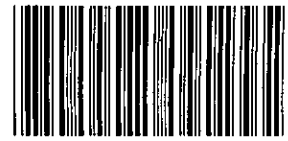


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Rockwell Medical Technologies, Greer, South Carolina: EIR
01/22-02/12/2008

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Establishment Inspection Report
Rockwell Medical Technologies, Inc.
Greer, SC 29650

FEI: **3003040753**
EI Start: 01/22/2008
EI End: 02/12/2008

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SUMMARY

The current inspection of this manufacturer of Dialysate Concentrates was conducted per ATL-DO Administrative Workplans for FY 2008 and CP7382.845, Inspection of Medical Device Manufacturers, (QSIT, Level II). Current inspection found the firm repackages bicarbonate concentrate and manufactures liquid acid concentrate and acetate concentrate. Operations were moved to the current location from Hodges, SC. The firm's name was previously Solution Technologies and it was purchased by Rockwell Medical Technologies, which continued to operate at the Hodges SC address from 2005-2006. Rockwell management moved operations to Greer, SC in January 2007.

The site is registered as a manufacturer. Medical device listings include Dialysate Concentrate for Hemodialysis (Liquid or Powder), 21 CFR 876.5820, Class II devices. The current inspection disclosed the following objectionable findings:

- Packaging process for the RenalPure® powder Bicarbonate has not been validated.
- Automated filling process for RenalPure® liquid acid concentrate gallon containers has not been validated.
- The formulation validation does not demonstrate that the firm can consistently formulate and mix acceptable RenalPure® liquid acid concentrate.

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- Mixing validation does not demonstrate the firm can manufacture RenalPure batches in excess of 6000 gallons
 - Validation of the water system found the firm failed to perform all chemical contaminate testing as specified in the established water testing panel.
 - Performance Qualification for the water system (August 2007) was conducted over a three day period and does not allow for seasonal variations.
 - The final report for DI water system sanitization process revalidation has not been reviewed and approved by management personnel.
 - The firm's quality system has not been reviewed by the management representative.
 - No quality audits have been conducted.
 - Formal procedures for conducting management review are not established.
 - Employees who manage, perform, and assess work affecting quality have not been assigned the appropriate independence and authority to accomplish their work.
 - Employees have not been provided with the appropriate training in quality assurance/quality control and there are insufficient personnel to assure that all procedures are appropriately carried out as required by the quality system.
 - Wall insulation is exposed above the liquid acid concentrate filling line. Procedures to prevent contamination to the product environment are not established.

Management promised that a written response will be provided to ATL-DO

ADMINISTRATIVE DATA

Inspected firm: Rockwell Medical Technologies, Inc.
Location: 604 High Tech Court
Greer, SC 29650
Phone: 864-942-8070
FAX: (864)942-8050
Mailing address: 30142 Wixom Road
Wixom, MI 48393

Dates of inspection: 1/22/2008, 1/23/2008, 1/24/2008, 1/25/2008, 1/28/2008, 1/29/2008,
1/30/2008, 1/31/2008, 2/12/2008

Days in the facility: 9

Participants: Claudette D Brooks, Investigator

HISTORY

Rockwell Medical Technologies, Inc. purchased Solution Technologies and moved operations to the current location in 2007. The firm's corporate office is located at 30142 Wixom Road, Wixom, Michigan 48393. The company was incorporated in the state of Michigan in 1996 and manufacturing includes hemodialysis concentrate solutions and dialysis kits. In March of 2005,

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Rockwell began manufacturing operations in Hodges, South Carolina. Rockwell Medical Technologies operates four plants in the US, Washington, IA; Wixom, MI; Greer, SC; and Grapevine, TX. The majority of domestic sales are delivered by Medi-Surg, a contract company with a fleet of trucks that perform services for customers that are generally not available from common carriers such as stock rotation, non-loading-dock delivery and drum pump offs. A portion of deliveries is provided by common carriers as well.

