the day observed (3/13/2012) in washing of containers used for (SOP). In and (SOP) and (SOP) and (SOP).	leaks detected in supporting QA I	leaks detected in the HEPA filters in the Grade a space of Suite were also found overdue and without			
iii-According to SOP-MAN-PRP-03270-RO, Cleaning of Bulk Manufacturing and Filling Equipment, Building 100, "Interest" detergent lot (a)(4) was observed labeled as beyond expiration (exp. 2/19/12) yet connected to the parts washer located in the Suite (a) Production Core of Building (b)(4) and (a)(5)(4) and (b)(4) lot (b)(4) and (b)(4) lot (b)(4) and (b)(4) lot (b)(4) and (b)(4) lot	during Filter Integrity Testing, documented under Deviation 2501. Exception Report approved by QA on 3/19/2012 f- Suite HEPA PM due 1/15/2012 performed 2/11/2012 resulting in detection of a leak during Filter Integrity Testing, documented under Deviation 2500. Exception Report approved by QA				
Building 100, "black detergent lot (b) (4) was observed labeled as beyond expiration (exp. 2/19/12) yet connected to the parts washer located in the Suite (4) Production Core of Building (b) (4) This parts washer had been used on the day observed (3/13/2012) in washing of containers used for (b) (4) and (b) (4) lot (b) (4) lot (c) (6) (6) (6) (6) (6) (6) (6) (6) (6) (6					
SEE REVERSE Rebecca E. Dombrowski, Investigator PC Sarah M. Napier, Investigator 03/29/2012	Building 100, " 3/13/2012, a dru (exp. 2/19/12) y Building (5)(4)	am of "Interest" detergent lot (b)(4) yet connected to the parts washer had been used or	was obsvasher located in the day observ	served labeled as beyond the Suite (a) Production	though on expiration Core of
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION				
DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION			
300 River Place, Suite 5900	03/13/2012 - 03/29/2012*			
Detroit, MI 48207	FEI NUMBER			
(313) 393-8100 Fax:(313) 393-8139	1818977			
Industry Information: www.fda.gov/oc/indu	astry			
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED				
TO: J. Donald Ferry Jr., General Manage:	r			
FIRM NAME	STREET ADDRESS			
JHP Pharmaceuticals, LLC	870 Parkdale Rd			
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED			
Rochester, MI 48307-1740	Manufacturer			

* DATES OF INSPECTION:

03/13/2012(Tue), 03/14/2012(Wed), 03/15/2012(Thu), 03/16/2012(Fri), 03/19/2012(Mon), 03/20/2012(Tue), 03/21/2012(Wed), 03/22/2012(Thu), 03/27/2012(Tue), 03/29/2012(Thu)

EMPLOYEE(S) SIGNATURE

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