DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	12/15/2008 - 02/02/2009
	FEI NUMBER ~~1937079~~ 3007259359

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

FIRM NAME	STREET ADDRESS
KV Pharmaceutical Co Westport	2280 Schuetz Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug 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.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observations cover inspections at the following firms inspected from 15Dec2008 - 02Feb2009

- KV Pharmaceuticals, Inc., 2503 South Hanley Road, St. Louis, MO 63144-FEI#1940015
- KV Pharmaceuticals, Inc., (Westport), 2303 Schuetz Road, St. Louis, MO 63146-FEI#1937079
- KV Pharmaceuticals, Inc., (R&D Lab Metro II), 10858 Metro Court, Maryland Heights, MO 63043-FEI#3002946714
- KV Pharmaceuticals, Inc., (Earth City I), 13622 Lakefront Dr., Earth City, MO 63045-FEI#3003266206
- KV Pharmaceuticals, Inc., (Earth City IV), One Corporate Woods Dr., Bridgeton, MO 63044-FEI#3004839832
- KV Pharmaceuticals, Inc., (Controlled Release), 8050 Litzinger Road, St. Louis, MO 63144-FEI#1922566
- KV Pharmaceuticals, Inc., 2258 Schuetz Road, Maryland Heights, MO 63043-No FEI
- KV Pharmaceuticals, Inc., 2280 Schuetz Road, St. Louis, MO 63146-FEI#3007259359
- KV Pharmaceuticals, Inc., 10876 Metro Court, Maryland Heights, MO 63043-No FEI
- KV Pharmaceuticals, Inc., 13910/13912 St. Charles Rock Road, Bridgeton, MO 63044-FEI#1922566

QUALITY SYSTEM

OBSERVATION 1

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

Specifically, the Quality Control/Quality Assurance (QC/QA) functions have failed as evidenced by the following examples

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and the remaining observations cited on the FDA 483.

For example,

a. After dissolution failures occurred with Metoprolol Succinate 25 mg ER Tablets manufactured with ER pellet lots with below target assay values, several lots of the ER pellets (#'s 96671, 96856, 96857, 96858, 96859, 96860), with assay values below the target were blended off with ER pellet lots with assay values at or above the target value. There is no formal documentation or justification for the blend-off process. This blending off of sub par product was conducted in approximately (b)lots of bulk tablets from September until November 2008. This was performed at the instruction of upper management and acceptance by Quality Assurance.

b. After dissolution problems were encountered with Metoprolol ER pellets due to high acetic acid values(b) (4) in (b) (4) a decision was made by upper management with no formal documentation or justification, to blend off lots of which assayed above (b) (4) with lots assayed at or below (b) (4) . Lot #121415 of (b) (4) had an acetic acid value of approximately (b) (4) and was used with lot# 122572 (b) (4) in at least (b) lots of ER pellets (#'s 98950-98954 and 101203-101214) in November of 2008.

c. The quality control unit has failed to implement adequate corrective and preventative action into the hundreds of complaints of leaking capsules received on PrimaCare One, Prenatal Multivitamin/Mineral Capsules. The firm continued distribution of this product despite continued complaints of leaking capsules as evidenced by the following. The investigation is ongoing and product is currently being reformulated.

- 2007 complaint statistics; over 350 complaints of leaking capsules for PrimaCare One, with 26 documented adverse event reports (ADEs);
- Correspondence from the manufacturing firm dated 02Jan2008 in which an "improvement plan" is addressed for the PrimaCare One manufacturing process; and by
- 2008 complaint statistics; over 630 complaints of leaking capsules with 21 documented ADEs.

d. Rework by re-screening due to unacceptable particle size was performed in August 2007, without change control, QA approval and validation, on IR pellets lot# 87843 (C-664). This pellet lot was used during the remainder of 2007 and early 2008 in the manufacture of (b) (4) Metoprolol Succinate 100 mg/200 mg tablet batches which were subsequently released. The batches included lot #'s (b) (4) (b) (4) Further, a pre-approval supplement was not pursued for this rework process nor was this rework process submitted in the Annual Report dated 05Jul2008. Notes from an upper management meeting indicate the re-screened product cannot be used for commercial sale until the pre-approval supplement is approved.

e. The quality unit did not effectively review the packaging batch record prior to the release of Oxycodone 15mg Tablets

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lot # 90330 to the market. This batch was packaged using bulk tablet lot # 83391 which had been rejected when it failed the finished product specifications for assay. Awareness of the release of the failed batch was realized when the warehouse could not locate the failed lot of product for destruction on 29Jun2008. The packaging batch record for lot # 90330 referenced the two different bulk tablet batches of Oxycodone 15 mg, lots #'s 91391 and 83391. However, only lot # 83391 was used. Additionally, the packaging batch record contained the incorrect COA (for lot 91391); it did not contain the COA for lot # 83391.

OBSERVATION 2

Control procedures are not established which 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.

Specifically, for Metoprolol Succinate Extended Release (ER) tablets, Hydromorphone Tablets, Morphine Sulfate ER Tablets, and prescription nutritional supplements, the process steps executed to accomplish manufacture have historically resulted in variable products of unreliable quality, different than the product results obtained from the designed, validated process studies.

Metoprolol Succinate ER Tablets

a. It does not appear the Metoprolol Succinate ER Tablets product line (25 mg, 50 mg, 100 mg, 200 mg) was developed in a scientifically sound manner with appropriate specifications and process controls. All strengths have historically resulted in drug product of variable quality when, the designed processes are executed as evidenced by the high numbers of batch rejects, in-process rejects, out-of-specification (OOS) test results and non-conformance reports (NCRs) at all manufacturing stages.

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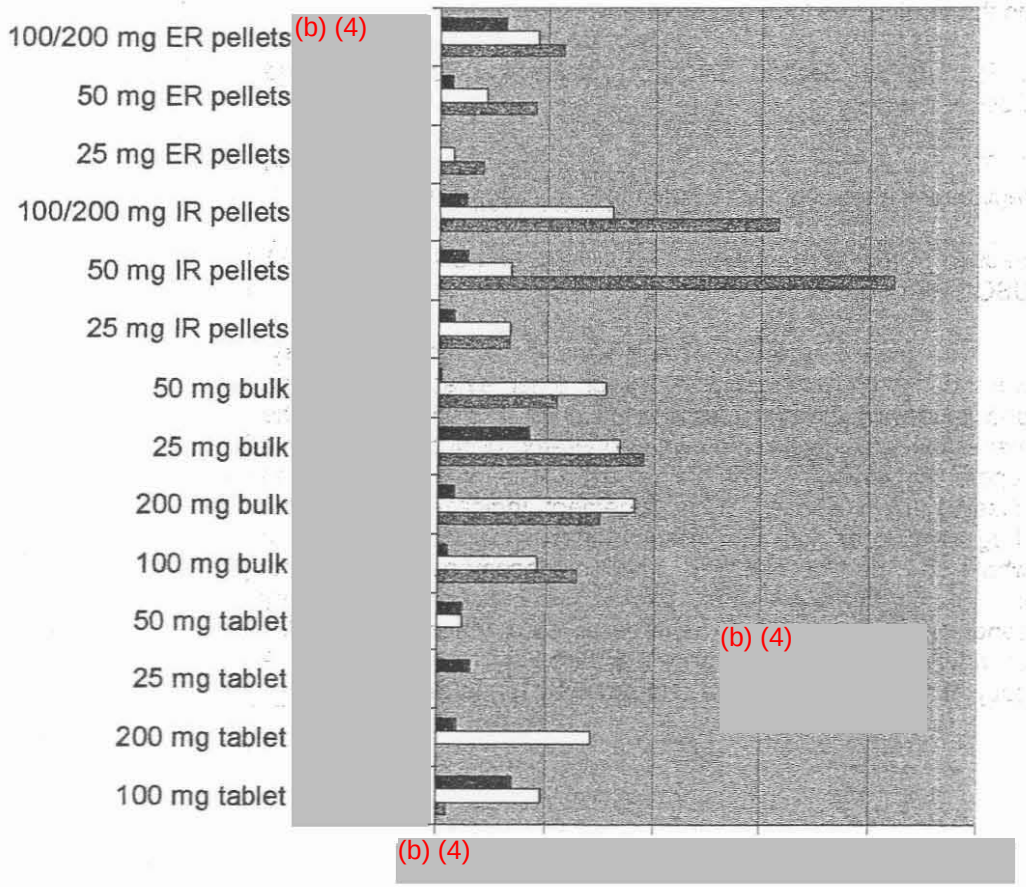
Metoprolol Manufacturing Issues
Since the FDA approval dates