The firm is registered (1065847) as a manufacturer and has listings for the Dialysate Concentrate for Hemodialysis (Liquid or Powder), Class II devices (See Exhibit 1). Liquid acid is manufactured onsite (RenalPure® Liquid Acid Concentrate for Hemodialysis) and Sodium Bicarbonate is received in 50 pound bags, repackaged, labeled (Renal Pure® Powder Bicarbonate) and then shipped (See Exhibit 2). Formulas of RenalPure® Liquid Acid Concentrate Solution are packaged in 55-gallon drums and/or cases of four 1-gallon (3.78 liters) containers. Renal Pure® Powder Bicarbonate is in packaged in packets to mix 2.5, 15 and 25 gallons. The facility is a 55,000 sq feet warehouse. The firm currently employs 54 full-time employees and production hours are Monday-Friday 6am-2pm and 3pm-11pm.

Current corporate officers include:

Robert L. Chioini, President & CEO

Thomas E. Klema, VP, Secretary, & Chief Financial Officer

Correspondences to the firm should be directed to Anthony Brown, 604 High Tec Court, Greer, SC.

INTERSTATE COMMERCE

Hemodialysis products are shipped to dialysis clinics in GA, SC, NC, VA, AL, and FL. A product list is attached as Exhibit 3.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The inspection was pre-announced on 1/14/08 to local management. Upon arrival at the firm, credentials were shown and the FDA-482, Notice of Inspection was issued to Mr. Anthony E. Brown, Plant Operations Manager. Credentials were presented to him and Mr. Zabdiel Velez, QA Manager. Mr. Brown stated he is the most responsible person and has the most authority at the firm on a day-to-day basis. He stated he has been with the company and in his current position since 10/22/07. He is responsible for the overall monitoring of manufacturing operations and assurance that they manufacture a quality product. Mr. Brown reports to Evan Moilan, Vice President of Manufacturing.

Zabdiel Velez stated he is responsible for firm's SOPs, training, batch record review and all documents related to the product. He has been in his current position since October 2007. He supervises one batch release technician and one label technician. He reports to Ms Jackie Fagerlie, who is reportedly the acting corporate QA manager.

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On 1/25/08 credentials were presented to Mr. Evan Moilan who traveled from his office in @ 111 Los Altos Lakeway, Austin, Texas 78734. He stated he is the management official with executive authority and reports to the CEO/President of the company. He did not participate in this inspection but was available at the firm on 1/25/08 and 2/12/08 for the exit interview. He explained several changes, proposed renovations for the building, and he provided information on the capital investments that the company is making. (NOTE: These improvements will be discussed later in this EIR). A list of the key personnel is available as Exhibit 4.

At the close of the inspection a List of Objections, FDA-483 was issued to Mr. Brown and discussed with him and Messrs. Moilan and Velez.

FIRM'S TRAINING PROGRAM

The firm has a training program and Mr. Brown stated they are working with local city representatives (thru the business sector) to tailor a program to provide current employees with Good Manufacturing Practice (GMP) training. Current training administered includes new employee orientation and specific OJT training, i.e., drum filling operator, production material handler, filler operator, and weigh right operator.

MANUFACTURING/DESIGN OPERATIONS

Operations at this site include formulation/mixing of liquid acid concentrate and packaging and labeling powdered bicarbonate under the "RenalPure" label. Five percent (5%) Acetic Acid is also manufactured at this location. The firm also distributes other Rockwell products, Dri-Sate® Dry Acid Concentrate and SteriLyte® Liquid Bicarbonate. Management reported they follow established standard, ANSI/AAMI RD61-2006 Concentrate for Hemodialysis and RD62-Water Treatment equipment for Hemodialysis. Design and development activities are not performed at this site and are routinely performed at the Wixom, Michigan location.

