- (b) (4) on 12/5/07 started @ (b) (4) failed system suitability. There was a failure to have (b) replicate standard injections with a %RSD at least less than or equal to (b) as required by the firm's method CCQC 34.1. In the (b) (4) standards was not used to calculate the standard area, and (b) (4) samples were not used to calculate %PCMX.

- (b) (4) on 12/5/07 started @ (b) (4) standard not used.

- (b) (4) on 12/06/07 started @ (b) (4) failed system suitability. There was a failure to have (b) replicate standard injections. In the (b) (4) standards were not used, and (b) (4) samples was not used to calculate %PCMX.

- %PCMX was calculated using the standard area of (standards from the (b) (4). However, the (b) standard area used (b) (4) to calculate the average of the areas was not found in the batch records. There is no documentation stating what run this random standard (b) (4) was tested. The %PCMX passed at (b) (%PCMX specification (b) (4).

Techni-care Batch (b)

- (b) (4) on 11/6/07 started @ (b) (4) failed system suitability. No investigation to determine the cause of the failure.

- (b) (4) on 11/6/07 started @ (b) (4) samples (b) (4) this data was not evaluated. Per management the data was "abandon" due to having to run the sample again.

- (b) (4) on 11/7/07 started @ (b) (4) was not used, and both samples (b) (4) were not included in the calculation of %PCMX.

- %PCMX was calculated using the standard area of (standards from the (b) (4) However the (b) standard area (b) (4) and the samples (b) (4) were from a (b) (4) and were in the calculation of %PCMX. The %PCMX passed at (b) The firm did not have (b) replicate standard injections.

b. Techni care surgical scrub samples and the active ingredient (Chloroxylenol) are not bracketed by a standard injection at the end of the HPLC analysis, to ensure instrument chromatogram system is performing correctly. For example,

- On 11/5/07, Techni care active ingredient Chloroxylenol (PCMX) lot 9403 failed its initial potency testing at (b) (4) The same sample was retested and the potency testing was at (b) (4) The OOS stated in part, (b) (4) (b) (4) (b) (4) The active ingredient samples were not bracketed by a standard injection at the end of the run to assure the system is suitable after analytical sequence.

- On 12/4/06, Techni care active ingredient Chloroxylenol (PCMX) lot 9321 failed it initial potency testing at (b) (4) The same sample was retested and the potency testing was at (b) (4) The OOS states in part, (b) (4) (b) (4)

c. After Tech 2000 dental rinse batch 3000 was processed on 4/28/08 the Quality Control Technician obtained a sample from tank (b) of the finished product and allowed it to cool prior to performing the assay. Method CCQ10.0 "QC Method for tank Sampling of Finished Product/Testing & Release," is inadequate in that it does not provide time and temperature specifications for this cooling step.

d. Standard Operating Procedure CCQC30.0 "QC Methods for the Operation and Calibration of the (b) (4) Viscometer," used to measure viscosity for Techni-care surgical scrub is inadequate in that it does not include the water bath step. The technician (b) (4) (b) (4) prior to analyzing the sample. In addition, method CCQC30.0 does not provide (b) (4) specifications for the (b) (4)

OBSERVATION 3

The accuracy, sensitivity, specificity, and reproducibility of test methods have not been established and documented.

Specifically,

a. The microbiological testing of drug products is deficient:

1. The method for microbiological testing of drug products including the antiseptic Techni-care (#CCQC38.1) has not been adequately validated in that:

   - the preparatory test for absence of inhibitory (antimicrobial) properties in the drug products has not been performed.
   - there has been no comparison of the in-house method with the Microbial Limits Test specified in the USP. The USP method requires a preparatory test, the use of a pour plate and specifies a sample size of 10mL. The in-house method requires the (b) (4)

2. (b) Neutralizing agar plates and (b) (4) plates which are purchased from an outside source and used to test drug products for microbiological quality, are not growth promoted to ensure they will support growth.

