DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	11/29/2010 - 01/07/2011* FEI NUMBER 2128643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric C. Haertle, Chief Operating Officer

FIRM NAME	STREET ADDRESS
H & P Industries, Inc.	700 W North Shore Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029-8358	OTC Drug and Device Manufacturer

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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Medical Devices - Sterile Lube Jelly

OBSERVATION 1

Procedures for corrective and preventive action have not been established.

Specifically, Corrective and Preventive Actions were not initiated and/or adequately conducted to further investigate the root cause of the following non-conformances, per the Laboratory Out of Specification (OOS) or CAPA procedure:

- Product irradiated prior to 10/1/10 that was under sterilized per the validation was accepted and released for distribution. No CAPA was initiated and no health hazard analysis was conducted for the under sterilized product on the market.

- Sterile Lubricating Jelly is tested for (b) (4) post-sterilization. The specification is no growth for both tests. Tests results included:

Micro ID #	Lot	Date Read	Results
194C	0B152	3/12/10	(b) (4)
459H (Stability)	9A114	8/20/10	
179J	0H234	9/10/10	

In each case, (b) (4) additional samples were checked and found negative for growth. The passing results were reported, product was released, and the failed results were not addressed. No failure investigation was initiated and no root cause was identified.

Additionally, the post-sterilization testing of Sterile Lubricating Jelly for (b) (4)

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(b) (4) in the product. On-going CAPA H-10-001 initiated 01/22/10, states in the follow-up, "(b) (4)
(b) (4)
(b) (4) "

- A stability sample of lubricating jelly lot 9H169 failed its viscosity specification at the (b) (4) month test point on 8/6/10. An OOS Investigation OOS-10-061 was opened on 8/11/10, but never completed. The (b) (4) month time point was tested and again failed the viscosity specification on 11/15/10. The OOS investigation has not been completed and no root cause has been determined.

- Follow-up to Complaint ID 13971 involved the testing of retains for lot 8D153, product 07-8472 of lubricating jelly. The retain sample failed the viscosity specification on 10/14/10. The complaint was closed and no OOS investigation into the failing results was implemented per SOP-QA-004.

- CAPA H-10-001 opened Jan 22, 2010, has yet to address (b) (4) in pre-sterile lubricating jelly products. Procedure 01-013, revision B - Corrective and Preventive Action Procedure (CAPA) which states in section 5.6 "***(b) (4)
(b) (4)
(b) (4) ***" has not be followed.

OBSERVATION 2

A process whose results cannot be fully verified by subsequent inspection and test has not been validated according to established procedures.

Sterile lubricating jelly is accepted and given a final QC/QA release upon return from the sterilizer. The sterilization process had never been validated prior to 6/14/10 and product was accepted with a (b) (4) for all packaging configurations. A validation for sterile lubricating jelly VAL-PQRPT-002 was completed and approved on 6/14/10. The minimum dosage required for the packaging configurations established during validation was (b) (4) for packets, (b) (4) for bottles, and (b) (4) for tubes. These new specifications were not updated with the contract sterilizer until 10/1/10.

Lube-Jelly Sterilization Process Validation Performance Qualification VAL-PQRPT-002 states, "(b) (4)
(b) (4) " The validation was not completed adequately because:

- There is no justification for (b) (4)

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(b) (4) determined during the validation.

- The bottle product family samples were not representative of routine manufacturing in that deviation H0310.014 allowed (b) (4) finished lots to be manufactured from (b) (4) production batch for the purpose of having (b) (4) finished lots to use in a validation.
- The development of product families was not justified.
- The collection of bioburden samples was not documented and did not ensure samples are representative of the manufacturing process.
- The bioburden recovered from product samples was not characterized.
- There is no justification for the maximum (b) (4)
- The final validation was signed for approval on 6/14/10, but it was not reviewed by the quality laboratory manager until 6/18/10.

OBSERVATION 3

Procedures to prevent contamination of equipment or product by substances that may have an adverse effect on product quality have not been adequately established.

Specifically, potential sources of bioburden in the production area for lubricating jelly were observed on 12/1/10:

- Lubricating jelly mixing and holding tanks were left uncovered during mixing and filling operations.
- Tank (b) (4) had holes that were a potential route of contamination. The top of this tank appeared to have had a stagnant puddle near these holes that had since dried up.
- Filling line (b) (4) and (b) (4) are used to fill the lubricating jelly packets. Rollers that contact the inner surface of the packaging were observed to have built-up dirt and dust. Filling nozzles were observed to be leaking with built-up product on them.
- Filling line (b) (4) is used to fill the lubricating jelly tubes. The indicator on the sterile air filter shows the filter needed to be changed.

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OBSERVATION 4

Procedures for monitoring and control of process parameters for a validated process have not been adequately established.

Specifically, bioburden monitoring and quarterly dose audits (QDA) of the lubricating jelly product families are to be completed on a quarterly basis per SOP-LAB-005-00.

- The third quarter bioburden monitoring for the packets had an average bioburden of (b) (4) cfu, exceeding the action limit of (b) (4) cfu, and the tubes had an average bioburden of (b) (4) cfu, exceeding the action limit of (b) (4) cfu. A Quality Assurance Investigation was not initiated in either instance as described in SOP-LAB-005-00.

- No bioburden monitoring or QDA has been done since the validation was approved 6/14/10 for the bottle product family. There were no bottles being manufactured when samples for the quarter three bioburden monitoring and dose audit were submitted in August of 2010. The firm manufactured bottles, lot 0K20, that was opened 10/13/10, but did not complete bioburden monitoring or a QDA for this lot.

OBSERVATION 5

Procedures for finished device acceptance have not been established.

Specifically, lot 0J257 of Sterile Lubricating Jelly was accepted, distributed, and the lot was closed on 11/11/10. However, there was no Post-sterilization Finished Goods Analysis conducted per Master Batch Formula and Mixing Instruction for specification 04-094.

OBSERVATION 6

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically,

- Specifications for the tubes used in manufacturing lubricating jelly state the tube must have a peelable foil seal. Incoming inspection of tubes is documented on FM-10-8917TB, but it does not include an inspection of the foil seals. No FM-10-8917TB could be provided for the tubes used in the packaging of lot 0F143, product 10-8917. Approved tube supplier (b) (4) has never been audited per the procedure "Supplier Qualification and Management System" #SOP-QA-010-01 effective 10/28/10.

  Additionally, 6 complaints were received of tubes manufactured July 2010-August 2010 concerning faulty seals

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with missing or broken pull tabs. During the complaint investigation, (b) (4) retain tubes from lot 0F143, product 10-8917, were examined and one of the pull tabs had fallen off. The complaints were closed as a "limited defect".

- Incoming lubricating jelly tubes received from (b) (4) on 6/9/10, part number 10-8917TB had the wrong revision of artwork. The tubes listed their old address but were still accepted and used under deviation H0610.004 "(b) (4) .". (b) (4) has not received an onsite audit per the procedure "Supplier Qualification and Management System" #SOP-QA-010-01 effective 10/28/10.