Liquid Batching

Batch sizes are routinely 3000-6000 gallons; however, some batches are of greater volumes. The batch is formulated in one of two mixing tanks and mixed for 45 minutes. See an example in Exhibit 5 - Mix tank #2. As previously reported product is distributed in 55 gallon drums and 1 gallon containers. The following photographs show firm operations:

Exhibit 6A- Drum cleaning operations area

B-Pressure Wand used for cleaning

C-Drum label removal area

D-Bong Cleaning

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Fifty-five gallon drums are stored outside in an uncovered area and are reusable. They are cleaned with pressurized hot water prior to filling. The following summarizes acidified dialysate concentrate manufacturing process:

Water meter controllers dispense the set volume of water into tank 1 or 2. De-ionized water is added to the tank and raw materials, i.e., sodium chloride, calcium chloride, magnesium chloride, acetic acid and dextrose are manually added to the batch.

Exhibit 7 Container of Acetic Acid as received

Staged quantities of other raw materials (calcium, magnesium, potassium) are added to the batch. Bags of sodium/dextrose are opened at the mouth of the mix tank and are added to the batch. Mix tanks are equipped with two agitators and RPMs are controlled and set at a gearbox. Mr. Brown stated the agitator speed is pre-set and is not routinely changed. Appropriate signatures are added as activities are performed on the bill of materials and batch records.

Time is manually monitored by a clock in the laboratory. See **Exhibit 8- Timing device in laboratory to monitor mixing time.** Batches are routinely mixed for 45 minutes.

The firm performs in-process, middle and ending testing on Sodium, Potassium, Magnesium, Dextrose and Acetic Acid. LAL testing is also performed on each batch of solution. Four employees in the laboratory perform the testing. The work instruction for liquid batch mixing is attached as Exhibit 9.

The remaining operations include re-packaging bicarbonate concentrate using the Weigh Right and Fugi Impulse/Steel Tek sealer. Operations include obtaining a tare weight of bags and adjusting the load cell. The Weigh Right system automatically dispenses material to the load cell at the selected setting. Poly bags are filled and the bag is weighed and the weight is recorded. The bag is weighed to determine if it is within tolerance. If so, it is prepared for sealing on the sealing machine. The bag is checked for leaks and then packaged. Employee work instructions are included as Exhibit 10.

See **Exhibit 11- Bicarb concentrate packaging room**

Exhibit 12- Weigh right filling and weighing equipment

Exhibit 13- Hopper/Conveyor system in packaging room

MANUFACTURING CODES

The following is a lot code breakdown for the 4th batch of liquid acid concentrates manufactured Jan 22, 2008:

Concentrates are identified with the ending year "8"

Month of manufacture "A"

Day of month "22"

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Sequential number "04"
Cases or Drums "C" or "D"

CUSTOMER COMPLAINT

Customer complaints on products manufactured at this site are received by the Wixom customer service group @ (800) 440-3353. The investigation and follow-up activities are performed at the firm. Complaints (2007) include several complaint of incorrect shipment of products; missing labels on 1 gallon containers; and unsealed packages of bicarbonate concentrate.

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

At the close of the inspection a FD-483 was issued to Mr. Anthony Brown and was discussed with him and other firm personnel. Each item was read aloud. Comments and points of clarification are included in the discussion.

Observations listed on form FDA 483

OBSERVATION 1

Management with executive responsibility has not ensured that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization.

Specifically,

1. The firm's quality system has not been reviewed by the management representative. The corporate QA Manager is responsible for ensuring that requirements of the quality system regulations are implemented and maintained on a semi-annual basis. The position is currently vacant and reviews have not been performed as specified in the quality manual.

According to established procedures, the corporate quality assurance manager will review, on a semi-annual basis, the required quality measures (See Exhibit #14). Mr. Evan Moilan stated the firm has hired a corporate quality assurance manager who is scheduled to report on 2/18/08.

2. Quality audits were not conducted at sufficient regular intervals, as prescribed by internal procedures to verify that the quality system is effective. No quality audits have been conducted.