3. Positive and negative controls are not used during microbial testing of drug products.

4. The microbiological agar plates are not incubated at the appropriate temperature and time for yeast and fungi (b) (b) (4) Additionally, there is no evidence to show the current method will detect yeast and fungi if samples are only incubated for (b) (4) The manufactures certificate of performance for the (b) (4) Neutralizer Agar instructs (b) (4)

b. The assay method CCQC35.1 "QC Method for HPLC Analysis of liquid, Gel, and Crème Care-Tech Products Containing Chloroxylenol, USP (PCMX) (Cont'd)" is deficient in that the method does not describe the necessity

(according to management) to heat, mix and cool the sample prior to analysis.

c. The firm has not evaluated the equivalency of the HPLC to the GC which is required for analysis in the monograph for the Techni-care surgical scrub active ingredient Chloroxylenol (PCMX).

OBSERVATION 4

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,

No investigation was performed when (b) **Formula Magic (Benzethonium Chloirde),** (b) (4) **Techni-care surgical scrub (Chloroxylenol),** and (b) **Tech 2000 dental rinse (Cetylpyridinium Chloride)** batches failed to meet the minimum and/or maximum percentage of theoretical yield. Method CCQC16.0 "QC Methods for Batch History Reconciliation and Verification Before Final Filling (% Yields and Completeness)" specifies a target % yield of (b) (b) and states any deficiencies must be corrected.

(b) (4) Techni-care batches failed actual yield specifications without investigation, was released and distributed:

- Batch # (b) (4) actual yield QC released for distribution on 12/10/07
- Batch # actual yield QC released for distribution on 11/12/07
- Batch # actual yield QC released for distribution on 4/11/08
- Batch # actual yield , QC released for distribution on 4/12/07
- Batch # actual yield QC released for distribution on 12/17/07

(b) (4) Formula Magic batches failed actual yield specifications without investigation, was released and distributed:

- Batch # (b) (4) actual yield QC released for distribution on 3/27/07
- Batch # (b) (4) actual yield QC released for distribution on1/10/08
- Batch # actual yield QC released for distribution on 8/02/07

(b) (4) batches of Tech 2000 Dental Rinse failed actual yield specifications without investigation, was released and distributed:

- Batch # (b) (4) actual yield , QC released for distribution on 4/30/07.
- Batch # actual yield QC released for distribution on 5/10/07.
- Batch # actual yield , QC released for distribution on 3/03/06.
- Batch # actual yield , QC released for distribution on 4/21/06.
- Batch # actual yield , QC released for distribution on 4/25/06.
- Batch # actual yield , QC released for distribution on 4/28/06.
- Batch # actual yield , QC released for distribution on 6/14/06.
- Batch # actual yield QC released for distribution on 9/6/06.

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Mr. John C Brereton , President

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- Batch # (b) (4) actual yield (b) (4) QC released for distribution on 11/2/06.
- Batch # (b) (4) actual yield (b) (4) QC released for distribution on 12/26/06.
- Batch # (b) (4) actual yield (b) (4) QC released for distribution on 7/19/05.

OBSERVATION 5

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,

The investigations performed when Techni-care surgical scrub batches tested OOS for % Chloroxylenol, pH and viscosity were deficient. For example,

a. Batch (b) (4) tested OOS for assay (% Chloroxylenol). The initial result was (b) (4) and the limit (b) (4)
   - The root cause of the OOS was not determined.
   - The investigation attributed the initial cause to laboratory error because the sample failed system suitability, and stated (b) (4) (b) (4) However, there is no indication of the tank level in the batch record and the correct amount of purified water (b) (4) was added to qs the batch. The batch was retested and again failed at (b) (4) The investigation report does not mention this failing result. Additionally, system suitability was not repeated in its entirety; only (b) (4) standard injection was run and system suitability was calculated using the standard areas of the new standard injection with (b) (4) prior standard injections.