OTC Drug Products

Quality System

OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed.

a) The Quality Assurance Unit authorities most responsible for overseeing daily operations at this facility did not ensure that the responsibilities of the Quality Control Unit and Quality Assurance Laboratory were enforced for rejection of product that contained (b) (4) contamination. Quarterly dose samples of lot 0L445 of sterile alcohol prep pads were found to be contaminated with (b) (4) organisms and were released for shipment after confirmation of the results. Responsible officials did not follow their own procedure "Responsibilities of the Quality Department" #01-050 effective 9/13/05 in that the product was not rejected.

b) The Quality Assurance Unit did not follow their procedure "Quality Assurance Investigations" #SOP-QA-004-00 effective 9/15/10 in that INV-10-003 initiated 12/01/10 regarding the sterile alcohol prep pads with (b) (4) contamination was not extended to other similar products, similiar investigations (CAPA-10-007), raw materials, customer complaints, and equipment used to manufacture alcohol prep pads.

c) As of December 1, 2010 the Quality Control Unit failed to initiate (b) (4) investigation of out of specification results as per SOP-LAB-001-00, "Out of Specification Investigations", effective 10/01/10 for (b) (4) Children's Multi Symptom Very Berry, lot OK227B. Confirmatory OOS assay results for (b) (4) were obtained for the bulk release on 10/18/10. A result of (b) (4) was obtained (specification (b) (4) %). (b) (4) investigation should have been initiated by

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November 18, 2010.

d) The Quality Control Unit failed to perform their responsibilities as required in procedure WI-LAB-0011, "Testing for Microbiological Contamination in Samples", dated 8/11/10 in that water ports which tested above the microbial action limit ((b) (4) cfu/mL) were not additionally sampled after re-cleaning and re-sanitizing to confirm the effectiveness of the re-cleaning.
1) On 4/2/10, microbial OOS results were obtained in Water Dispensing Values (DIV) #(b) (4) Results ranging from (b) (4) were obtained. Products including Blue Mouth Rinse (b) (4) Towel were manufactured in Tanks (b) (4) which used this port between 4/1-5/10.
2) On 5/6/10, microbial OOS results were obtained for DIV # (b) (4). A result of (b) (4) cfu was obtained. Products including Yellow Mouthrinse were manufactured in Tank (b) (4) which used this port on 5/4/10.
3) On 9/3/10, microbial OOS results were obtained in DIV # (b) (4). A result of (b) (4) cfu was obtained. Products including Glycerin Suppository were manufactured in Tank (b) (4) which used this port on 9/3/10.

e) No destruction documents were provided for the rejected products listed below. Procedure WI-ADM-0006, "Form Instruction for Notice of Destruction", dated 3/23/09 states that Quality Management is responsible for logging and filing all Notices of Destruction:
1) Rejected Lot 500327 Sinus Relief Nasal Spray. The Bill of Lading documents the shipment of this product from the NJ location to Wisconsin on November 6, 2009 and was subsequently rejected by NJ. However no destruction documentation was provided for this lot.
2) Cases (b) (4) of (b) (4) Alcohol Prep w/Benzocaine, lot 0G478, were designated for destruction on August 13, 2010. Destruction of this product was never documented and the product is no longer on hand.
3) OOS-10-053 investigated 0G154B. The OOS investigation stated the batch was scrapped, but there is no documentation of the destruction and the analyst completing the investigation stated she did not have any supporting information when she wrote that the batch was scrapped. The batch is no longer on hand.

OBSERVATION 8

Drug products failing to meet established specifications are not rejected.

a) Samples from lot 0L445 of sterile alcohol prep pads were submitted for a quarterly dose audit. Triad was informed by their contract testing laboratory on 11/30/10 the sterility test failed because (b) (4) of the (b) (4) samples had growth. A QA investigation, INV-10-003, was initiated on 12/1/10, but no lots of sterile alcohol pads were placed on hold. (b) (4) cases of lot 0L445 were shipped to customers on 12/2/10. Identification of the sterility isolates were confirmed as (b) (4) on 12/3/10. (b) (4) additional cases of lot 0L445 were shipped from 12/10/10-12/14/10.

b) There was no Sterile Alcohol Swabstick sterilization validation prior to 6/14/10 and product was accepted with a minimum (b) (4). A validation ,VAL-0085-PVRPT-002, was completed and approved on 6/14/10 establishing the minimum (b) (4) These new specifications have not been updated with the contract sterilizer. Product that was under sterilized per the validation was accepted and released for distribution.

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c) There was no sterile alcohol prep pad validation prior to 3/12/10. Specifications were not updated with the contract sterilizer from (b) (4) until 6/1/10. No investigation or health hazard analysis was conducted for the product on the market that was made without a validation and with a sterilization dose that was determined to be too low during the validation.

OBSERVATION 9

The quality control unit lacks the responsibility and authority to approve all drug products.

Finished product is being released into inventory prior to QA release. SOP-QA-005-01 - "Record Review and Product Disposition", effective 10/28/10 states, ***(b) (4) (b) (4) *** The procedure states QA should complete form FRM-QA-007 prior to the release of a product. Examples include but are not limited to the following cases:

Product Name	Lot #	QA Release	Product Released to Inventory
Children's Night Time Cough and Cold, Grape	OK199	10/22/10	10/19/10
(b) (4) Sore Throat Spray, Menthol	OL130	12/03/10	11/12/10
(b) (4) Night Time Cold, Cherry, Liquid, 6 oz.	OL167	No QA release	11/19/10
(b) (4) Cold Multi-Symptom Night Time, Warming	OK81	12/27/10	11/04/10

OBSERVATION 10

Control procedures are not established which monitor the output and validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

a) Products to be transferred from the New Jersey facility include oral liquids, powders, nasal sprays, and tablets. There was no strategic plan documenting the transfer of the manufacture of these products to this location. Originally the company anticipated the transfer of all production of these new products to be complete by (b) (4) The (b) (4) validation studies for the oral products currently transferred from the New Jersey facility do not demonstrate a high degree of scientific evidence that the batching / compounding processes are capable of consistently delivering quality products. The following observations were made during review of the validation studies:

1) The oral products are made in bulk mixing tanks (b) (4) In addition, a number of portable tanks can be used for premixes which will then be transferred to one of the bulk mixing tanks. Each of the bulk mixing tanks and each of the portable tanks are different in their dimensions, capacities, type of mixer and mixing speeds. No documentation is available at the firm to demonstrate that the tanks are operationally equivalent or that the specified mixing parameters listed in the

validation batch records for each tank are equivalent. Some of the products involve the use of multiple tanks which, in the absence of a comparability study, introduces the potential for batch-to-batch variability as multiple combinations of tanks can be used.