Mr. Velez stated he has established an annual audit 2008 schedule and plans to attend auditor training at a local technical school in a few weeks.

3. Formal procedures for conducting management review are not established. Sources of non-conformances, frequency of reviews, and required attendees are not identified. *[Promised to Correct]*

The quality manual defined the management representative and briefly assigns responsibility for conducting management review. Management informed me that they were working on new detailed procedures for conducting management review.

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4. Employees who manage, perform, and assess work affecting quality have not been assigned the appropriate independence and authority to accomplish their work. For example, the Plant Manager overruled the QA Manager in the release of product that failed to meet the firm's established specifications. *[Under Consideration]*

During revalidation of the DI water system in July 2007, LAL results failed to meet established in house specifications. The plant manager released the product based on products being with-in the AAMI guidelines (See Exhibit 15 pg 2). I stated QA should have the independence to reject or release product and the decision should be totally up to quality as to whether the batch met quality specifications. Mr. Brown provided an addendum dtd 8/30/07 stating initial objections of releasing product were due to timing of product release (See Exhibit 16). Mr. Moilan stated he understood the observation and agreed that QA should have the authority and independence as related to quality issues. He further stated there was a conflict between the two personalities (QA manager and plant manager) involved. Both individuals subsequently left the firm. The observation is annotated "Under Consideration".

5. Employees have not been provided with the appropriate training in quality assurance/quality control and there are insufficient personnel to assure that all procedures are appropriately carried out as required by the quality system.

[Promised to Correct]

Individuals who work in quality have not received training. The QA Manager has been in his current position since the resignation of the previous QA Manager. He currently supervises one batch release technician, one person in the labeling room and the laboratory supervisor. Management promised that additional training is scheduled for quality employees. The objection is annotated "promised to correct".

6. Quality system procedures were not established and documented for all operations at the firm. For example, management has not established formal procedures for performing Bacterial Endotoxin Tests (LAL) or Dextrose Testing.

[Promised to Correct]

The firm was using Solution Technologies procedures, signed by their management team (See Exhibit 17 and Exhibit 18). I stated the firm needs to establish testing procedures that are applicable to the current LAL and dextrose testing. Mr. Robert Piel, Laboratory Supervisor stated the procedures are the same. Management promised to correct this objection.

OBSERVATION 2

Process validation activities and results have not been fully documented.

Specifically, the following processes/operations have not been fully validated:

Dry Powder Sodium Bicarbonate

1. The packaging process for the RenalPure Powder Bicarbonate has not been validated.

a. Validation of the Weigh Right PEI product dispensing machine used to dispense RenalPure Powder Bicarbonate is incomplete. The IQ and OO were performed on 11/23/07 and specifies that 100 consecutive bags @ 1, 2.5 and 5 pounds

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each will be dispensed and verified using a calibrated scale. Fifty bags from each setting were tested.

Qualification of the Weigh Right unit does not include testing 100 bags as outlined (See Exhibit 19). Mr. Moilan stated the firm will continue to manually weigh every filled bag.

b. The Fugi Impulse/Steel Tek sealer has not been validated. *[Promised to Correct]*

The sealing process has not been validated. The sealer is not qualified. (See Exhibit 12). Customer complaints have been received on Management requested that I annotate the item with "promised to correct".

Liquid Acid

2. Automated filling processing for the RenalPure liquid acid concentrate gallon containers has not been validated.

See Exhibit 20A – Fogg filler and filling line

Exhibit 20B-Close-up of rusty filling equipment

One gallon plastic containers are filled on this line. Solution comes from the mix tank thru a 1 um filter and four 0.5 micron filters. After filtration, solution goes to the filler. The containers are sealed and capped on this line also. Management stated the filler speed is controlled; however, no formal validation has been done.