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Product	OOS	NCR Initiated	Lots Rejected
100 mg tablet (b) (4)	(b) (4)	(b) (4)	(b) (4)
200 mg tablet			
25 mg tablet (			
50 mg tablet (			
100 mg bulk (			
200 mg bulk (			
25 mg bulk (b) (4)			
50 mg bulk			
25 mg IR pellets (b) (4)			
50 mg IR pellets			
100/200 mg IR pellets (b) (4)			
25 mg ER pellets (b) (4)			
50 mg ER pellets			
100/200 mg ER pellets (b) (4)			

The OOS test reports included but were not limited to the following: *Assay; Loss on Drying; Dissolution; Content Uniformity, and Particle Size.*

The NCRs included but were not limited to the following: *Foreign Tablet; unapproved deviation; Speed Study; Failed AQL-broken tablet; Omission of IR Pellets; Expired ER pellets, Content Uniformity; Metal shaving found on* (b) (4) *Press; IR pellet Particle Size; Sample Prep error; and ER pellet particle size.*

b. There is insufficient evidence to support the release of Metoprolol Succinate 100 mg ER Tablets processed with active pharmaceutical ingredient (API), Metoprolol Succinate USP, which was different from that used in the designed process. Since your 05Aug2007 IR pellet validation study (07CRC-664 [R7] PE-14-08) using the Mexican Intermediate of Metoprolol Succinate in the production of 100mg and 200mg tablets, you have had approximately (b) NCRs relating to particle size. The particle size of post-validation lots of this API, are smaller than the particle size of the API used in the 2007 validation study.

You continued to manufacture and distribute approximately (b) lots of these tablets until 17Oct2008, when you ceased production. The IR and ER pellet batches used in the tablet batches have sporadically failed particle size tests since that

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time. In fact, since 03Jul2008, 23 IR Pellet batches were rejected for particle size problems. You have also released several batches of Metoprolol Succinate 100 mg ER Tablets manufactured using the API lots received with a changed, smaller particle size that had been received prior to 03Jul2008. These include batch #'s (b) (4) (b) (4) anufactured in July of 2008 to mid October 2008, using Pellet lots that had included API lot #'s

c. You failed to take appropriate corrective actions after investigational findings identified the root cause for dissolution failures of Metoprolol Succinate ER Tablets, 50 mg. During the 06Aug2008 investigation of NCR #'s 14969 and 14181, you identified excessive press speed (b) (4) to be the root cause of the dissolution failures for lot #'s 93394 and 93862. This data brings the validation study, (08WP70369 00 [R1] PV-07-01), under suspect, in which the press speed range is (b) (4) In addition, you continued to operate at press speeds of (b) (4) and released approximate (b) lots of Metoprolol Succinate Tablets 50mg from 06Aug2008 to the time of this inspection.

d. Rework by re-screening due to unacceptable particle size, was performed in August 2007, without change control, QA approval and validation, on IR pellets lot# 87843 (C-664) used in the manufacture, release and distribution of the following (b) Metoprolol 100 mg/200 mg tablet batches, lot #'s: (b) (4) (b) (4) Further, a pre-approval supplement was not pursued for this rework process nor was this rework process submitted in the Annual Report dated 05Jul2008. Notes from an upper management meeting indicate the re-screened product cannot be used for commercial sale until the pre-approval supplement is approved.

Hydromorphone HCl Tablets

e. (b) (4) batches of Hydromorphone HCl IR 4mg Tablets on the market within their expiry, were manufactured utilizing an un-validated, auto-fill process. The batches are lot #'s (b) (4) (b) (4)

Validation batches manufactured Dec2005 and Jan2006, failed to demonstrate control and reproducibility; blend uniformity and potency failures occurred. Modifications were made to the compression stage of the manufacturing process and a new validation study was performed in Jun2006 with acceptable results. The modifications included decreasing the press speed during compression to (b) (4) and using a manual hand fill process for transferring the blend to the press hopper. The Auto-Fill powder transfer system which is a vacuum system used to transfer the powder blend to the tablet press hopper was previously used. The master batch record was not revised to require the blend to be hand fed to the tablet press resulting in all (b) batches manufactured from Jun2006 to Aug2008 being manufactured using the Auto-Fill transfer system instead of hand (4) filling.

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The validation study was also flawed:

- There is no documentation of the times the samples were collected to ensure adequacy of compression across the batch.
- Discrepancies were noted in the data for tablet hardness samples collected at various hardness levels. The validation protocol required collecting samples at (b) (4) for dissolution, weight variation, hardness, thickness and friability testing.
  - The samples at target hardness of (b) (4) collected from lot #'s 72722 and 73523 ranged from (b) (b) (4) respectively.
  - The samples collected for (b) (4) from lot # 73523 ranged from (b) (4)
  - Samples were not collected at the (b) (4) due to "the fact that no tablets compressed at (b) (4) level exhibited proper physical characteristics for weight and thickness specifications stated in the MBR." However, the master batch record was not revised to change the hardness range which is currently (b) (4)
- During compression of one the validation batches, lot # 73523, to evaluate tablets at a press speed of (b) (4) (b) the press was run at a speed of (b) (4) which equates to about (b) tablets. There is no documentation of this in the validation report, data or batch record or of the disposition of these tablets.

AQL Failures for Tablet Products

f. You have failed to adequately study causes for the acceptable quality limit (AQL) failures which occur across product lines and include among others, nutritional, Metoprolol Succinate and Morphine family products. The AQL encompasses statistical sampling to evaluate aesthetic tablet defects, setting limits on the amount of statistically acceptable defects per batch. Despite changes to manufacturing equipment in tablet coating, product failures continue. This brings into doubt the validation of this process step for all coated products and the quality of products on the market. Investigations exist which occasionally list upstream manufacturing of core tablet issues as possible causes to coated tablet failures. Some of these encompass, hardness, % loss on drying of the granulation, compression speeds and compression force. None of these issues is adequately investigated to determine the root cause and instead coating is solely blamed with system upgrades.

AQL failures are summarized as evidenced by

1) (b) (4) bulk batches spanning a 4 ½ month period from 18July2008 through 7Nov2008 of the Morphine Sulfate ER and IR families, failed to perform as validated during compression and coating due to AQL failures. (b) (4) of those batches were (b) re-inspected for AQL; on average about (b) of all re-inspected batches were discarded; in one instance (b) (4) of the batch was discarded. The acceptable portions were subsequently released for further processing, packaging or were sold (b) (4) total batches were sold, at close of the inspection several were still

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awaiting a disposition). The investigation did not extend to complaints received for batches manufactured in this period. Forty-eight complaints have been received concerning tablet defects. The size of the AQL sample for routine batches has not been increased to evaluate and ensure the effectiveness of the corrective actions. The probable cause of the failure was identified as problems with the air handling unit for the coating pans and upgrades to the air handling system were completed in Dec 2008. Some batches which failed specifications during the compression and coating process are (note: this table is not all inclusive):

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Date	Morphine Sulfate Product	Batch	NCR	Percentage waste from re-inspection	Reason
7/7/08	60 mg ER	91290	15810	Inspection data not available; missing from batch records	Fails sorted AQL for surface spots and code number illegible/incomplete
7/18/08	60 mg ER	95572	15360	(b) (4)	Failed AQL for defect
7/18/08	60 mg ER	95573	15384	Rejected; not inspected	Code number illegible/incomplete; local erosion
7/27/08	30 mg ER	94421	15553	Inspection data not available; missing from batch records	Failed sorted AQL; tablet not uniform in color/color variation
8/2/08	60 mg ER	95575	15682	(b) (4)	Fails AQL for illegible code and broken tablets
8/6/08	60 mg ER	97337	15729		Fails AQL for tablets not smooth
8/22/08	30 mg ER	97332	15993		During coating pan failed AQL for tablets not smooth, illegible debossing
8/28/08	60 mg ER	97340	16119	Rejected; not inspected	Fails AQL for illegible code
9/4/08	60 mg ER	98019	16220	(b) (4)	Fails AQL for incomplete code
9/9/08	30 mg ER	97335	16339	(b) (full inspection data not available; missing from batch records)	Failed AQL for not smooth and illegible tablets
9/11/08	15 mg ER	98757	16397	(b)	Failed AQL for not smooth and illegible tablets
9/12/08	15 mg ER	98758	16400	Rejected; not inspected	During coating pan failed AQL for tablets not smooth, illegible debossing
11/6/08	15 mg ER	99751	17418	Inspection data not available; missing from batch records	Failed AQL for not smooth and illegible tablets and not uniformly polished
11/6/08	60 mg ER	99766	17433	(b) (4)	Failed AQL for not smooth tablets and illegible codes
11/708	15 mg ER	100553	17464		Failed AQL for not smooth tablets and illegible codes
11/7/08	15 mg ER	100554	17465		Failed AQL for not smooth tablets and illegible codes

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2) The table below summarizes (b) bulk batches of Prenatal Rx1 Multivitamin Tablets spanning from Oct 2008 through Dec 2008. These batches failed AQL inspection after coating. The investigation did not extend to complaints received for batches manufactured in this period. Fifteen (15) complaints have been received concerning tablet defects in 2007 and 2008. Finally, the size of the AQL sample for routine batches has not been increased to evaluate and ensure the effectiveness of the corrective actions.