2) For each of the validation studies, the initial validation batch record contains several handwritten annotations for process improvements which are then transcribed on the batch records for the subsequent validation batches. These process improvements are also listed in the validation reports. The amount of annotations on the initial validation batch records and their nature, such as (b) (4) renders the initial run a research and development batch and demonstrates that the batching process is not well established at the outset of the validation study. In addition, many of the validation studies involve (b) (4) batch size from the batch size previously validated at the New Jersey facility. Examples of products in which the validation studies involved (b) (4) batch size to (b) (4) batch size at the Hartland facility include, Sore Throat Liquid Spray-Cherry, Sore Throat Liquid Spray - Menthol, (b) (4) Children's Mixed Berry, and (b) (4) Children's Grape.

3) The oral products may be transferred from one of the main mixing tanks to a holding tank following batch release testing and prior to finished product packaging. No studies have been conducted to determine the duration that the oral products can remain in holding tanks (b) (4) prior to finished product packaging time, can range from (b) (4) hours. In addition, the holding tanks do not have agitators in them. The firm's "Tote or Tank Activity Record" (Form No: WI-PM-0090) identifies the batches held in the holding tanks, but it does not demonstrate the duration for which the batches were held.

4) Amendment 01, associated with VAL-0120-MBF-002, for (b) (4) Children's Multi-Symptom-Very Berry, was written to include tank (b) (4) in the manufacture of this product without re-validation of the batching process. The original validation of this product was conducted in tanks (b) (4) The justification to not re-validate was based on tank (b) (4) being used in the validations for (b) (4) Children's Cherry and (b) (4) Mixed Berry, which were both deemed successful. However, each of the (b) (4) products has different compositions including different combinations of active ingredients. The Children's Multi-Symptom Very Berry product contains the active ingredients Guaifenesin, Dextromethorphan Hydrobromide, and Phenylephine HCl whereas the Children's Cherry product contains Guaifenesin and Dextromethorphan Hydrobromide and the Children's Mixed Berry product contains Guaifenesin and Phenylephrine HCl.

5) Multiple finished product lots manufactured from the validation batches were released to inventory prior to formal documented approval of the validation reports. The products and associated finished product lot numbers for products released prior to approval of the validation report include:

- Night Time Cold & Multi-Symptom Liquid - Warming Honey Lemon, lot 0F227
- Sore Throat Liquid Spray - Menthol, lot 0J117
- (b) (4) Children's - Mixed Berry, lots 0J118, 0J150, 0J138
- Acetaminophen Oral Suspension Infants' Drops - Grape, lot 0J289
- Children's Night Time Cough & Cold - Grape, lots 0H177, 0H175
- (b) (4) Children's Multi-Symptom - Very Berry, lots 0H153, 0H159, 0H156
- (b) (4) Children's Cherry, lots 0H260, 0H261, 0H262

6) Finished product lots made from the validation batches were not always put on stability. The product and associated lot

numbers representing validation batches that were not put on stability include:

- o (b) (4) Children's - Mixed Berry, lot 0J150
- o Night Time Cold Liquid - Cherry, lots 0E229, 0E223
- o Night Time Cold & Multi-Symptom Liquid - Warming Honey Lemon, lot 0G150
- o Sore Throat Liquid Spray - Cherry, lots 0J143, 0J144

7) The three process validation batches for Night Time Cold & Multi-Symptom Liquid - Warming Honey Lemon were manufactured on 06/26/2010 (batch 0F227B), 07/08/2010 (batch 0G150B), and 10/28/2010 (batch 0K90B). Two batches of this product were made prior to the first validation batch; OF227B. The first validation batch - OF227B - was then followed sequentially by the second validation batch - 0G150B, but (b)(4) batches were manufactured between this batch and the third validation batch; 0K90B. Per the QA Manager, all of the lots of product manufactured prior to the first validation batch and between the second and third validation batches were released.

8) OOS Preliminary Investigation Report OOS-10-052, dated 11/11/10, was written to address a failing result for deliverable volume determination for Night Time Cold & Multi-Symptom Liquid - Warming Honey Lemon, lot OF162. The root cause determination for this result was "(b) (4) " The investigation report also demonstrated that (b)(4) cases were reworked, (b)(4) cases were released, and (b)(4) cases were scrapped. Per the firm's Validation Final Report, VAL-0109-MBF-002, batch OF162B was manufactured prior to the first validation batch. This batch was not accepted for the first validation run due to the failing result and was placed on hold pending approval of OOS-10-052. OOS-10-052 was approved on 12/06/10.

b) the packaging process validation on the (b) (4) packaging lines, used to package oral liquid products including (b) (4) Night Time Cough and Cold Syrup, (b) (4) Guaifenesin and Phenylephrine Oral Pediatric, (b) (4) Cold Syrup, and (b) (4) Sore Throat Spray Menthol Liquid, did not include critical elements of the process and the affect on the drug products including:
1) The use of a (b) (4) filter, these filters were not included in the packaging validation but have been used on subsequent batches of product. The use of the filters was not always documented in the subsequent batch records. No studies have been done to show that these filters are appropriate for use with these products.

2) The pre-filter and final filter are changed during packaging if the filters are clogged with product. The affect of the filter change on the packaging process was not part of the packaging validation.

3) The conveyor speed during the packaging validation was not recorded and was not deemed important to the process. A subsequent batch of product had a deviation due to conveyor speed problems i.e. DEV-10-INT-063.

4) Oven temperature for the tamper evident seal around the neck of the bottle was not part of the packaging validation and was not deemed important to the process.

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OBSERVATION 11

Control procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

1) Many of the validation batch records included (b) (4) step that stated, "(b) (4) (b) (4) (b) (4) " prior to batch release sampling. This demonstrates that the batching process as described in the batch record may not provide a homogenous product in the tank. Examples of products with this (b) (4) step include Children's Night Time Cough & Cold Grape, Night Time Cold & Multi-Symptom Liquid-Warming Honey, (b) (4) Children's Grape and Sore Throat Spray Menthol and Cherry.

2) The (b) (4) in-process sample for Children's Mixed Berry, batch 0J118B, failed for (b) (4) An analyst noted on an in-process & bulk release results data sheet that, "(b) (4) " An investigation was conducted and OOS-10-064 was generated. The investigation concluded that the (b) (4) (b) (4) . The documented root cause determination was, "(b) (4) (b) (4) Step (b) (4) " The original sample was retested and the initial results were confirmed in addition to (b) (4) sample failing for (b) (4) (b) (4) Batch 0J118B was transferred from tank (b) (4) to a holding tank and samples were collected from the holding tank. The samples taken from the holding tank met specifications and the batch was released.

3) Following validation of Acetaminophen Oral Suspension Infants Drops - Grape,VAL-0149-MBF-002, the firm manufactured batch 0L238B. The batch record (Revision No.: D), specifies the inclusion of the following instructions at step (b) (4) "(b) (4) (b) (4) " A similar step was included in the current master batch record (Revision No.: C) for the Acetaminophen Cherry product as well. This (b) (4) step, just prior to batch release testing, was not part of the validation study, demonstrating that the process was not well established during the validation study. This (b) (4) step is addressed in Deviation Investigation Form DEV-10-INT-065. The root cause for this deviation was documented as follows: "(b) (4) (b) (4) " There is no documentation of a (b) (4) on the third validation batch record OK114B.