3. The formulation validation documentation does not demonstrate that the firm can consistently formulate and mix acceptable RenalPure liquid acid concentrate which meets established product specifications. Of the twelve batches used to show formulation, six required adjustment in raw materials quantities to make acceptable liquid acid batches.

Six validation batches of twelve were re-adjusted at the in-process check (See Exhibit 21, all are validation batches). I stated to management that validation should show the firm can consistently manufacture acceptable batches otherwise it is simply trail-and-error. The validation report is included as Exhibit 22. Mr. Moilan stated they will respond to the observation.

4. The firm has not fully validated the formulation process for batches of RenalPure in excess of 6000 gallons. At least one of three 6710 gallon batches of Product C-208 in Tank #2 failed to meet initial specifications. Additionally, the amounts of raw materials added to a batch are equal for both 6,000 gallon batches and 6710 gallon batches. *[Promised to Correct]*

See Exhibit 23. Three 6710 gallon batches were run in both tanks 1&2. NOTE: Failing batch was manufactured in Tank #1. Although these large batches were manufactured, the raw material quantities used are the same for both 6000 gallons and 6710 gallons. The only change is in the amount of water (See Exhibit 24 pg 2). Management requested annotation of the item "promised to correct".

Water System Validation

5. The firm failed to perform all chemical contaminate testing as specified in the established water testing panel. Water is not tested for Cyanide, chloramines and free chlorine levels per the established protocol, Validation of Formulation, Design Control #07102.

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The firm's water testing is included as Exhibit 25. The firm's management stated they follow the AAMI standard for hemodialysis concentrate manufacturing. According to the final validation report for formulation, the mix tanks were evaluated per AAMI water panel and microbiology (See Exhibit 22 pg 1). Water is not routinely monitored for cyanide, chloramines and free chlorine as required by the AAMI panel.

6. Performance Qualification for the water system (August 2007) was conducted over a three day period. The validation activities do not include monitoring the system for seasonal variations or changes. *[Promised to Correct]*

The firm has not monitored the water system over a period of time. Current testing schedule is included as Exhibit 26. The DI water system was initially validated Feb 07. In July they removed the ozone generator and added UV filtration. In Sep 07 the firm re-validated after adding 0.05 micron filter housings to increase efficiency. The revalidation final report is attached as Exhibit 27. A diagram of the water system is included as Exhibit 28.

7. The final report for DI water system sanitization process revalidation has not been reviewed and approved by management personnel. *[Promised to Correct]*

See Exhibit 27. Mr. Moilan stated he believed the original report is missing. He requested that I annotate the item "promised to correct".

OBSERVATION 3

Buildings are not of suitable design to perform necessary operations and assure orderly handling of product.

Specifically, the building layout does not facilitate the orderly storage, cleaning, filling and packaging of hemodialysis concentrates. For example:

1. Filling equipment is currently located in a large storage warehouse with no environmental controls. Wall insulation is exposed above the liquid acid filling line. Procedures to prevent contamination to the product environment are not established. *[Promised to Correct]*

Exhibit 29-Wall of production area Many areas of the warehouse have exposed insulation
Management promised to correct these conditions.

2. The dry powder packaging area is not equipped with appropriate air/dust controls.

No air handling units are available in the packaging area. See Exhibit 11 and Exhibit 13.

OBSERVATION 4

Appropriate design, construction, placement, and installation of manufacturing equipment have not been ensured.

Specifically,

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1. Process equipment is old, rusty and in need of general upgrade (conveyors, case makers, mix tanks, storage tanks).
See Exhibit 30 – Production line in open warehouse

Exhibit 31 Class 100 hood in laboratory. Hood is not certified and is currently used for nitric acid testing.

See Exhibit 32A Case Line on Liquid Acid Concentrate filling line

Exhibit 32B Conveyor on filling line

Exhibit 32C Section of Case making on filling line

Exhibit 32D Case Making Equipment

Exhibit 32E Labeling Equipment on filling line. Equipment is in need of upgrade.