Batches which failed specifications during the compression and coating process are:

Date Coated	Bulk Batch/ Pkgd. Batch	NCR	Reason	Percentage waste from re-inspection	Listed Probable Cause of Failure
12/10-11/08	102121	17967	Local erosion, surface blemishes chips & adhering spots	(b) pans manufactured are rejected; (b) (4) doses or nearly (b) of total batch	Process formulation issues--amount of Disintegrant in coating solution
6/09/08 & 10/ 3,7-8&20/08	95495/ 97487	14774	Surface blemishes & not uniformly polished	(b) (4) of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA 15456)
6/3-4&608	95493	14674	Surface blemishes, chipped tablets & illegible codes	(b) (4)- All rejected no inspection	Tooling, compression & coating parameters not optimal (CAPA 15456)
5/30-6/2/08	95492/ 95279	14635	Surface blemishes & illegible codes	(b) of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA 15456)
5/29-30/08	95491/ 95280	14623	Surface blemishes & illegible codes	(b) of reinspected portion	Tooling, compression & coating parameters not optimal (CAPA

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					15456)
9/23/08	95489	16601	Erosion, surface blemishes & illegible Code	(b) All rejected no inspection	Changes in coating parameters under planned deviation.
5/20/08	95488/ 95276	14526	Surface blemishes, breaks, chips and illegible codes	failed (b) pans; (b) (4) of total batch	Product formulation and manufacturing process
4/23-24/08	94192/ 95275	14036	Not fully covered, breaks, not smooth, illegible code	(b) pans rejected; (b) of total batch	Operating Pan Air Flow & Spray Rate at the minimum control limits of (b) (4)
3/8-14/08	92360/ 91751	13271	Local erosion	(b) of reinspected portion	Improper dedusting
1/27-28/08	91270/ 91752	12636	Local erosion & surface blemishes	(b) (4) of reinspected portion	Inadequate process parameters (low pump rpm & spray rate)
1/26-27/08	91269/ 91749	12615	Tablets not smooth and not fully covered	(b) (4) of reinspected portion	Equipment Failure during coating
1/2-5/08	88707/ 89081	12306	Local erosion, surface blemishes, chips	(b) of reinspected portion	Inadequate temperature in the coating pan
12/10-11/08	86593/ 91695	12034	Local erosion & surface blemishes	(b) (4) of reinspected portion	Inadequate heating of tablets during coating
10/31-11/1/07	86594/ 87759	11622	Surface blemishes, chips, breaks & tablets not smooth	(b) of reinspected portion	Inadequate heating of tablets during coating

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Tara L. King, Investigator

DATE ISSUED
02/02/2009

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11630 W. 80th Street Lenexa, KS 66214 (913) 752-2100 Fax:(913) 752-2111 Industry Information: www.fda.gov/oc/industry	12/15/2008 - 02/02/2009 FEI NUMBER ~~1937079~~ 3007259359 MSD

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

FIRM NAME	STREET ADDRESS
KV Pharmaceutical Co Westport	2280 Schuetz Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug Manufacturer

OBSERVATION 3

Written records are not always made of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications.

Specifically,

a. There was no investigation into conflicting assay results between the release bead uniformity potency results for Metoprolol Succinate ER pellet batches, which were lower than target but within specification, and the results from a second subsequent test on a composite (retain) sample, performed under special request by the production department. There is no raw data for the composite sample results collected under this special request. These composite results were higher than the original bead uniformity results for (b) (4) C-759 pellet batches (lot #'s (b) (4) (b) (4) batches of Metoprolol Succinate ER Tablets 23.75 mg, were manufactured in July and August of 2008, using the composite potency values from the pellet batches rather than the bead uniformity potency results. No evaluation has been performed of validation data to ensure 23.75 mg tablets will meet specification when blended with pellets with potency values below the target blend uniformity specification limit.

b. No investigation to determine the root cause was performed for the following incidents:

- Metoprolol Succinate ER pellet batch, lot # 98459 (47.5 mg tablets) which failed dissolution testing and was confirmed by OOS (# OOS-08-SEP-012). NCR # 17634 was initiated 17Nov2008.
- Potassium Chloride bead batch, lot # 99938 which was confirmed to be OOS (#OOS-08-SEP-005) for time release dissolution. The results were outside of the proven acceptable range at hours (b) (4) NCR #16706 was initiated 29Sep2008.
- Potassium Chloride (KCl) blend batches, lot #'s 99900 (OOS-08-OCT-017) and 99910 (OOS-08-OCT-045) which were confirmed OOS for timed release dissolution on 30Oct2008 and 04Nov2008, respectively. NCR #17397 was initiated for both lots on 05Nov2008.
- Complaints of "black spots" and "moldy looking areas" were received for PreCare Premier prenatal vitamins; batch #'s 76051, 91544, 90006, 79697, 91545, 95301. At least eight (8) complaints of this nature were listed for lot 90006 alone, yet a letter was sent to a complainant stating this was an "isolated incident."

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OBSERVATION 4

Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up.

Specifically,

a. Corrective and preventive actions have not been carried out regarding NCR 12156 when Hydromorphone HCl Tablets 2 mg, lot 82575 failed the acceptance criteria for content uniformity in Dec 2007. The NCR determined the cause was segregation due to the use of the Auto Filler to transfer the powder blend into the press hopper. The report states (b) (4) (b) (4) (b) (4) The master record was not revised until July 2008 with the correction being implemented in September 2008. During that time numerous batches were manufactured using the Auto Filler; (b of these remain within their expiry period.

b. Corrective actions were not taken to rectify a systematic problem allowing compression prior to verification of acceptable blend uniformity data for products including Oxycodone HCl. QA approval of the blending process prior to compression is required. For example, Oxycodone HCl lot # 96621 was blended on 23Jun2008 and compressed on 24Jun08. The batch failed blend uniformity on 08Jul2008. An investigation indicates the cause was sampling error yet no re-sample could be taken to confirm or refute the results because the batch had been compressed.

c. No corrective or preventive action has been recommended concerning NCRs 14181 and 14969 which were initiated for lot #'s 93394 and 93862 of Metoprolol Succinate ER Tablets 47.5 mg which failed dissolution. The NCRs identify the root cause of the failures as *"Excessive speed on the tablet press"* despite, press speed range specified in the master record of (b) (4) The batches continue to be manufactured at a press speed of (b) Approximately (b) batches have been made since this time.

d. Appropriate corrective and preventive actions were not taken when problems were encountered with cap torque during packaging of Prednisolone 5mg/5mL, lot #96179. The investigation did not extend to other affected product lots.
   - CAPA # 16409 opened 12Sep2008 stated the vendor was previously disqualified from producing any more closures due to significant quality issues. However, you continued to use this supplier's closures.
   - Personnel were not trained to document quality issues at the time of occurrence. Information in NCR 15949 initiated in response to this cap torque problem indicated that closure P5303 has always been problematic; yet, the problems have not been documented in the past.
   - Additional monitoring of torques during packaging was not conducted for lots 10568, 10569, 1023471, 102372, 102373 and 102374 as instructed in CAPA 16409.