     The batch was again retested. Not all data was included. Data for the (b) (4) standard injection and (b) (4) sample injections were not included. There is no documentation explaining why the data was rejected. The batch met specification at (b) (4) and was subsequently released.

b. Batch (b) (4) tested OOS deficient for assay (% Chloroxylenol), pH and viscosity. However, the investigation was inadequate:
   - The investigation reports indicate the tank qs point appeared (b) (4) than expected yet there is no indication of this in the batch record and the correct amount of purified water (b) (4) was added to qs the batch.
   - Not all data was included. Data for (b) (4) sample injections were not included. There is no documentation explaining why the data was rejected.
   - The report states the batch was not mixed and cooled as long as most batches prior to analysis. However, the report does not include any data to support this statement and the master formula record and production record for this batch do not specify a mixing and cooling time.
   - The reprocessing process for this batch was not validated. The investigation report states this batch was (b) (4) (b) (4) (b) (4) However, there is insufficient documentation of this reprocess in that the times these activities occurred were not documented in the batch record.

c. Batch (b) tested OOS for pH and viscosity.

- The root causes for the pH and viscosity failures were not determined.
- The investigation did not mention that an (b) (4) was added to the batch and no deviation report was initiated regarding this discrepancy.

d. Batch (b) tested OOS for %Chloroxylenol. This batch initially was found subpotent at (b) (4)
   - PMCX. The firm determined the cause was due to (b) (4) The batch was retested after additional (b) (4) was added and the batch met specification at (b) (4) PCMX. However, not all data was included. Data from (b) (4) standard injections and from (b) (4) sample injections were disregarded. There is no documentation explaining why this data was rejected. Additionally, to calculate system suitability the firmed averages the standard area for (b) replicate standard injections. Within the calculation the firm used the standard area for (b) (4) standard injections and area from a (b) injection, for which there is no chromatogram to support.

e. No lab investigation documented for Tech 2000 Dental Rinse batch # (b) Initial result (b) (4) Cetylpyridinium Chloride (CPC). (% CPC Specified Range = (b) (4) The OOS report 3/16/07 stated (b) (4) (b) (4) (b) (4) The initial analysis data documents the time of (b) (4) with results of (b) (4) The (b) (4) analysis data documents the time of (b) (4) with the results of (b) (4) The actual time between the (b) (4) analysis was (b) (4) In addition, no temperatures are taken nor documented in the batch record or in the sample analysis raw data to prevent reoccurrence.

f. Specifically, according to management from approximately 11/14/2007 to 2/21/2008 the firm had numerous significant problems with the (b) (4) HPLC instrumentation. Problems Included, out-of-specification potency tests for the active ingredient Chloroxylenol (PCMX). The firm did not evaluate the potential impact this deficiency had on other batches made, and lots of active ingredients tested during this time period and . There were approximately (b) batches made during this time and (b) (4) initial %PCMX testing. There were approximately (b) lots of active ingredients Chloroxylenol tested and (b) failed initial % PCMX testing.

The HPLC maintenance log notebook states on 11/30/07, (b) (4) (b) (4) (b) (4)

1/30/08 the notebook states, (b) (4) (b) (4) (b) (4)

OBSERVATION 6

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

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a. Retrospective "Techni-Care Process Validation Update" for Techni-care surgical scrub performed 3/21/2008 is deficient. The validation did not include an evaluation of all out-of-specification (OOS) batches over the selected time frame 2003-2007 (5 years). The validation was based on data from released batches after reprocessing. The validation did not address batches that may have required reprocessing due to OOS results for % chloroxylenol, pH, and viscosity.

b.

The "Techni-Care Process Validation Update" report did not include manufacturing directions for reprocessing batches to bring them into compliance for pH and the active ingredient Chloroxylenol.

The "Techni-Care Process Validation Update" validation states in (b) (4) micro tests, Techni-care has performed as expected and passed each and every micro test, for example:

- The micro validation results did not include the out-of-specification dated 6/13/07 for batch (b) manufactured on 6/4/07 which failed the initial (b) Neutral Agar micro streak case (b) (4) of incubation. Lab notebook NB045-061 entry at (b) (4) of incubation. The retest passed at (b) (4)

- The micro validation results did not include the out-of-specification dated 8/14/06 for batch (b) (4) manufactured on 8/9/06 which failed the initial (b) Neutral Agar micro streak for the last case after (b) (4) (b) (4) of incubation. Lab notebook NB029-060 entry at (b) (4) (b) (4) The retest passed at (b) (4)

- Micro validation results did not include the OOS dated 10/30/06 for Batch (b) manufactured on 10/24/06 which failed initial case (b) (4) Lab notebook NB029-085 entry at (b) (4) The retest passed at (b) (4)