4) Per the Validation Final Report for (b) (4) Children's Cherry, VAL-0126-MBF-002, while performing the third validation batch, an additional (b) (4) were included on tank (b) (4) that were not included during production of the first two batches. Deviation 01 was written for these changes that describe the addition of the (b) (4) as it facilitated obtaining a passing result. The (b) (4) step was included during (b) (4) sampling.

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OBSERVATION 12

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.

a) Quarterly dose audits of the sterilization cycle for sterile alcohol pads test (b) (4) of product that represents all of the manufactured sterile alcohol pads for that quarter. On 11/30/10 Triad was informed the fourth quarter dose audit failed the sterility test. No lots of sterile alcohol pads were placed on hold, sterile alcohol prep pads distributed 12/1/10-12/14/10 totaled approximately (b) (4) cases.

b) For the oral products line, including but not limited to children's medicine, a composite sample from the (b) (4) produced is tested for Finished Goods Release. Out of specifications for (b) (4) have occurred when testing the composite sample. The OOS determined (b) (4) can occur in (b) (4) due to (b) (4) (b) (4) prior to packaging. Although the out of specifications span from August to December of 2010 and failures in (b) (4) cases could be masked due to the composite sampling plan, no investigation has been initiated into whether current product on the market could potentially contain (b) (4)

c) Since the previous inspection in May 2010, several OTC batches involving various products failed during annual stability studies. No investigation was documented determining the affect of these failures to product currently on the market.

Product	Lot	Date tested	Mo. Failed	Expiration Date
BZK Solution for Prep Pads	8J123	11/18/10	(b) (4)	09/2011
Lubricating Jelly	9H169	11/15/10		08/2012
Lubricating Jelly	0D192	11/15/10		04/2013
Lubricating Jelly	0D32	11/15/10		04/2013
Insect Sting Relief	0E434	11/12/10		05/2013
Hemorrhoidal Cream	8J178	09/02/10		09/2011
Hemorrhoidal Suppository	9M126	10/12/10		12/2012
Hemorrhoidal Suppository	9K164	10/12/10		10/2012
Hemorrhoidal Ointment	0F187	10/12/10		06/2013
Antibacterial Wipes Solution	7H43	08/09/10		08/2010
Antibacterial Wipes Solution	7H05	08/09/10		08/2010
BZK Swabstick Solution	7F39	07/07/10		11/2010

d) Batches are partially rejected when an OOS is found. Investigations do not extend to other packing configurations that were packaged from the same bulk batch or to other batches of the same product.

1) Batch 0J163B of Bisacodyl Suppositories was used to fill (b) (4) cases of 33-1016 (b) (4) (b) (4) cases of 33-10108 (b) (4) and (b) (4)

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EMPLOYEE(S) SIGNATURE

Marie A. Fadden, Consumer Safety Officer MAF
Joel D. Hustedt, Investigator JDH
Sandra A. Hughes, Investigator SAH
Justin A. Boyd, Investigator JAB

DATE ISSUED

01/07/2011

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	11/29/2010 - 01/07/2011* FEI NUMBER 2128643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric C. Haertle, Chief Operating Officer

FIRM NAME	STREET ADDRESS
H & P Industries, Inc.	700 W North Shore Dr
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Hartland, WI 53029-8358	OTC Drug and Device Manufacturer

cases of 33-1016-(b)(4) 33-1016-(b)(4) failed on the initial test for a (b)(4) assay. A recheck sample was found to be within specification and the initial OOS was attributed to (b)(4) The product was released. 33-1016-(b)(4) was found to be out of specification with a (b)(4) assay and an investigation confirmed the result, however this investigation did not extend to the other portions of the same batch. From 33-1016-(b)(4) (b)(4) cases were destroyed and (b)(4) cases that were inadvertently released were recalled.

2) Batch 0K136 of Hemrrohidal Cooling gel was used to fill (b)(4) cases of 33-50048-(b)(4) (b)(4) cases of 33-50048-(b)(4) (b)(4) cases of 33-50046-(b)(4), (b)(4) cases of 33-50036-(b)(4), and (b)(4) cases of 33-50036-(b)(4) (b)(4) sample was taken from each product number, 33-50036-(b)(4) failed on the initial test for (b)(4) assay. A recheck sample was found to be within specification and the initial OOS was attributed to (b)(4) Product #33-50036-(b)(4) also failed (b)(4) assay and an investigation confirmed the result. However, the investigation into the failing assay was discontinued because 33-50036-(b)(4) was packaged into the wrong tubes and the (b)(4) cases were destroyed. All other cases made with batch 0K136B were released.

3) Batch 0G478B was used to fill (b)(4) cases (b)(4) Alcohol Prep Pad with Benzocaine, lot #0G478. Samples of the (b)(4) (b)(4) case were tested with case (b)(4) failing (b)(4) assay and case # (b)(4) being in specification. Additional samples were then collected of case (b)(4), which also failed (b)(4) and case #, which passed. Cases # (b)(4) were scrapped and the remaining cases were released.

OBSERVATION 13

Individuals responsible for supervising the processing and holding of a drug product lack the education to perform their assigned functions in such a manner as to assure the drug product has the safety, identity, strength, quality and purity that it purports or is represented to possess.

Specifically, the individual responsible for providing training to the Microbiological Laboratory personnel is a Chemist with limited background in Microbiology.

OBSERVATION 14

Employees engaged in the processing and holding of a drug product lack the education required to perform their assigned functions.

a) Employees performing the Microbiological testing of finished products and process water used to manufacture products and clean equipment, do not have an education in Microbiology.

b) There is no one currently employed that has the education in the engineering field to design equipment for the production of pharmaceutical products i.e. alcohol swabstick production lines have (b)(4) after the product contact area, non-cleanable product contact surfaces on numerous pieces of equipment, lack of a preventative maintenance schedule for the compressed air system, lack of routine preventative maintenance of the (b)(4) in the Deionized Water system.

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OBSERVATION 15

Employees are not given training in the particular operations they perform as part of their function, current good manufacturing practices, and written procedures required by current good manufacturing practice regulations.

Specifically:

a) Temporary employees are given cGMP training by the temporary agency that employs them, they do not receive any additional training at this company such as job specific training. In addition, cGMP training is not provided on a routine basis. For example:
1) Operator (b)(6) a temporary employee, received training from the temporary agency on 7/28/09 and started at this company on 7/29/09. Training since that time has included line clearance, raw data integrity and 10-up monthly maintenance.
2) Temporary employee (b)(6) received training from the temporary agency on 8/4/08 and started at this company on 8/5/08, he hasn't received cGMP training since then.
3) Temporary employee (b)(6) received training from the temporary agency on 11/13/09 and started at this company on 9/14/09, he hasn't received cGMP training since then.

b) On 12/2/10 an employee was observed to perform step (b)(4) of the master batch formula and mixing instruction for batch 0M100B. This step involved a (b) (4) of the batch. The employee completed the check, but there was not a second employee to verify the step. The operator explained the second employee that verifies this step in the (b) (4) was busy. The operator would tell the second employee the check had been completed and the second operator would sign the "verified by" place in the record.

c) The analysts performing the microbial out of specification investigation had never been trained on the procedure SOP-LAB-002-00 00 "Microbiological Out of Specification (OOS) Investigations" effective 10/28/10.