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e. After compressing Prenatal Rx1 Tablets lot # 95489 in May of 2008, compression tooling was found damaged with chips and broken keys. The cause was attributed to exceeding the allowable compression force of the tooling. The tooling is rated for (b) of compression force and the press was set at (b) (4) The compression force is a critical parameter but is not recorded in batch records. The master and batch production records have not been revised to specify the tooling rating and to require documenting the compression force.

f. Corrective actions per CAPA 17038, to (b) (4) specification and to revise the MBR for input adjustment of Prednisolone USP based on potency for Prednisolone Syrup, USP, 5 mg/5mL were not implemented. Stability data showed potency results trended downward through product expiry.

g. No CAPA follow up or master batch record (MBR) revision has been documented concerning, NCR 16469 opened on 16 Sep 2008 for Morphine Sulfate ER 100 mg tablets. The NCR captures excursion outside written procedures where bulk batch # 97343 was not compressed within the (b) limit as stated in the batch record.

The NCR discussed that the limit was not established according to stability data and a CAPA, #17728, 24 Nov 2008, was opened to revise the hold time in the MBR between blending and compression.

h. No corrective and preventive action was initiated for OOS-08-OCT-038 when a supervisor and data auditor failed to note the total recovery for the timed release dissolution was out of range for Potassium Chloride bead lot # 100098. The data auditor and supervisor failed to realize the lot should have been retested due to total recovery of the potassium chloride being out of specification and retraining should have been conducted for failure to recognize the need to retest.

i. There is a failure to implement corrective and preventative actions or follow up on investigations concerning several products which are not limited to Morphine Sulfate Tablets, Metoprolol Succinate ER Tablets and Prenatal Rx1 Tablet AQL coating failures (surface blemishes, chips, breaks, erosion, rough surfaces, illegible code, etc.). Issues are identified in non-conformance reports. Trending has identified repeated failures for tablet defects. Yet, AQL tablet coating failures persist despite coating equipment upgrades, and equipment qualification.

Notably,

- When Prenatal Rx1 bulk tablet batch # 86594 (packaged lot # 87759) failed the AQL in Nov2007, the cause was attributed to inadequate heating of the tablets during the coating process; however, there is no evidence to support this conclusion. Process parameters used to process the tablet pans which failed were similar to other pans which passed and were released.

- When Prenatal Rx1 bulk tablet batch # 91270 (packaged lot # 91752) failed the AQL in Jan 2008 for local erosion

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and surface blemishes, the cause was attributed to inadequate process parameters during tablet coating which affected tablet appearance (low pump rpm and spray rate). However, these are the batch operating parameters specified in the MPR (master production record).

- Prenatal Rx1 bulk tablet lot #'s 86593 (packaged lot # 91695) and 88707 (packaged lot # 89091) failed the AQL on 11-12Dec2007 and 03-05Jan2008, respectively. Root cause was determined to be inadequate temperature in the coating pans. CAPA 12429 was initiated to replace the temperature probes and display for the coating pans yet they have not been replaced on coating pans (b) (4) which were used for these batches.

- Prenatal Rx1, bulk tablet lot #'s 95491 (pkgd. lot 95280), 95492 (pkgd. lot 95279), 95493 (rejected) and 95495 (pkgd. lot 97487), failed the AQL, 29May2008 - 09Jun2008. The cause was attributed to a combination of tooling, compression and coating parameters not optimal for this product. CAPA # 15456 was initiated 23Jul2008 to evaluate and modify as appropriate the tooling, compression and coating parameters. To date this CAPA has not occurred.

- Prenatal Rx1 bulk tablet lot # 94192 (pkgd. lot 95275) failed the AQL in April 2008. The investigation indicated there is an ongoing project to improve/replace coating equipment and to review and improve all coating record parameters and instructions. The coating equipment has since been upgraded and has undergone qualification; yet the product process parameters have not been reevaluated nor revalidated with new coating parameters.

- During packaging of Prenatal Rx1 Tablets, bulk batch # 95488 (pkgd. lot 95276), operators noted unacceptable tablets. A second AQL sample was collected in April 2008 and (product pans of (failed. Tablet weight and hardness checks performed during compression of pans (b) were low but were within the acceptable limits. The cause of the defects was not determined; however, the product formulation and manufacturing process were identified as "strong factors." Follow up states the Research and Development and Operations departments will define appropriate parameters to use in the coating process for this product. The coating equipment has been upgraded and has undergone qualification; yet the product process parameters have not been re-evaluated nor revalidated with new coating parameters. The CAPA is still open pending validation approval.

- Metoprolol ER Tablets, 23.75mg, lot # 95931 failed the AQL for broken tablets in July 2008. The ARN (Analytical Research and Development) department determined the coating process should begin when the exhaust temperature meets (b) (4) due to Metoprolol sensitivity to heat yet no corrective action was taken. The batch record currently specifies a start exhaust temperature range of (b) (4)

- NCR 15223 was initiated for Metoprolol Succinate ER Tablets, 47.5mg, lot # 93933 when the tablets failed the coating AQL in July 2008. The investigation determined the most likely cause was due to reduced air flow during the coating process. The batch was processed using a pan air flow of (b) (4) The target is (b) (4) with

control limits of (b) (4) and an operating range limit of (b) (4) The investigation did not extend to other batches processed at (b) (4) Operators were trained to keep the air flow in the pan at a high rate and at the established targets, yet the batch record was not revised to reflect this requirement. The investigation also did not extend to the core tablets which were observed with similar 'not smooth' areas on the bisect side of the tablet and edge erosion.

- NCRs 10374 (Morphine ER 200 mg tablets), 17418 (Morphine ER 15), 17464 (Morphine ER 15), 17465 (Morphine ER 15), 9363 (Morphine ER 15) all cite numerous reasons for tablets failing AQL, and content uniformity, including but not limited to low LOD % (loss on drying), tablet hardness, changes in recipe, blending and granulation parameters etc. None of the above NCRs adequately followed each of the suspected root causes to investigation completion to obtain definitive results regarding the actual root cause of the failures. The coating process is instead blamed as the causative factor in all prior and subsequent AQL failures. Despite coating pan upgrades, Surface AQL failures persist.

- Identified "possible" root causes of tablet hardness linked to coating issues was not fully investigated. NCR 15810 (12 Aug 2008) was opened to investigate AQL failures of bulk batch # 91290, Morphine ER 60 mg tablets (packaged lot 91765). The NCR Root Cause Analysis states: (b) (4) (b) (4) The investigation failed to examine the hardness issue; no other investigations were opened to address this issue.

- NCRs 17464 and 17465 were opened on 7Nov2008 for Morphine Sulfate ER 15 mg tablets lot #'s 100553 and 100554 documenting AQL failures for coated tablets. A planned deviation 17297, 30Oct2008 was opened to address changing Pan Air Flow parameters from a target of (b) (4) control limits) to a target of (b) (4) (control limits of (b) (4) . A change initiation form (CIF) was opened 30Oct2008 to correct the batch record with the new Pan Air Flow parameters, but as of 06Jan2009 the MBR has not been updated, and the CIF has been closed.

OBSERVATION 5

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.

Specifically,

a. You failed to extend an investigation on oversized Potassium Chloride 10 mEq Capsules to products currently on the market. The ongoing investigation starting 21Nov08 and concerning lot #'s 99906, 99907 and 99908, stated your weight

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sampling procedure was unable to assure that 100% of the distributed encapsulated products were within specifications. These additional products include: Pangestyme CN20, Pangestyme MT16, Pangestyme UL18, Pangestyme UL20, Disopyramide, Potassium Chloride 10 mEq, Micro-K 8 mEq, Micro-K 10 mEq and Potassium Chloride 8 mEq.

b. The investigation of complaint # 17365 concerning an oversized tablet of Hydromorphone HCl USP, 2 mg, packaged lot # 90219, did not extend to other Hydromorphone HCl 2 mg batches to determine if Compression Events logs document the production of oversized tablets. During the investigation, the compression event log was reviewed and found the Main Compression Roll and Dosing allowed for the production of oversized tablets during set-up, which is believed to be due to failure to accept the recipe settings prior to the addition of powder to the hopper.

c. There was a failure to thoroughly investigate discrepancies in stage testing investigations in which the results were invalidated due to "injection error." Identified injection error did not prompt all other injections from the same lot and other lots run on the HPLC to be re-run to determine the extent of the error. Examples include invalidated data for the following:

- Metoprolol IR beads, C-735, lot# 95795, sublot G-blend uniformity samples (b) (4) blend uniformity samples (b) (4) (Stage Testing (ST), ST-08-JUL-001).
- Metoprolol IR beads, C-664, lot# 95005EF-blend uniformity sample ((ST-08-JUL-003).
- Metoprolol IR beads, C-735, lot# 97059D-blend uniformity sample ((ST-08-JUL-006).
- ST-38-JUL-007 on Metoprolol IR beads, C-735, lot# 97059F-blend uniformity sample (
- ST-08-SEP-005 on Metoprolol ER, C-665, lot# 98454-blend uniformity samples (b) (4) and lot# 98462 (on the same HPLC run) blend uniformity samples (b) (4)
- ST-08-SEP-015 on Metoprolol IR beads, C-664, lot# 98478 A/B-blend uniformity sample (b)
- ST-08-OCT-004 on Oxycodone IR blend lot# 97443-blend uniformity sample (
- ST-08-DEC-10 on Metoprolol ER beads, C-665, lot# 102834-blend uniformity sample (b)

OBSERVATION 6

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.