- The micro validation results did not include the out-of-specification dated 9/19/05 for batch (b) manufactured on 9/13/05 which failed the initial (b) (4) (b) (4) Lab notebook NB021-051 entry at (b) (4) (b) (4) The retest passed at (b) (4)

Additionally, "Techni-Care Process Validation Update" allows for (b) (4) (b) (4) However, these conditions are not defined and the firm lacks written environmental control procedures such as temperature and humidity. Finally, the validation did not include an evaluation of critical operating parameters such as time and temperature.

c. The "Microbiologic Plate Streaking Validation" dated 7/26/04 is deficient. The validation did not include the sample size in which to inoculate each plate with finished product. In addition, the validation did not include an evaluation of all out-of-specifications due to growth.

d. Process validation has not been conducted for **Formula Magic (Benzethonium Chloirde).**

e. Process validation has not been conducted for **Tech 2000 Dental Rinse** since the 2005 installation and 6/26/06

validation of the water purification system.

f. There is no written procedure for the cleaning validation of the ribbon blender including the responsibility for development, performance and approval of the validation study.

Validation issues are a repeat observation from 2004 Warning letter.

OBSERVATION 7

Reprocessing procedures lack the steps to be taken to insure that reprocessed batches will conform with all established standards, specifications, and characteristics.

Specifically,

The firm's reprocessing standard operating procedure CCQC10.0 "QC Methods for Tank Sampling of Finished Product/Testing & Release (Procedure [redacted]) is inadequate in that it allows [redacted] (emphasis added) The procedure is not detailed enough to describe the critical steps and specifications for reprocessing for the Techni-Care surgical scrub batches. When Techni-care batches are reprocessed, significant manufacturing steps are not adequately documented.

For example, Techni-care surgical scrub lot [redacted] was reprocessed when it failed assay (subpotent) and pH. [redacted] was added to the batch to adjust the pH. The batch was reheated, mixed, and cooled over night which according to the investigation report [redacted] The active ingredient Chloroxylenol is also known as PCMX. The reprocessing method does not describe the [redacted] Additionally, these critical reprocessing steps were not documented in the batch record. Other batches which were reprocessed with inadequate documentation include Techni-care lot #s: [redacted]

OBSERVATION 8

Written production and process control procedures are not followed in the execution of production and process control functions and documented at the time of performance.

Specifically,

The firm does not have a quality assurance system in place which requires the timely revalidation of processes whenever there are changes in formulation and processes which could have impact on the effectiveness or product characteristics, and whenever there are changes in product characteristics. For example,

a. The monograph for % Cetylpyruidium Chloride active ingredient used in the manufacturing of Tech 2000 dental rinse product was changed. However, the firm failed to perform revalidation to assure analytical method is suitable for the Tech 2000 dental rinse process. In addition, updates to the validation plan and procedure according to the changes has not been implemented.

b. There was failure to document a significant change in the preparation of the standard stock for Techni-care surgical scrub. For example, method CCQC35: "QC Method for HPLC Analysis of Liquid, Gel, and Crème Care-Tech Products Containing Chloroxylenol, USP (PCMX)" in the initial validation for the detection of PCMX in Tech - Care products instruct to weigh approximately (b) (4) of Chloroxylenol, USP to make the standard stock. The firm amended this amount to (b) (4) without the proper change control. In addition, there was no justification or written documentation regarding a significant unit change from (b) (4) when calculating the Percent PCMX in the product.

OBSERVATION 9

Batch production and control records do not include complete information relating to the production and control of each batch.