OBSERVATION 16

The number of qualified personnel is inadequate to perform and supervise the manufacture, processing, packing, and holding of each drug product.

a) According to the QA individual responsible for following up on complaints, she does not have enough time to adequately investigate every complaint received. As of 12/29/10 this employee was terminated, all complaints received after that date are not being investigated.

b) There are (b)(4) people in the Quality Assurance department that are responsible for Quality Assurance for the entire company. With the short staff not all of the CAPA's are investigated in a timely manner for example:
1) CAPA H-10-002, Failed (b) (4) was opened 2/2/10 to address OOS (b) (4)

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and has yet to be completed.
2) CAPA H-10-001 opened Jan 22, 2010, has yet to address (b) (4) products.
3) CAPA H-10-005 opened 2/23/10, has yet to address (b) (4)

c) According to the Laboratory Manager, they do not have the staff to adequately investigate OOS test results, refer to observation #27 for a list of OOS investigations that were not timely. In addition, the Quality Control Manager stated they need (b) (4) people to conduct all of the testing (including transferred products), at the start of this inspection there were (b) (4) laboratory staff members.

d) At the start of this inspection there was one indvidual responsible for reviewing all batch records and lot history packages generated. This company generally produces over (b) (4) batch records and lot history records in a month.

OBSERVATION 17

Written procedures are not followed for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products, and investigations conducted for each drug product.

Specifically, annual product reviews are not done for any of the OTC drug products manufactured at this facility in accordance with the procedure "Annual Product Review" #WI-QA-0012 effective 9/23/09.

OBSERVATION 18

Drug products are not quarantined before being released by the quality control unit.

Specifically, during a tour of the warehouse on 12/10/10, we observed no less than (b) (4) pallets of alcohol prep pads which were not tagged as 'HOLD", even though the firm agreed to put all such products on hold on 12/02/10. Additionally, on 1/5/11 investigators observed lube jelly and alcohol prep pads not on "HOLD".

Laboratory Control System

OBSERVATION 19

Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements.

Specifically, there is no finished product sterility testing or laboratory (b) (4) testing for sterile alcohol prep pads or sterile alcohol swabsticks.

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OBSERVATION 20

Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.

There is no microbiological testing of the non-sterile alcohol prep pads and non-sterile swabsticks.

OBSERVATION 21

Deviations from written specifications and sampling plans are not justified.

a) The finished product sampling plan for Night Time Cold Liquid - Cherry was changed from (b) (4) testing (b) (4) samples to (b) (4) sample, consisting of a (b) (4) (b) (4) of a packaging run. Testing consists of assay tests to determine (b) (4). This change was reflected in all the oral liquid products transferred from the New Jersey location to this facility.

b) Lot 0J22 of Triad Antiseptic Hand Gel failed the finished product assay for (b) (4). Investigation OOS-W10-003 was conducted, the failing results were confirmed, and the investigation concluded the specification was not appropriate. The product specifications were changed and the product was released. No deviation was written.

c) Lot 0D203B of Obstetricial Towelette Solution used Benzalkonium Chloride that was (b) (4)% and did not meet ingredient specifications of (b) (4) % for the active ingredient. Adjustments were made to the master formula to account for using non-conforming ingredient. No deviation was written for using a non-conforming ingredient or adjusting the master formula.

d) Lot #0K274 of (b) (4) Bisacodyl Suppositories initially failed the Microbiological testing for (b) (4) pecification of (b) (4) actual result (b) (4), the result was changed to (b) (4) with no investigation or justification.

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OBSERVATION 22

Established sampling plans are not followed.

a) Bioburden monitoring and quarterly dose audits (QDA) of the sterile alcohol pads and swabsticks are to be completed on a quarterly basis per SOP-LAB-005-00 "Performing Quarterly Dose Audits of Sterilized Products" effective 9/22/10 which replaced SOP-WI-QA-0006 effective 1/11/07, the following audits did not follow these procedures:
1) There was no quarterly dose audit conducted in quarter two of 2010 for sterile alcohol pads.
2) There was no quarterly dose audit conducted in quarter three of 2010 for sterile alcohol swabsticks.

OBSERVATION 23

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

a) CAPA H-10-002, Failed (b) (4) was opened 2/2/10 to address OOS (b) (4) results and has yet to be completed. There continues to be OOS (b) (4) results. Procedure 01-013, revision B - "Corrective and Preventive Action Procedure (CAPA)" which states in section 5.6 "*** (b) (4)
(b) (4)
(b) (4) .***" has not been followed.

b) OOS-W10-016 investigated a microbial failure of (b) (4) The microbial OOS investigation was not conducted per SOP-LAB-002-00 "Microbiological Out of Specification (OOS) Investigations" effective 10/28/10.

OBSERVATION 24

Written records of investigations into unexplained discrepancies do not always include the conclusions and follow-up.

a) Out of Specification investigations are not performed nor initiated in a timely manner. SOP-LAB-001-00 - "Out of Specification Investigations", effective date 10/01/10 states an investigation must be conducted at the time an OOS result is generated and that the investigation should be completed within (b) (4) days. The following investigations were not initiated nor completed in a timely manner.

Lot	Date OOS Occurred	OOS #	Date OOS was initiated	Date OOS was

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				closed.
8J123	11/18/10	OOS-W10-030	12/14/10	open
9K59	11/16/10	OOS-10-039	05/05/10*	open
9H169	11/15/10	OOS-10-061	08/11/10*	open
0D192	11/15/10	No OOS investigation was initiated.		
0D32	11/15/10	No OOS investigation was initiated.		
0E434	11/12/10	OOS-W10-031	12/14/10	open
9M126	10/12/10	OOS-W10-010	10/22/10	open
9K164	10/12/10	OOS-W10-010	10/22/10	open
7E169	09/02/10	OOS-10-066	09/10/10	open
7E169	09/02/10	OOS-10-042	05/17/10	open
8J426	09/02/10	OOS-W10-029	12/14/10	open
8J178	09/02/10	OOS-10-061	09/10/10	open
7H43	08/09/10	OOS-10-068	09/10/10	open
7H05	08/09/10	OOS-10-069	09/10/10	open
7F39	07/07/10	OOS-W10-035	12/15/10	open
0F187	10/12/10	OOS-W10-008	10/22/10	open
7E10	05/25/10	OOS-10-046	05/27/10	open
7F210	05/13/10	OOS-10-045	05/13/10	open
8G02	03/12/10	OOS-10-074	03/12/10	open
0D194B	4/26/10	OOS-10-032	4/26/10	12/4/10
0D203B	4/27/10	OOS-10-033	4/27/10	Open
0D211B	4/29/10	OOS-10-036	4/29/10	8/18/10
0G154B	7/8/10	OOS-10-053	7/8/10	12/13/10
0G478B	7/23/10	OOS-10-055	7/23/10	Open
9H169	8/11/10	OOS-10-061	8/11/10	open

*Added to a previously opened OOS investigation for issue.

b) Deviation investigations are not performed in a timely manner. The following are examples of deviation investigations that were not timely:

1) Deviation P1006.002, initiated 12/05/02, was issued to change the testing of all alcohol prep pad products from (b) (4) (b) (4) to (b) (4) for the batch. This result is for all lots for that day with the same batch number. Although not referenced, this deviation is still used for testing all prep pad products. This deviation has no end date.