Specifically,

a. Investigations, 9209 and 9820, conducted 06Feb2007 and 01May2007 respectively and covering several batches of Histinex HC Syrup packaged with an incorrect closure, were deficient. In Feb2007, Histinex batches were packaged, in part, using closures which did not have the required foil liners. A partial shipment of faulty closures was received from the vendor. Part of the shipment had an incorrect liner in the cap while the other portion of the shipment contained the

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specified cap liner. The lot of closures in question was vendor's lot # 200623449770. The investigation was closed on 16May2007. (b) (4) batches of Histinex were packaged using this lot of closures and were subsequently released ~~based on a flawed stability study~~. The investigation did not extend to other lots of closures from the same manufacturer, in-house at the time of this investigation.

A second incident occurred on 01May2007. Closure lot # 20070376381 which was received from the same manufacturer on 09Feb2007 contained closures which were again mixed containing the correct and incorrect closures. These closures were once more used to package (b) lots of various drug products; four of which were distributed between 3/20/07 and 05/03/07. The (b) batches included Histinex HC Syrup lots (b) (4) NCR 9820 states an MRB (material review board) will convene to evaluate the four distributed lots. There is no evidence that this occurred.

b. In response to the above investigation a corrective action was initiated to ascertain which bottled lots contained the correct cap. This was to be carried out by using the metal detection system which would identify correctly bottled product. This was performed in June 2007. The corrective action was deficient. Lot # 79677 was not evaluated with the metal detection system as required in the planned deviation report # 9946.

c. No root cause has been identified for (b) (4) batches of Metoprolol Succinate ER Tablets 23.75 mg, which failed dissolution. Lot #'s 95927, 95929, 95930, 95931, 95932, 95933 and 96880 were compressed in July of 2008. Investigations to determine the cause for the dissolution failures were not initiated or were untimely. For example, the investigation into lot # 95931 has not been initiated, the investigation into lot #'s 95929, 95930, 95932 and 96880 were not initiated until 17Dec2008 and are currently open, and the investigations for lot #'s 95927 and 95933, opened 22Sep2008 and 29Oct2008 respectively, have not been completed.

d. The investigations were not timely after (b) batches of Metoprolol Succinate ER Tablets 23.75 mg, lot #'s 93680, 93681, 93684 and 93685 failed dissolution in May (4) 2008. The NCR # 14285 which was initiated on 06May2008, was not completed until 15Aug2008. Investigation 14337 for NCR #14285 was not completed and approved by Quality until 15Aug2008.

e. On or about 08Jul2008, Metoprolol Succinate 23.75 mg ER tablets lot # 95928 failed dissolution at the (b) (4) interval at (b) (specification is (b) (4) An NCR #16532 for this failure was not initiated until 19Sep2008 and investigation # (4) 0639 was not completed and approved until 18Dec2008; the NCR remains open.

f. You failed to adequately investigate and follow up NCR 14908 which was opened 18Jun2008 for Morphine ER 100 mg tablets lot # 96669. The NCR documents chipped tooling (tool set (b) during compression which was replaced with tool set (b) An associated investigation, (b) (4) documents (b) ssues to examine and review-tooling history, tooling destruction, bulk batch tooling set up for lot # 96669, and dies and die locks used for lot # 96669. No documentation of

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the last two issues concerning set up or review of dies and die locks exists.

The investigation failed to expand the inquiry into why the tips were chipping. Review of the compression tool record for tool sets (b) (4) shows a maximum tip force for the tooling set at (b) (4) The recipe report for the (b) (4) (b) (4) for Morphine ER 100 mg tablets, sets the control parameters for Max Punch Force at (b) (4) No investigation is documented to see if the force control went outside (b) (4) during the compression run and the Event Log report for the entire run is unavailable.

g. NCR #'s 13657, and 13699 were initiated on 2Apr2008 and 7Apr2008 respectively, which document under and overage yields outside the (b) (4) stated specifications for Morphine Sulfate ER 60 mg lot # 91290. Scale equipment failure is cited as the causative factor for the overage OOS, however, no investigation into the equipment failure was performed, rather a new scale was used to reweigh material.

h. The investigation was not timely when Hydromorphone HCl 2mg Tablets lot #'s 97847, 97846 and 97848 tested out of specification for blend uniformity on 06Oct2008. The OOS investigation was completed on 14Oct2008. A non-conformance report was initiated on 27 Oct 2008. The investigation has not been completed to date.

i. Your investigations failed to determine the exact source and nature of metal found in drug products manufactured between 7/22/08 and 12/24/08. The metal contamination was found during manufacturing operations in at least (b) batches observed in at least four different products.

Your investigations state possible sources of this metal contamination are raw materials (b) (4) and (b) (4) used to manufacture over 20 different products. As part of your investigation you initiated NCR 17072 for Oxycodone HCl 5 mg, lot 98065. The NCR states (b) (4) (b) (4) But, you failed to initiate an investigation with the raw material supplier for (b) (4) until questioned during this establishment inspection.

OBSERVATION 7

An NDA-Field Alert Report was not submitted within three working days of receipt of information concerning a failure of one or more distributed batches of a drug to meet the specifications established for it in the application.

Specifically,

a. You failed to submit a field alert report to the FDA within three working days for Potassium Chloride Extended Release Capsules lot #'s 99906, 99907 and 99908 as required in procedure 211.100.90 "FDA Field Alert Reporting." Overfilled capsules for these batches were found on 21Nov2008 and not reported to FDA until 06Jan2009.

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b. As part of your investigation of oversized Morphine Sulfate tablets, which was initiated on/about 15May2008, you sorted all tablet products on hand and found oversized tablets with at least 10 more products. No field alert was ever filed and FDA was not notified until 10Oct2008. Products include:

- Isosorbide 30 mg and 60 mg
- Propafenone HCl Tabs 150 mg and 225 mg
- Dextroamphetamine Sulfate Tabs 5 mg
- Plaratase 8000 Tabs

OBSERVATION 8

An annual report did not include a full description of the manufacturing and control changes not requiring a supplemental application, listed by date in the order in which they were implemented.

In a 11Apr1997 Annual Report, there is no explanation or justification for changing time release dissolution specifications for Potassium Chloride ER granules from those referenced in previous annual reports. Currently, when Potassium Chloride ER granules are tested for time release dissolution and the results are not within the specifications, they are compared to PAR (proven acceptable range) specifications which are broader. If results are within PAR, the lot is accepted for further processing of the Potassium Chloride Capsules with no investigation. The specifications are as follows:

PAR Specifications	Specifications
(b) (4)	(b) (4)

The 2008 annual report neglected to reflect a change in the method for Potassium Chloride ER granules allowing the release of in-process material without investigation as long as results are within PAR specifications. Numerous batches which were outside the specification but within PAR have been released with no investigation. For example, ER granules lot #'s 91918 and 91931 were outside the specification but within PAR for (b) (4) No investigation was performed. The ER granule lots were further processed as packaged lot 91830 in Feb2008 and were subsequently released.

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OBSERVATION 9

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, sorting processes are deficient. On 16Mar2008 per NCR 13360, bulk batch # 91290, Morphine ER 60 mg tablets failed AQL due to broken tablets. The batch was (b) (4) re-inspected for AQL failures and passed this initial post-inspection. The product was packaged into finished product lot 91765.