Specifically, batch production and control records for the Techni-care surgical scrub and Tech 2000 dental rinse products are deficient in that they do not document the time and date each ingredient is added to the bulk tank during the manufacturing process to ensure ingredients are added at the temperature specified in the master batch record. Additionally, the batch records do not specify the cooling and mixing steps, which management identified as critical to the process. For example,

a. The production manager failed to record on the Techni-care surgical scrub batch record the time when the ingredient (b) (4) was added to the batch 2952. An (b) (4) added on 12/4/07. However, on 12/5/07 an (b) (4) was added to obtain a total amount of (b) (4) The master batch record formula requires (b) (4)

b. The production manager failed to record on the Techni-care batch surgical scrub record the time when the ingredient (b) (4) was added to the batch 2962. The initial amount of (b) (4) was added on 1/14/08. However, on 1/15/08 an additional amount of (b) (4) was added to the batch. The master batch record formula requires (b) (4)

OBSERVATION 10

Written procedures are not established and followed that describe the in-process controls, tests, and examinations to be conducted on appropriate samples of in-process materials of each batch.

Specifically, there is no in-process testing procedure for Techni-care surgical scrub pH for which acceptance criteria is established in spite of the fact there are numerous out-of-specification test results on the final product for pH (range (b) (4) There is no procedure for managing failed in-process results and no manufacturing instruction describing which ingredient to use for adjustments.

a. Notations on Techni-care surgical scrub batch record dated 1/15/08 specify an initial in process test for pH failed at (b) for batch (b) There was another failed in process check at pH (b) (4) after the addition of (b) (4) of (b) (4) The final in process was a subsequent pH check which passed at (b) after an additional (b) (4) of The batch record did not document the date, time and identify the person who performed the checks on the batch sheet.

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b. Notations on Techni-care surgical scrub batch record dated 4/7/08 specify an initial in process test for pH at (b) (4) A pH was taken at (b) (4) after the (b) (4) ingredient and it failed. Subsequently, the pH was taken at (b) (4) The batch record did not document the date, time and identify the person who performed the checks on the batch sheet.

OBSERVATION 11

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

Specifically, changes to the batch formula for Techni care surgical scrub including the (b) (4) and the use of (b) (4) have been made without sufficient justification or change control.

For example, the master record for Techni care surgical scrub requires the (b) (4) However, when formulating batch (b) of this product only (b) (4) was added followed by an (b) (4) for pH adjustments. No deviation was initiated regarding this discrepancy (b) (4) The Master record does not provide a step for making pH adjustment to the formulation.

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.

Specifically, according to management from approximately 11/14/2007 to 2/21/2008 the firm had numerous problems with the (b) (4) HPLC instrumentation. Problems Included, out-of-specification tests for the active ingredient Chloroxylenol (PCMX). The firm did not evaluate the potential impact this deficiency had on other batches made, and lots of active ingredients tested during this time period. There were approximately (b) batches made during this time and (b) failed initial %PCMX testing. There were approximately (b) lots of active ingredients Chloroxylenol tested and (b) failed initial % PCMX testing.

The HPLC maintenance log notebook states on 11/30/07, (b) (4)
(b) (4)

1/30/08 the notebook states, (b) (4)
(b) (4)
(b) (4)

OBSERVATION 13

Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational unit and reviewed and approved by the quality control unit.

Specifically,

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a. The specification for viscosity for Techni-care surgical scrub was changed from (b) (4) on 1/3/08 without scientific justification. Additionally, several Techni-care lots have been released which failed the original specification for viscosity without justification. The investigation reports state, (b) (4) (b) (4) However, there is no scientific evidence to support this conclusion.

b. There is no change control procedure to support all of the significant formulation and process changes that have been made:

Techni-care surgical scrub

- In 1/2008 in-process checks were included as a critical manufacturing step to assists in the monitoring of pH in Techni-care.
- In 1/2007 the amount of (b) (4) in Techni-care was (b) (4) to account for the incorporation of the (b) (4)
- In 1/2007 the Techni-care pH range was re-established to include its original pH maximum from (b) (4) to a new range (b) (4)
- In 1/2007 there was a change in the Techni-care product expiration date for (b) (4)

OBSERVATION 14

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. There was no written record in the "Tank Cleaning and Usage Log" notebook NB062-02 documenting that the ribbon blender has ever had a major cleaning. There has been approximately medicated Formula Magic batches (Benzethonium Chloride) and non-medicated batches made from 10/24/06-5/12/08. On 1/3/08 Formula Magic batch (b) was manufactured and subsequently a non-medicated batch (b) was manufactured on 1/24/08. There is no documented evidence to ensure the non-medicated batch was not contaminated with batch (b) In addition, during the inspection on 5/16/08 the ribbon blinder had product remaining in it from a previous batch (b) manufactured on 3/6/08.

b. On 5/16/08 it was observed in the powder filling room loose duct tape around the chute just above an open funnel where product sits while filling the bottles with Formula Magic. The room was not being used during the time of the inspection. In addition, there is corrosion on ceiling above the production line in the powder filling room.