2. Hoses and fittings are not properly stored to facilitate draining and cleanliness when not in use. [*Promised to Correct*]
Hoses were lying on the floor when not in use. Management promised that hooks will be installed to hang hoses.

3. Mixing tanks/operations are not designed to prevent the addition of foreign materials to the open mix tanks when formulating the batch. For example, fiber bags of raw materials are opened and poured directly into the tank and large containers of liquid materials are lifted on pallets directly over the mouth of the mix tanks. Additionally, there are no controls in place to prevent spillage of raw materials and to ensure that adequate amounts are added to the batch.

Exhibit 33A & B Mouth of Mix Tank.

Employees stand on platform and open fiber bags over the mix tank #1.

4. Mixing tanks are not designed with appropriate timing devices to ensure uniform mixing. [*Under Consideration*]

See Exhibit 8. Mr. Piel stated it is up to the laboratory to ensure that product is mixed for 45 minutes. Mr. Moilan stated the objection is under consideration.

OBSERVATION 5

Procedures were not followed for the control of products that do not conform to specifications.

Specifically,

I. Several non-conformances (NCRs) are outstanding for several months, for example:

Date NCR Non-conformance

1/12/07 010705 QA released 118 drums; 122 drums were in lot

1/15/07 010707 Product shipped before finished testing complete; later found OOS

1/20/07 010711 Production mistakenly dumped good product instead of OOS material destined for destruction.

9/28/07 110703 Customer cancelled order; customer service shipped anyway

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[Under Consideration]

(See Exhibit 34A) Review of the non-conformance log found several outstanding reports. Management requested that I note that the objection is under consideration.

2. Customer reports of dissatisfaction (complaints) are outstanding and are documented within the non-conformance system, for example,

6/29/07 060724 Customer shorted 2 bags of salt
7/16/07 070717 3 drums of C-216-55 delivered customer needed 5
7/26/07 070730-070731 customers short one drum
7/27/07 070733-070736 incorrect numbers of drums delivered
8/23/07 080719 customer short one drum *[Under Consideration]*

(See Exhibit 34B pg 1-5) I asked Mr. Velez if it is common practice to document customer service issues in the non-conformance system. He stated incorrect quantities and other customer issues are documented in the complaint handling system. The observation is under consideration.

3. Non-conformance #080730 was not available in which plastic materials from super sacks was dropped into a mix tank and wrapped around the propeller.

The documentation of this non-conformance and/or corrective action could not be located by management (See Exhibit 34B pg 5).

4. Approximately ninety-six (96) cases of RenalPure liquid acid concentrate, Batch Number 7C15-01 were destroyed due to "quality issues". Testing release documents indicate the batch failed initial calcium testing 0.34. Pallets #7-16 were released and remaining pallets were held. The firm released 722 cases from the batch without investigation or corrective action of the non-conformance.

(See Exhibit 35 pg 1, 3-4) Review of a customer complaint found that 34 cases / 4 gallons per case of liquid acid concentrate were shipped without labels. Further review of the batch record found 96 cases from the batch were destroyed and the remaining 722 cases were distributed. No other information regarding the non-conformance is available.

5. The firm failed to document a failure of the sanitization process for the water system in September 2007 within the non-conformance system. Water sample endotoxin levels were higher than 2.0EU/ml at several sites and resulted in re-sanitization/re-testing and finished lot investigations for liquid acid concentrate manufactured Sep 26-27, 2007. Established procedure, Non-conformance/Corrective Action Procedure, 900-07, was not followed in documenting the non-conformance/corrective action taken by the firm. *[Reported Corrected not Verified]*

(See Exhibit 36) The firm did not document this incident, along with the investigation and corrective action in the non-conformance system. The established procedure is included as Exhibit 37 pg 2. Mr. Velez stated at the exit interview that he has corrected this deficiency. The item was annotated 'reported corrected not verified'.