2) Deviation DEV-INT-054, initiated 11/11/10, does not list all the stability studies it pertains to. The deviation description states, "***(b) (4) (b) (4) ***"

3) Deviation DEV-INT-055, initiated 11/11/10, does not list all the stability studies it pertains to. The deviation description states, "***(b) (4)

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(b) (4) ..***"

OBSERVATION 25

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that components and drug products conform to appropriate standards of identity, strength, quality and purity.

a) the method validation titled "Validation of Microbiological Testing" #VAL-R-0011 dated 12/23/09 for the microbiological testing of all products and Deionized Water, used in production and cleaning, was not completed adequately in that the following were not determined: Precision, Specificity, and Linearity/Accuracy. In addition, the failure of the system suitability was not investigated and only a few of the many products tested were used in the method validation.

b) method transfers were not completed on the following test methods prior to using them to release oral adult and children's drug products. In addition, there is no documentation to support that these methods, which are used for stability testing, are stability indicating.

Document #	Title	Effective Date
WI-LAB-0188	(b) (4)	05/19/10
WI-LAB-0189		08/06/10
WI-LAB-0190		06/11/10
WI-LAB-0192		08/07/10
WI-LAB-0194		07/29/10
WI-LAB-0195		08/07/10
WI-LAB-0197		05/22/10
WI-LAB-0204		09/03/10
WI-LAB-0205		10/11/10

OBSERVATION 26

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications prior to release.

a) Procedure WI-LAB-0018 - "Daily Verification of (b) (4) Assay", Effective 10/23/06, describes the daily verification of the assay of solutions being packaged on th (b) (4) (prep pad) packaging lines. The following batch histories were not tested daily and yet still released by Quality:

1) Lot OF501, Product PL-1068, (b) (4) Alcohol Prep Pads 20/100, dated 06/25/10 was packaged on 6/25/10, 6/26/10,

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6/28/10. Of the (b) (4) cases packaged, only case (b) (4) were tested on 6/25/10.
2) Lot OE450, Product PL-1068, (b) (4) Alcohol Prep Pads 20/100, dated 05/26/10 was packaged on 5/26/10, 5/27/10, 5/28/10. Of the (b) (4) cases packaged, only case (b) (4) was tested on 5/27/10.
3) Lot OK440, Product 04-3001, (b) (4) Alcohol Prep Pad, medium 15/100, dated 10/14/10 was packaged on 10/14/10, 10/15/10, and 10/18/10. Of the (b) (4) cases packaged, only case (b) (4) was tested for (b) (4) on 10/14/10, (b) (4) (b) (4) was tested on 10/14/10 and 10/18/10.

b) The form "Finished Goods Analysis and Approval" for Bisacodyl Suppository (Form Number 04-161, effective 1/11/10) states "(b) (4) ". (b) (4) Bisacodyl Suppositories, lot #0K274 was released without all testing on (b) (4) samples.

c) Numerous parameters listed on the finished Goods Inspection Check Sheet for oral liquid products are listed as "Not Applicable" although they pertain to the product being tested. The firm stated these attributes are inspected during in-process checks so they do not reinspect for them during finished product testing. This does not hold true for all potential defects listed. Parameters to be checked during in-process testing vs. finished goods inspection are not defined.

OBSERVATION 27

The written stability testing program is not followed.

Specifically, the firm has continued to miss stability time points since the previous inspection in May 2010 in which the firm was cited for this observation. They are not following their own procedure SOP-LAB-003-00 - "Stability Study Program", effective 10/28/10 which states ***(b) (4) (b) (4) ***.

Solution	Lot	Time pt. missed	Date of missed time pt.	Date testing was initiated.
70% Isopropyl Alcohol	8G02	(b) (4) month	07/14/10	11/30/10
CH Clear Ultrasound Jelly	6J05	month	09/12/10	11/30/10
BZK Solution for Prep Pads	8J123	month	10/15/10	11/18/10

OBSERVATION 28

Results of stability testing are not used in determining expiration dates.

a) since the previous inspection in May 2010, several OTC batches involving various products failed during annual stability studies. Data obtained during stability testing is not used to determine if expiration dates need to be adjusted.

Solution	Lot	Date tested	Mo. Failed	Expiration

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				Date
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Lubricating Jelly	9H169	11/15/10		08/2012
Lubricating Jelly	0D192	11/15/10		04/2013
Lubricating Jelly	0D32	11/15/10		04/2013
Insect Sting Relief	0E434	11/12/10		05/2013
Hemorrhoidal Cream	8J178	09/02/10		09/2011
Hemorrhoidal Suppository	9M126	10/12/10		12/2012
Hemorrhoidal Suppository	9K164	10/12/10		10/2012
Hemorrhoidal Ointment	0F187	10/12/10		06/2013
Antibacterial Wipes	7H43	08/09/10		08/2010
Antibacterial Wipes	7H05	08/09/10		08/2010
BZK Swabstick Solution	7F39	07/07/10		11/2010

b) The firm does not have a document which defines how products are categorized into 'families' even though product families determine which products are put on stability.

OBSERVATION 29

Laboratory records do not include the lot number or other distinctive code of the sample.

The Quality Control Unit failed to ensure that laboratory records, containing environmental monitoring and water testing raw data results, are traceable in that these documents do not contain a sample identification number. The following are examples of incomplete laboratory records:

a) (b) (4) Glycerin suppository room swabbing microbial results for 2/10 and 8/10
b) (b) (4) Swab Stick room swabbing microbial results for 5/10, 8/10, and 11/10
c) [redacted] Water Dispensing Valves microbial testing results for 4/10, 5/10, 6/10, and 9/10

Production System

OBSERVATION 30

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically, the validation for sterile alcohol pads only collected samples for bioburden determination from one production line. There are [redacted] production lines for alcohol pads. Additionally, the recovered bioburden was not identified.