Per the gauge sorting project for oversize tablets the packaged product, packaged batch 91765 (bulk batch 91290) was de-bottled and a second, subsequent sort occurred on 7Jul2008. This successive sort of the packaged lot, revealed tablets **again** failed AQL for surface spots and illegible or incomplete code number.

This second AQL failure was not discovered nor caused a batch rejection during the initial sampling and testing performed in March.

Additionally, two other NCRs 13657, and 13699 were initiated on 2Apr2008 and 7Apr2008 respectively, which document under and overage yields outside the (b) (4) stated specifications. Neither of these instances of failure caused the batch to be rejected, at the time the NCRs were initiated and closed out.

OBSERVATION 10

Rejected closures are not controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

Specifically, you failed to quarantine Applicator Caps lot#123095 for the product Clindesse/Gynasole-1, per NCR #18177, dated 29Dec2008. These applicator tips jammed the production line due to extra flashing on the bottom portion of the cap, resulting in a rough surface. During the inspection, 16Jan2009, the status of the applicators was investigated and found to be in "approved" status for use.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

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FIRM NAME	STREET ADDRESS
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CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug Manufacturer

OBSERVATION 11

Returned drug products held, stored or shipped before or during their return under conditions which cast doubt on their safety, identity, strength, quality or purity are not destroyed.

Specifically, the reason for the return on 10Jun2008 of (b) units of Metoprolol 100 mg, lot #74289, was not documented. This order was initially processed on 17Aug2007. Further, there is no documentation of the storage temperature for the tablets while out of your possession. According to the "Processing of Returned Goods" form dated 10Jun2008, this product was returned to stock without investigation of storage conditions and the resultant effect on the tablets.

OBSERVATION 12

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, you failed to follow your SOP 211.198.8.1.1, which states that consumer complaints shall be closed 45 days of initial entry of the product complaint into the system. Customer complaint numbers 16789 and 16463 for Potassium Chloride 750 mg capsules were opened respectively on 11/6/08 and 10/16/08. On 1/21/09, these two complaint files had yet to be closed by the persons responsible to close the investigation. Both of these consumer complaints were due to a foreign object found in a single capsule at the consumer level.

OBSERVATION 13

Changes to written procedures are not reviewed and approved by the quality control unit.

The procedure on QC general laboratory techniques, submitted for approval 14Feb2008 through the change control process as #12906, was not approved until 17Dec2008. This delay resulted in two laboratory investigations, #'s OOS-08-JUN-048 dated 26Jun08 and ST-08-SEP-010 dated 26Sep08, concerning the incomplete transfer of sample material for Hydromorphone HCl blend lot #'s 95531, 95532 and 97846.

PACKAGING AND LABELING SYSTEM

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OBSERVATION 14

Inspection of the packaging facilities immediately before use is not done to assure that all drug products have been removed from previous operations.

Specifically, line clearance practices are deficient. Nearly 100 NCRs document "Foreign" tablets and other materials found in rooms and on packaging lines during 2007, despite SOPs and work instructions which outline and define pre- and post-inspection procedures. Trending was performed per "EC IV Line Clearance NCR's" graph and CAPA implemented, however, NCR's continued to be document through 2008 and January 2009; at least 72 new NCR's were logged during 2008 after CAPA implementation in August-Nov 2007.

OBSERVATION 15

Examination of packaging and labeling materials for suitability and correctness before packaging operations is not performed.

You continued to use packaging components supplied by the company (b) (4) which was disqualified as a result of your 29May2007 vendor audit without adequate justification. Between 11Sep2008 and 07Nov2008, you continued to package and distribute drug products with closure items, stock numbers P3056, P2772, P27772, manufactured by (b) (4) which were used to package among others, the following products: Metoprolol Succinate ER Tablets 50 mg; Potassium Chloride ER Tablets, 1500 mg; Potassium Chloride ER 750 mg Capsules; Hydrocodone Bitartrate/APAP 16oz/15mL; Prednisolone Syrup 5 mg/5 mL; and Prednisolone Sodium Phosphate Syrup 15 mg/5 mL.

FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 16

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. Cleaning at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality, or purity

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of the drug product has not been sufficient to mitigate foreign material during manufacturing.

At least thirty (30) NCR's in 2008 and twenty-four (24) NCR's in 2007 document escalating issues with the discovery of foreign tablet and materials at various stages of manufacturing from blending through compression and up to the point of packaging. Though several changes to gowning procedures and personnel flow have been implemented, trending has not occurred in the manufacturing departments, and no formal CAPA has been initiated.

b. Sanitization of hoses used in drawing purified water from the closed loop, continuous circulation system does not occur weekly as regularly scheduled per SOP 211.48.01 "Use, Maintenance, and Sanitization of Purified Water USP Point-of-Use Valves and Hoses." Additionally, water ports which are used more frequently are not sanitized at a more frequent rate.

For example, during a documented two month period beginning 01Nov2008 through 31Dec2008, numerous deficiencies exist concerning lack of hose sanitization within a 7 day period. An NCR, #17997, occurring on 09Dec2008 was initiated after coliform bacteria were found in a routine sampling at (b) in granulation room (b) The isolated organism was identified as *Pantoea* spp. Point of Use logs for (b) (4) show hose sanitization occurred on 30Nov2008 and again on 09Dec2008; (b) (4) between cleanings which is outside the time range specified per SOP 211.48.01 as referenced above. Other microbiological failures have occurred as noted in NCR #'s 13584, 14620, 17830, 17831 and 17839 at different plant locations including ECIV, ECIII, and Westport facilities indicating this is a global issue.

Further, you failed to sanitize hoses on the following ports during the dates listed:

- (b) (4) hoses sanitized on (b) (4) and again on (b) (4) ((b) (4) between cleaning) with (b) points of use.
- Port (b) (4) hoses sanitized on (b) (4) and again on (b) (4) (b) days between cleaning).
- Port hoses sanitized on and again on (4) days between cleaning).
- Port hoses sanitized on and again on days between cleaning).
- Port (b) Liquid Manufacturing; hoses sanitized on 10Nov2008 and again 25Nov2008 (b) days between cleaning).
- Port (4) Research and Development; hoses not sanitized from (b) (4) until (b) (4) (at least (b) days between cleanings).
- Port (b) (4) hoses not sanitized from (b) (4) (at least (b days between cleanings).
- Port (b) (4) hose sanitization not documented at all between (b) (4) (at least (b) (4) days between cleanings.)
- Port (b) (4) room (b) (4) hoses sanitized on (b) (4) and again (b) (4) days between cleanings.)
- Port (b) (4) hoses sanitized on (b) (4) and again on (b) (4) days between cleanings.)

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OBSERVATION 17

Routine calibration of automatic, mechanical, and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

a. The following four instruments used in the monitoring of your USP purified water system are not calibrated or verified for accuracy.

- Calibration Group pH Meter, (b) (4)
- (b) (4)
- Flow Rate Indicator, (b) (4) A sticker denotes "Calibration Not Required", but this indicator is monitored in (b) checks on the "Westport USP Water (b) (4) Operations Log," (b) (4)
- Flow Rate Indicator, (b) (4) A sticker denotes "Calibration Not Required", but this indicator is monitored in (b) checks on the "Westport USP Water (b) (4) Operations Log", (b) (4) Unit Outlet". (4)

b. There is no formal procedure describing calibration of the (b) (4) detergent dispensers (b) used to prepare the equipment cleaning solutions (b) (4).

c. The manufacturer's inspection report which specifies the dimensions for punch and die set (b) (4) used to press Hydromorphone 2 mg tablets, was not verified.

d. Specifically, Work Instruction WI-2250-5001-00 "Set up of a (b) (4) does not require the tool match report to be used as the lower punches are placed into the turret.

OBSERVATION 18

Records are not kept for the cleaning and inspection of equipment.

There is no documentation of cleaning the Auto-Fill transfer systems, a vacuum system used to transfer powder blends to the tablet press hopper and cleaning and use logs are not maintained for these systems. This system may be used for approximately 186 different products including but not limited to the following: Isosorbide ER Tablets 60 mg, Morphine Sulfate ER Tablets 100 mg and 200 mg, CareNatal Tablets, and Potassium Chloride ER Capsules, 20 mg.

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OBSERVATION 19

Procedures for the cleaning and maintenance of equipment are deficient regarding sufficient detail of the methods, equipment, and materials used in the cleaning and maintenance operation, and the methods of disassembly and reassembling equipment as necessary to assure proper cleaning and maintenance.