OBSERVATION 15

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, there is no cleaning procedure for the ribbon blinder (used to manufacture powdered products) including Formula Magic. In addition the method of cleaning demonstrated by management is not effective to reduce product residues

and objectionable microorganisms to an acceptable level **(repeat observation from 2004 Warning Letter).**

OBSERVATION 16

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

Specifically,

You failed to perform degradation testing on the active ingredient (Cetylpyridinium chloride USP) which had an expiration date of (b) (4) and was used in the manufacturing of Tech 2000 Dental Rinse, batch 3000 with a finished product expiration date of 4/09.

OBSERVATION 17

Accelerated stability studies, combined with basic stability information, used to support tentative expiration dates are not supported with ongoing full shelf life studies.

Specifically,

You failed to put a sample on a Stability Study to document how the use of expired Cetylpyridinium Chloride USP effects the finished product Tech 2000 Dental Rinse (batch 3000) expiration. No relevant historical data is available for this concern.

OBSERVATION 18

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

Specifically, there is no written procedure for annual product reviews. The firm does have an annual procedure in place and there are records maintained and evaluated. However, there are no records and or for the evaluation of returned or salvaged drug products. The annual product review failed to include:

- Change control
- Reprocess/reworks/returns/salvages
- Batch rejects
- Validation status

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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OBSERVATION 19

Adequate lighting is not provided in all areas.

Specifically,

There is no light fixture in the (b) (4) production room where the Formula Magic (Benzethonium Chloride) product is manufactured. In addition, the firm's only method of verification that the ribbon blinder is clean is to perform a visual check; this would require adequate lighting to check for powder residue.

OBSERVATION 20

Input to and output from the computer, related systems of formulas, and records or data are not checked for accuracy.

Specifically,

Input and output verification from the computer, related systems of formulas, and records or data are not checked for accuracy.

Specifically, the program used to electronically calculate the assay of Techni-care by HPLC has not been validated and calculations performed by computer are not checked for accuracy.

OBSERVATION 21

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

Specifically,

Batch records for Techni-care surgical scrub do not to have written documentation of a second person verifying the addition of each weighed component on the batch record.

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OBSERVATION 22

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

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 supplier's certificates of analysis for (b) (4) are accepted in lieu of testing these materials for purity, strength and quality without establishing the reliability of the supplier's analyses through validation.

OBSERVATION 23

The quality control unit lacks the responsibility and authority to approve and reject all components, drug product containers, closures, in process materials, packaging material, labeling, and drug products.

As demonstrated by:

a. Care-Tech Laboratories Inc., Standard Operating Procedures CCQC10.0: QC Methods for Tank Sampling of Finished Product/Testing & Release states...

"Procedure:

4. (b) (4)
(b) (4)
(b) (4)

b. Procedure CCQC55.0 "Out Of Specification (OOS) Results" states in part, (b) (4)
(b) (4)
(b) (4)

SEE REVERSE OF THIS PAGE		DATE ISSUED
	WJL	05/22/2008

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	04/28/2008 - 05/22/2008* FEI NUMBER 1940465

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. John C Brereton , President

FIRM NAME	STREET ADDRESS
Care-Tech Labs Inc	3224 S Kingshighway
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Saint Louis, MO 63139	Human Drug Manufacturer

*** DATES OF INSPECTION:**
04/28/2008(Mon), 04/29/2008(Tue), 04/30/2008(Wed), 05/01/2008(Thu), 05/02/2008(Fri), 05/12/2008(Mon), 05/13/2008(Tue), 05/15/2008(Thu), 05/16/2008(Fri), 05/22/2008(Thu)

FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:

Ingrid Y Johnson, Investigator

Warren J. Lopicka, Investigator

SEE REVERSE OF THIS PAGE

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