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250 Marquette Avenue, Suite 600 Minneapolis, MN 55401 (612) 334-4100 Fax:(612) 334-4134 Industry Information: www.fda.gov/oc/industry	11/29/2010 - 01/07/2011* FEI NUMBER 2128643

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Eric C. Haertle, Chief Operating Officer

FIRM NAME	STREET ADDRESS
H & P Industries, Inc.	700 W North Shore Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hartland, WI 53029-8358	OTC Drug and Device Manufacturer

OBSERVATION 31

Deviations from written production and process control procedures are not recorded and justified.

a) The Plant Manager stated the (b) (4) (b) (4) This practice is not described in batch records and not documented by production employees.

b) A QC Inspector stated there is a (b) (4) production of alcohol prep pads with benzocaine to (b) (4), but it is not documented or described in production paperwork.

c) numerous deviations have been documented approving the release of product or the use of inaccurate labeling without adequate justification including:

1) (b) (4) Medium Sterile Alcohol Prep Pad Foil, the last 4 rolls of foil printed with the old TRIAD address (REV A), although TRIAD moved to the current location in 2008 and REV B has been available since August 2009. (DEV-10- INT-053)
2) (b) (4) Guaifenesin and Dextromethorphan Cough Pediatric, Cherry, Lot 0K109 was given an expiration date of October 2012, and not September 2012. Product was released. (DEV-10- INT-036)
3) Sterile Lubricating Jelly, Lot 0G192 was incorrectly coded with lot 0G190. Product was released. (H0910.009)
4) Triadine PVP Scrub, 16 oz., Lot OH13, (b) (4) cases were produced with the product label containing LOT 08/13 EXP 0H13 instead of LOT 0H13 EXP 08/13. Product was released. (H0810.010)

OBSERVATION 32

The master production and control records for each batch size of drug product are not prepared, dated, and signed by one person with a full handwritten signature and independently checked, dated, and signed by a second person.

Specifically, the electronic batch record files for every product manufactured at this facility are kept on a shared network drive that is accessible to at least (b) (4) people. The Label Clerk responsible for issuing batch records demonstrated her ability to change any part of the batch record prior to issuance (including in process and finished product specifications), these fields can be changed by anyone with access to the shared drive. In addition, the Label Clerk said she routinely changes the batch size based upon the production schedule to ensure that enough product is manufactured to meet demand. Batch records generated for production are not checked against the master batch record for accuracy. Master batch records are not signed.

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OBSERVATION 33

Written production and process control procedures are not documented at the time of performance.

Specifically:

a) On November 29, 2010 the production of Adult Glycerin Suppository lot #0L268 was observed. The operators were observed weighing the bulk totes and placing them in the appropriate area. Review of the batch record revealed that the weights had not been recorded for the first 25 totes of suppositories. Further discussion with the operator revealed that only one of the three could read and write english, as a result he is the only operator that can record information on the batch record and was not able to keep up with production and recording the information.

b) An interview with an operator on December 2, 2010 revealed that the operator documented in the batch record that he had added the active ingredient Phenylephrine to a batch of (b) (4) Children's Multi-Symptom Very Berry, lot #0K227B, when in fact it had not been added. In addition, the batch record has the addition of the active ingredient to the batch documented as "verified" by a second individual.

OBSERVATION 34

Examination and testing of samples is not done to assure that in-process materials conform to specifications.

a) QC inspectors perform the In-Process Inspection according to the procedure "In-Process Product Inspection - Prep Pad Products" #WI-QC-0008 effective 9/23/09, however they do not record the actual number of (b) (4) units found per section 3.2.2.1, for example:

1) Triad Sterile Alcohol Pads, lot #0K423, 0M435, and 0M422 - recorded "yes" rather then the number of (b) (4) units
2) (b) (4) non-sterile Alcohol Pads, lot #0K440 - did not record the number, a note states "(b) (4))***"

b) In-process and finished product (b) (4) testing is inadequate in that:
1) the QC Inspector performs a (b) (4) exam of approximately (b) (4) packets at one time to determine if any one of them ar(b) (4) There were 47 complaints regarding (b) (4) issues between April - November, 2010.

c) The procedure "(b) (4) Test" #WI-LAB-0042 effective 2/16/10 is not followed in that:
1) according to the QC Supervisor, section 3.1.1.4 is never done
2) according to the QC Supervisor, the procedure is never used for the prep pad products, however in the scope it states "***(b) (4)
3) according to the Laboratory Manager, this testing is never done in the laboratory as described in the "Responsibilities" section "***(b) (4)
(b) (4) ."
4) according to the QC Supervisor, this procedure is used t(b) (4) test all products that are packaged into tubes, however

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there is no reference in the procedure to testing tubes.

OBSERVATION 35

The batch records do not record the distinctive identification number to identify major equipment to show the specific equipment used in the manufacture of a batch of a drug product.

Specifically, tanks used for batching the oral products are not specifically identified at the steps in which they are used in the execution of the batch record. The only place specific tanks are identified is in the "Process Equipment Cleaning and Sanitization" section of the batch record which demonstrates the tanks were cleaned prior to use.

OBSERVATION 36

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

a) The calculation of yield page was not completed in the batch record for the production of the Lemon Glycerin Swab Solution, lot #0M04B, the batch was released for packaging by (b) (6) on 12/2/10.

b) The batch record documenting the production of Swab-Forming Solution, lot #0M120B does not include a yield calculation page, this batch was released for the manufacture of swabsticks by (b) (6) on 12/8/10.

c) The yield calculation page was not completed in the batch record for the production of Hemorrhoidal Suppository with phenylephrine, lot #0L245B.

Facilities and Equipment System

OBSERVATION 37

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its cleaning and maintenance.

(b) (4) Room:
Alcohol Sterile and non-sterile prep pads packaging lines ((b) (4) :
a) plastic "zip ties" are used to form the cotton into a fold - these "zip ties" touch every prep pad and have surfaces that are not cleanable
b) a rubber neoprene wheel that was observed to have debris build up on it touches every prep pad on that side of the equipment
c) the bars on which the prep pad material passes under were observed to have debris build up on it

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d) a fiber strap was observed hanging on the bulk roll of prep pad material, this strap is not a cleanable surface and cannot be sanitized
e) a white residue was observed in the isopropyl alcohol bath, through which the pad material passes, just prior to the prep pad cross slicer
f) a stiff bristled brush was observed sitting on the piece of equipment, the brush is used to brush off the first two rollers in the sealing process prior to the packet being sealed

Sterile and non-sterile swabsticks packaging lines:
a) swabsticks are moved from the (b) (4) to the packaging line via (b) (4)
(b) (4) is not filtered at the point of use, but is filtered after the point of use

(b) (4) Room:
Adult, Children and Infant oral product manufacturing:
a) Tank # [redacted] was observed to have blue tape on the outside of the tank on November 29, 2010, tape is not an easily cleanable surface
b) the (b) (4) hose used for the addition of Deionized Water to the batching tanks for production of the oral products has not been shown to be appropriate for this use
c) a bucket labeled as "Purified Water" is in fact Deionized Water used to rinse equipment after cleaning

Glycerin Suppository Room:
Adult and Infant Glycerin suppository manufacturing:
a) the ejector pin plate on the Glycerin Suppository Press used in the manufacture of adult and infant glycerin suppositories had several cracked and missing ejector pins. The last documented maintenance and replacement of broken pins took place on 10/16/2009. The plastic ejector pins come into direct contact with the suppositories to eject them from the mold. The current inspection and documentation mechanisms do not ensure repair and replacement of the pins as necessary to minimize the potential for the inclusion of plastic fragments in suppositories. The ejector pins and the glycerin suppositories are opaque, making identification of pin fragments difficult.