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OBSERVATION 6

Corrective and preventive action activities have not been documented, including implementation of corrective and preventive actions.

Specifically, the firm has failed to implement stated corrective action in response to identified quality issues. For example, customers have complained that hydrometers are broken upon receipt. Corrective action (June 2007) that hydrometers are inspected at receiving and again at distribution is not documented.

Mr. Brown stated the hydrometers are inspected; however, the inspections are not documented (See Exhibit 38 pg 1-2).

OBSERVATION 7

Complaints involving the possible failure of a device and packaging to meet any of its specifications were not reviewed, evaluated, and investigated where necessary.

Specifically,

1. At least two customer complaints (0710S011 and 0711S011) that several bags of RenalPure Powder Bicarbonate with holes in the packaging and opened seams were received in Oct and Nov 2007. No corrective actions are documented.

(See Exhibit 39) As previously reported, the sealing process for powder packaging has not been validated.

2. Complaints of delivery of liquid acid into the wrong tank at customer sites are not investigated and no corrective/preventive action is taken, for example, 0707S004 and 0708S003.

(See Exhibit 40 pg 1-2) Root cause investigation and corrective/preventive actions are not documented.

3. The compliant investigation for complaint 0712S015 found the re-tain testing of RenalPure Batch #7E22-04, Product R-240-55 was low in acid. Corrective/preventive action is not documented.

(See Exhibit 41 pg 1-2) The firm confirmed in their investigation that the acid is low for this batch. However, no corrective action was taken in response to confirmation of low acetic acid.

OBSERVATION 8

Procedures for acceptance or rejection of finished device production runs, lots, or batches were not complete and implemented.

Specifically, a corporate procedure for Sampling, Testing and Releasing Hemodialysis Concentrate is currently being used for finished device testing, however specific testing/sampling requirements for hemodialysis products manufactured at this site are not addressed, for example,

- Liquid batch mixing time is not identified

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- All testing on liquid acid concentrate is not performed per the procedure (microbial count, pH, conductivity)
- Powder bicarbonate testing does not include all testing per the procedure (conductivity, pH, density testing).

[Promised to Correct]

(See Exhibit 42 pg 1, 6,7). This procedure is unclear and has not been detailed to include solutions made and distributed from this site. Mr. Brown agreed that the procedure should be clarified and should include operations and testing at this location. The item was annotated promise to correct.

OBSERVATION 9

Process controls do not provide for monitoring and control of process parameters and component and device characteristics during production.

Specifically,

1. DI water was out-of-specification at 76 degrees on 1/29/08. At least two batches of liquid acid concentrate were manufactured.

(See Exhibit 43) The section for temperature is 65-75 degrees.

2. No documentation is available showing water system cleaning and sanitization each month. For example, no records are available for Jan-July 2007 or October 2007.

(See Exhibit 44) Mr. Velez stated the firm is now monitoring and documenting cleaning/sanitization. The system is sanitized using 1% Minnacare cold sterilant and the system is exposed for 30 minutes.

3. The DI water system does not have controls in place to alert employees when water conductivity falls below established specifications (20 uS/cm).

Conductivity is performed daily; however, there are no measures in place to alert employees when conductivity falls as required.

OBSERVATION 10

Equipment used in the manufacturing process has not been appropriately constructed and installed to facilitate maintenance, adjustment, cleaning, and use.

1. Pre-filters (1 um) and post filters (0.05 um) on the water system and filling pumps (1.2 um) are not tested for integrity.