Specifically,

a. There is no cleaning procedure for the Auto-Fill transfer systems(b) with the exception of the Autofiller for the(b) (4) (b) (4) Procedure #WI-CLN-0100-00 for cleaning the(b) (4) is deficient in that it does not specifically address the Autofiller, it only states to clean the "hoppers." It also does not describe how to clean the filler hoses or hopper filter on the Autofiller.

b. The investigation into microbial failures for cleaning validation swab samples collected from the(b) (4) tank after the production of Butaconazole Nitrate Cream 2.0%, was deficient. No additional swabbing for microbial contamination was performed after subsequent cleaning activities.

c. There is insufficient evidence to support adequate cleaning of small areas of equipment such as hoses, piping and valves where swabbing(b) (4) areas is required. Procedures require swabbing for micro, active then surfactant contamination without accounting for the possibility of overlapping samples. Specific examples include but are not limited to:(b) (4) steel tank bottom outlet valve,(b) filling pump body end cap and(b) (4) Applicator filler hopper drain tubes.

OBSERVATION 20

Written records of major equipment cleaning, maintenance, and use are not included in individual equipment logs.

Specifically,

a. The results of visual inspection, cleaning and polishing performed on punch and die sets after use in production are not documented. There are approximately(b) (4) punch and die sets used in the manufacture of about 140 different drug and nutritional products.

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b. A Tool Match Report for punch and die set (b) (4) used in the manufacture of Hydromorphone HCl Tablets, 2 mg, was not run to determine a new pairing when punches were destroyed. For example, upper punches #'s (b) (4) from set (b) (4) were destroyed in May and July and new pairings were not determined.

c. Lower punch # (b) (4) which is used to compress Metoprolol 25 mg tablets, was destroyed on 27May08 and a Tool Match Report was not run to determine a new pairing.

d. The use of tool set (b) (4) for compressing PreNatal Rx1 Tablets batch # 95489 was not documented in the compression tool record.

e. The Compression Tool Record for punch and die set (b) (4) used in the manufacture of Hydromorphone HCl Tablets, 2 mg describes the (b) (4) use with batch number, quantity manufactured and machine number. However, there is no entry for the (b) (4) No investigation was performed to determine what batch (if any) this punch and die was used on.

f. The compression tool record for punch and die (b) used to press Metoprolol 25 mg tablets does not document the machine number, set up initials and start by initials for use (b) No investigation was performed to determine why this information was not recorded.

OBSERVATION 21

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

a. There are no documented specifications for evaluating defects during visual examination of the tool and die sets.
b. During the observation of the equipment set up for Morphine IR 30 mg lot# 98774, on 15Dec2008, the technician used a (b) (4) torque wrench to tighten the turret bolts. The SOP WI-2250-5001-00, "Set up of a (b) (4) requires the use of a (b) (4) torque wrench.

OBSERVATION 22

The building lacks adequate space for the orderly placement of equipment and materials to prevent mix-ups between different components, in-process materials, and drug products and to prevent contamination.

Specifically, the quarantine area and both DEA vaults at the Westport location were over-full with a variety of in-process and finished products preventing adequate cleaning, inspection, and normal movement.

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LABORATORY CONTROL SYSTEM

OBSERVATION 23

The written stability program does not assure testing of the drug product in the same container-closure system as that in which the drug product is marketed.

(b) (4)

(b) (4)

(b) (4)

OBSERVATION 24

Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

Specifically,

a. Metoprolol Succinate ER pellets, product code C-759, lot #'s 96857 and 96858, for use in 23.75 mg tablets, were analyzed for dissolution on 01Jul08 and the raw data reviewed by a member of the data management team on 06Jul08. The review failed to identify the following discrepancies on the worksheet.

- HPLC is circled as being used for dissolution analysis when in fact the UV was used.
- The lot numbers (96957 and 96958) listed on the balance printout for sample weights do not represent the actual lot numbers (96857 and 96858) weighed.

b. The worksheet for dissolution analysis of Metoprolol Tablets 47.5 mg lot #'s 93973 and 94006 does not identify the equipment used as required. This worksheet was reviewed by a data auditor in Aug2008.

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OBSERVATION 25

Verification of the suitability of the testing methods is deficient in that they are not performed under actual conditions of use.

Specifically,

a. The dissolution methods (#1-2115 and #9960) used for analysis of Metoprolol Succinate ER Tablets 50 mg, 100 mg and 200 mg were not properly transferred to the Quality Control Laboratory from Analytical Research department after a significant change to the preparation of dissolution medium occurred in November of 2006.

b. The assay methods for determination of vitamin D3 in stability analysis of products such as Prenatal Rx, Advanced NatalCare and PrimaCare tablets have not been shown to be stability indicating. Also, unknown peaks appearing in chromatograms are not identified or quantified.

OBSERVATION 26

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, the quality unit has failed to review the supplier's laser particle size results for the active pharmaceutical ingredient (API) Metoprolol Succinate USP, to ensure this API meets the internal specifications of (b) (4) (b) (4) and has not qualified the supplier's capability to meet the internal particle size specifications.

OBSERVATION 27

Complete records are not maintained of any modification of an established method employed in testing.

Specifically, for the dissolution analysis of Metoprolol ER pellets lot numbers 96857 and 96858 performed on 01Jul08, the sample preparation was modified to use a sample weight approximately (b) (4) the amount specified in the method.

OBSERVATION 28

Established laboratory control mechanisms are not followed.

Specifically, the yearly preventive maintenance has not been conducted on HPLC (b) as required by LOP 216.00,

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"Shimadzu HPLC Preventative Maintenance Procedure-QC." The last yearly preventative maintenance was performed on 12Oct07.

OBSERVATION 29

Laboratory records do not include complete records of the periodic calibration of laboratory instruments.

Specifically, the data used to show system precision on HPLC (b) after maintenance was performed on 07Aug08, is non existent. Suitability of the instrument can not be verified before proceeding with sample analyses. This HPLC is used for Metoprolol analyses.

OBSERVATION 30

Laboratory records are deficient in that they do not include a complete record of all data obtained during testing.

Specifically, data obtained during visual examination of retain samples performed on 04Dec2008 for Hydromorphone HCl 2 mg Tablets lot #'s 94184, 94186, 94188, 94190, 94191 and 95532, were not recorded in a laboratory notebook at the time analysis was performed.

MATERIALS SYSTEM

OBSERVATION 31

There is a lack of rotation so that the oldest approved stock of components is used first.

a. The use of Metoprolol ER pellets 25 mg (approximately (b) (4) per batch) is not performed in sequential order. Batches of ER pellets are consistently used across multiple batches of Metoprolol tablets 25 mg (approximately (b) (4) of pellets used per batch depending on the assay value) without exhausting one batch before using the subsequent batch. The most prevalent example of this practice is demonstrated with (b) (4) batches of Metoprolol ER pellets 25 mg assayed at values below the desirable target of (b) (4) used in manufacture of approximately (b) (4) lots of Metoprolol ER 25 mg Tablets from August to November 2008. This was done with no formal justification.

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ER Pellets lot#	Release Date	Expiration Date	Assay (mg/g)	Date Used	Quantity Used (kg)	Bulk Tablet	Packaged Lot#
96671	7/8/2008	12/31/2008	(b) (4)	7/30/2008	(b) (4)	95564	95919
				7/31/2008		98503	98871
				8/5/2008		98505	95921
				8/4/2008		98509	Rejected
96855	7/2/2008	12/31/2008	(b)	8/5/2008	(b) (4)	98505	Rejected
				8/4/2008		98507	Rejected
				8/4/2008		98508	Rejected
				11/15/2008		100769	96474
96856	8/11/2008	12/31/2008	(b) (4)	8/5/2008	(b) (4)	98504	98872
				10/31/2008		98535	101587
				10/31/2008		99235	101599
				10/10/2008		100544	ECIV Inventory
96857	7/8/2008	12/31/2008	(b)	9/10/2008	(b) (4)	98523	99663
				10/8/2008		100540	95905
				10/8/2008		100541	95906
				10/9/2008		100542	100927
				10/10/2008		100543	100928
96858	7/6/2008	12/31/2008	(b) (4)	8/5/2008	(b) (4)	98505	95921
				8/4/2008		98510	Rejected
				11/1/2008		100758	101591
				11/3/2008		100762	101595
				11/15/2008		100769	96474
96859	7/9/2008	12/31/2008	(b) (4)	10/28/2008	(b) (4)	98533	101588
				10/27/2008		98534	101589
				10/10/2008		100545	101581
				10/13/2008		100546	101582
				10/14/2008		100547	101583&101585
96860	7/10/2008	12/31/2008	(b) (4)	10/30/2008	(b) (4)	99242	95908
				11/3/2008		100759	101592
				11/3/2008		100760	101593
				11/3/2008		100761	101594