(b) (4) Room:
Pad press and packaging lines:
a) the press used to cut pads for acne pads and hemorrhoidal ointment pads was not easily cleanable and patched with tape
b) the press had foam that contacted the pad material, the foam is not an easily cleanable surface
c) employees used bare hands to place the pads into the product container.

Swabstick room:
Swabstick manufacturing:
a) the swabsticks are placed in large bins or small metal baskets where they are left to dry for a minimum of (b) (4)
(b) (4) the room does not have a filtered/controlled air supply. After drying, these swabsticks are combined with an active ingredient and packaged as either sterile or non-sterile drug products.

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OBSERVATION 38

Written procedures for sanitation are not followed.

Specifically, on several occasions while in the (b) (4) room, the trash cans were observed to have wet residue inside them as well as other debris adhering to the sides. Form #FM-MTL-0014 states "Verify that all trash containers are properly labeled."

OBSERVATION 39

Equipment and utensils are not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

a) The Deionized Water system which the firm uses to formulate both oral and topical products, as well as for cleaning equipment, is not adequately maintained in that:
1) There is no written procedure describing how to obtain the water samples that are taken (b) (4) for (b) (4) (b) (4) analysis.
2) There is no procedure or preventative maintenance describing the routine cleaning and replacement of the (b) (4) (b) (4)

b) There are (b) (4) identical "(b) (4)" alcohol prep pad packaging lines located in the (b) (4) room which are used to package the sterile and non-sterile 70% alcohol prep pads of various brands. These packaging lines are cleaned and sanitized once a month, however, these packaging lines are used (b) (4) The cleaning is specified in the "(b) (4) Monthly Preventive Maintenance" and does not specify the cleaning solution to use.

c) The (b) (4) hose used to add deionized water to the oral liquid products and for cleaning equipment in the (b) (4) room was observed laying on the floor in such a manner than water could not drain from it.

d) the compressed air system which is used throughout the facility in product contact areas and equipment operation does not have a preventative maintenance program describing routine filter changes at the compressor and at points of use.

e) The cleaning conducted between packaging batches of products does not include adequate flushing of the filling line, this has been documented in the following OOS investigations OOS-10-056, OOS-10-065, OOS-W10-011, OOS-W10-012, and OOS-W10-041.

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OBSERVATION 40

The plumbing system contains defects that could contribute to the contamination of drug products.

On 12/21/10 water was observed to be backed up around drains in the batching tank area. The waste water pump in this room was observed to contain solids creating a blockage that prevented waste water from being pumped into the waste water area. The pump was emitting a visual alarm.

OBSERVATION 41

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Currently there is no procedure for the swabbing of equipment to determine if there is any microbiological contamination on the manufacturing and packaging equipment to determine if the cleaning procedures are adequate, with the exception of the Glycerin suppository manufacturing equipment and the (b) (4) swabstick manufacturing equipment, for example sterile and non-sterile alcohol prep pad packaging equipment, sterile and non-sterile swabstick packaging equipment, adult and childrens oral product manufacturing and filling equipment.

Materials System

OBSERVATION 42

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, according to the procedure "Supplier Qualification and Management System" #SOP-QA-010-01 effective 10/28/10, the definition of major suppliers includes suppliers of API's and critical raw materials, product contact components and label (packaging) components. In addition it states "(b) (4) " Section V. A. 1. a. specifies: "(b) (4) (b) (4) " There have been no site visits to any suppliers of critical raw materials. Critical raw materials that rely on the suppliers report of analysis include, but is not limited to: foil used to package sterile and non-sterile alcohol prep pads (immediate product contact surface), prep pad material, sterile and non-sterile swabstick components, sucralose, Bisacodyl USP, Glycerin etc.

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OBSERVATION 43

The production area air supply lacks an appropriate air filtration system.

Specifically, the air supplied to the (b) (4) room, sterile and non-sterile alcohol prep pad and sterile and non-sterile swabstick packaging area, is through (b) (4) HVAC units that are designed to deliver room temperature air for the employees comfort only. This same type of air supply system is used in all areas of this facility, except the "(b) (4) Room" used for oral product manufacturing and packaging.

OBSERVATION 44

Each lot of a component, drug product container, and closure that is liable to microbiological contamination that is objectionable in view of its intended use is not subjected to microbiological tests before use.

a) The prep pad material, isopropyl alcohol, and packaging foil used in the packaging of sterile and non-sterile alcohol prep pads are not tested prior to use to determine if microbiological contamination is present.

b) The hot melt adhesive, cotton coil, polystyrene sticks, and packaging foil used to manufacture the swabsticks and package the sterile and non-sterile swabstick products are not tested prior to use to determine if microbiological contamination is present.

OBSERVATION 45

Procedures describing the warehousing of drug products are not established and followed.

a) There is no written procedure describing the warehousing of finished product in the warehouse. While in the warehouse on December 8, 2010 several cases of PVP-1 Scrub Solution, lot #9J07 were observed to be leaking. At least (b) (4) cases were observed with visible leakage on the boxes. In addition, the floor around the cases had product residue visible on it.

b) According to the procedure "General Rejection Procedure" #WI-QC-0094 effective 5/6/09, section 3.2.3 states "(b) (4) (b) (4) During the tour of the facility on November 29, 2010 several items were observed in hold locations without status or NC HOLD tags, for example:
1) outside of the (b) (4) Room - (b) (4) Alcohol prep pad and Triad Alcohol prep pad foil
2) outside of the (b) (4) Room - (b) (4) Night Time Multi Symptom, lot #0H141, (b) (4) Sore Throat Spray, lot #0L184, (b) (4) Nitetime Cold Cherry, lot 0L166 and 0L167, (b) (4) Cold Liquid Mixed Berry, lot #0L134 (b) (4) Cherry Acetaminophen, lot #0J89 and (b) (4) Night time Cough and Cold, lot #0G128

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Packaging and Labeling System

OBSERVATION 46

The drug product is not identified with a lot or control number that permits the determination of the history of the manufacture and control of the batch.

Specifically, the individual non-sterile alcohol prep pad packages are not all identified with a unique lot number.

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Observation Annotations

Observations intentionally left blank.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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*** DATES OF INSPECTION:**
11/29/2010(Mon), 11/30/2010(Tue), 12/01/2010(Wed), 12/02/2010(Thu), 12/03/2010(Fri), 12/08/2010(Wed), 12/09/2010(Thu), 12/10/2010(Fri), 12/14/2010(Tue), 12/15/2010(Wed), 12/16/2010(Thu), 12/17/2010(Fri), 12/20/2010(Mon), 12/21/2010(Tue), 12/22/2010(Wed), 12/28/2010(Tue), 01/03/2011(Mon), 01/04/2011(Tue), 01/05/2011(Wed), 01/07/2011(Fri)

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