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. David A. Van Vliet, Interim President and Interim Chief Executive Officer

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KV Pharmaceutical Co Westport	2280 Schuetz Road
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63146-3411	Human Drug Manufacturer

Additionally, of the above lots of Metoprolol Tablets 25 mg using ER pellets of lower potency, none have been placed on stability.

b. The use of (b) (4) (approximately (b) (4) per batch) is not performed in sequential order. (b) (4) is consistently used across multiple batches of Metoprolol ER pellets, 25 mg (approximately (b) (4) used per batch) without exhausting one lot before using subsequent batches. The most prevalent example of this practice is demonstrated with batch # 121415 of (b) (4) being used in conjunction with batch # 122572, received approximately three months later. It was used in approximately (b) batches of Metoprolol ER pellets. There were (b) other batches of (b) (4) received between these (b) batches. This was done with no formal justification.

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(b) (4) lot#	Received Date	Expiration Date	Assay (ppm)	ER Pellet lot #	Date Used	Amount Used (kg)
122572	8/20/2008	17000.0000	(b)	98950	11/26/2008	(b) (4)
				98951	11/24/2008	
				98952	11/24/2008	
				98953	11/26/2008	
				98954	11/24/2008	
				101203	11/24/2008	
				101204	11/24/2008	
				101205	11/25/2008	
				101206	11/25/2008	
				101207	11/25/2008	
				101208	11/25/2008	
				101209	11/25/2008	
				101210	11/25/2008	
				101211	11/25/2008	
				101212	11/25/2008	
				101213	11/25/2008	
				101214	11/26/2008	
				101215	12/19/2008	
				101216	12/19/2008	
				101217	12/19/2008	
				101218	12/19/2008	
				101219	1/2/2009	
				101220	1/2/2009	
				101221	1/2/2009	
				101222	1/2/2009	
				101223	1/2/2009	
121415	5/7/2008	17000.0000	(b) (4)	98950	11/26/2008	(b) (4)
				98951	11/24/2008	
				98952	11/24/2009	
				98953	11/26/2008	
				98954	11/24/2008	
				101203	11/24/2008	
				101204	11/24/2008	
				101205	11/25/2008	
				101206	11/25/2008	
				101207	11/25/2008	
				101208	11/25/2008	
				101209	11/25/2008	
				101210	11/25/2008	
				101211	11/25/2008	
				101212	11/25/2008	
				101213	11/25/2008	
				101214	11/26/2008	

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c. Bulk batch 98794 of Hydromorphone was manufactured using (b) (4) lots of Hydromorphone API, lot number 00119768 and 00122132. Lot 0019768 was received prior to receipt of lot no. 00122132. The firm has in stock a total of (b) (4) of Hydromorphone lot 00122132 received 11Jul2008 and 0.455 kg of Hydromorphone lot 0119768 which was received 11Dec2007. Instead of exhausting the entire first in lot of Hydromorphone lot 00119768 a decision was made to use 00122132 received 11Jul2008 first, without justification.

OBSERVATION 32

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

Specifically, the manner in which the water samples are collected does not allow you to determine the actual quality of the water.

QA/QC sampling and testing of water from the closed loop, continuously circulated purified USP water system (SOP 211.84.01 "Sampling, Testing, and Approval of Purified Water USP, Deionized Water, and Potable Water") is not performed at a minimum of (b) (4) nor performed at a frequency to encompass worse case testing. Sampling is not performed more frequently on water ports which have a greater use rate, and sampling is not organized to ensure it is representative of true use scenarios when sampling occasionally occurs post sanitization. SOP 211.84.01 section 7.2.6.2.2 states (b) (4) (b) (4)

- Port (b) (4) **No sampling is documented in the point of use log from 3Oct2008 through 29Nov2008; nearly a two month time span.**
- Port (b) (4) No sampling is documented in the point of use log encompassing the dates from 27Oct2008 until 1Dec2008, which is **outside the time of** (b) (4) **as specified in the SOP. Additionally, a sample was collected** (b) (4) **after hose sanitization with no production use documented between those points.**
- Port (b) (4) Sampling occurred on 27Oct2008 as documented in the point of use log. Sampling failed to occur again until 8Dec2008 and **was not documented again, showing sampling** (b) (4) **during a 2 month time span.**

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PRODUCTION SYSTEM

OBSERVATION 33

Written production and process control procedures are not followed in the execution of production and process control functions.

Specifically,

a. You failed to follow your procedure, 211.68.343, "Assignment and Control of Passwords and Recipes Used for Production Equipment," in which no change documentation was submitted for numerous updated recipe versions. This procedure requires that a (b) (4) (b) (4)

The procedure also requires the (b) (4) (b) (4) NCR #16175 was initiated 31Aug2008 for lack of training and a formal program to ensure compliance with this procedure. CAPA #16175 was initiated 14Nov2008 to implement a program to ensure compliance. However, to date, the program has not been fully implemented. (b) (4) (b) (4) For example (b) (4) for Hydromorphone HCl Tablets, 2 mg is currently on version (b (b) (4) there is no log documenting these changes or copies of the (b) (4) available for review. Additionally, CME, Press Technician has not been trained regarding this procedure. (4)

b. You failed to justify the deletion of (b) (4) testing in the master production record (MPR) for Potassium Chloride Extended-Release Granules (VPCL-2C) with the proper change control documentation. Review of the MPR history for this product found the following description added to revision (This revision reads in part (b) (4) (b) (4) The reason for the revision listed in the MPR is (b) (4) (b) (4) However, during the review of the most recent revision to the MPR (revision (b) the required test wasn't present and hadn't been present since revision (b) The history does not indicate this test was removed, nor does it give a justification for its deletion.

c. You failed to follow your SOP 211.100.94-03 "Change Control" for Change Initiation Form CIF-0007492 for the revision of Potassium Chloride ER Capsule 750 mg method no. 5128.19. Review of the redline document for this method finds Proven Acceptable Range (PAR) specifications were added to the method for the timed release test and states in part: (b) (4)

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(b) (4) specifications. These are shown below. (b) (4)) (b) (4) The (b) specifications are listed in the method and are outside the specifications in LIMS.

The Change Control procedure was not followed in that the CIF document under (b) (4) and (b) (4) does not describe the (b) (4) and the justification for the use of this specification by the analysts.

d. You failed to follow procedure 1300.05-04 which in section 7.6.2 states, (b) (4) (b) (4) The drum will be (b) (4) (b) (4) Upon inspection of the controlled substance vault, (b) (4) (b) (4) numerous containers were found unsealed and in some cases polyplastic bags were the only containment of controlled substances such as Morphine and Oxycodone drug products. In this same procedure in section 7.7.2.1 it states, (b) (4) It was observed that waste had spilled out of unsealed plastic bags and were not contained in the typical fiber drums.

e. Master Production Records (MPRs) for bulk Morphine Sulfate 30 & 60 mg ER Tablets are deficient in that;

- There are no in-process time limits for the time between date of manufacture and the end of the processing of the tablets
- There are two different (b) (4) codes listed for one granulation process
- The 60 mg MPR incorrectly directs omitting of the milling step.

OBSERVATION 34

All processing lines used during the production of a batch of drug product is not properly identified at all times to indicate the phase of processing of the batch.

Specifically, the cleaning and use log for bay number (and (b) (4) did not agree with the in-process batch number listed on the placard at the entrance to Bay (b) (4) ( ) According to the cleaning and use logs, Oxycodone 30 mg, lot # 98705 was to be manufactured and approved on 16Dec2008. However, the placard indicated Oxycodone 30 mg, lot # 98706 had been approved for use on 16Dec2008.

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OBSERVATION 35

Batch production and control records do not include the identification of the persons performing each significant step in the operation, for each batch of drug product produced.

Specifically, prior to production, maintenance technician (b) (4) adjusted press parameters on the PLC and checked tablet characteristics for Hydromorphone 2 mg lot number 94184. However, he did not sign the batch production record as having participated in the batch preparation.

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