The water system operates in the following manner: a large mixing tank system takes the city water and splits it into two different streams. One cold stream flows to the double backflow prevent valve and the other flows to the hot water heaters. Once the two lines converge, a tempering valve meters the final feed water pass a thermometer that reads the temperature and it enters a lined hose where it flows directly into the 42 cu ft carbon tank. Once the water exits the carbon tank, the water goes thru a DI tank. Once the water is deionized it exits the

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tank and flows thru a 30 inch stainless steel filter housing to trap the resin and the water enters a bulk storage water tank. The water exits the water storage tank and flows thru a 100 GPM 254 nanometer UV light sterilization system. After the water exits the UV sterilization system it continues to flow through 2" scheduled 80 PVC piping passing another sample port prior to entering two 20" stainless steel filter housing equipped with three FiberFlo 50-203 0.05 um filters in the first housing and five FiberFlo 50-203 0.05 um filters in the second housing. The water exits the second 20" stainless steel filter housing thru 2" scheduled 80 PVC passing Site 5 (post filtration of 0.05 um) then splits into two separate lines to feed each mixing tank. Additional filters are on the filling pumps that deliver the solution to the filler. FiberFlo filters are integrity testable (See Exhibit 45).

2. The re-circulation pump on the DI water system was noted cracked and leaking on 1/31/08.

[Under Consideration]

Mr. Brown observed the leak and stated it is scheduled for repairs at the next sanitization. He requested that I annotate the item 'under consideration'.

OBSERVATION 11

The evaluation of potential contractors was not documented.

Specifically, the firm has not evaluated the contract testing laboratory used for monthly water and product testing.

D & D Laboratories, Greenwood, SC has not been evaluated as a contractor for the firm. The inspection found that the firm used an older standard to perform water testing (2001) for the hemodialysis water panel in 2007. A newer standard for this testing is available (2006).

REFUSALS

No refusals were encountered.

GENERAL DISCUSSION WITH MANAGEMENT

Daily discussions were held with management outlining concerns and issues observed during the day's review of operations. Present for the discussion were: Zeb Velez and Anthony Brown. Mr. Evan Moilan stated at the discussion with management that he is the firm's representative with executive authority in the absence of the President Mr. Rob Chioini. He provided detailed information (documents and drawings) of the firm's plans for capital improvements (See Exhibit 46). Proposed upgrades include construction of a new liquid filling area with sanitary finish upgrades; construction of a new powder packaging area; new equipment upgrades and additions to the liquid filling equipment including conveyors and other line components and a new form-fill-seal machine in the powder packaging area. Mr. Moilan explained that he assumed the role of VP of Manufacturing in the August/September time frame 2007 and stated he immediately recognized the need for improvement at this site. He stated he has worked expeditiously to obtain approval from the building landlord to make modifications to plant and to structure suitable liquid and powder filling

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rooms. He provided a copy of the blueprints which are dated 10/5/07. The facility upgrades are scheduled to begin in March 2008 at an estimated cost of \$240,000. Mr. Moilan expressed the firm's willingness to be in compliance with the Agency's requirements and promised that necessary corrections will be made. He stated he would schedule a meeting with district management to discuss the improvements to manufacturing operations and other changes.

ADDITIONAL INFORMATION

Production equipment and the warehouse layout are not conducive to facilitate an orderly processing environment. The following exhibits document current firm conditions.

Exhibit 47 - Carbon & DI Tanks

Exhibit 48 - Dusty cases of finished product stored in warehouse

Exhibit 49 - Ultraviolet Sterilization unit on DI water system

Exhibit 50 - Outside Drum Storage

Exhibit 51 - Back wall of Warehouse

SAMPLES COLLECTED

Documentary sample 301(k) was collected to document IS movement of the raw material, Sodium Chloride USP and movement of finished product Lot 7M26-01C, Renal Pure Liquid Acid Concentrate, Sample #DOC 458660.

VOLUNTARY CORRECTIONS

The Class 100 Laminar flow hood was certified prior to my departure from the firm.

EXHIBITS COLLECTED

- 1-List of 510(k) numbers
- 2-Info on RenalPure Liquid Acid Concentrates/Powder Bicarbonate
- 3-Customer List
- 4-Organizational Chart
- 5- Photo Mix Tank #2
- 6A-D Photo Drum Cleaning Area
- 7-Photo Container Acetic Acid
- 8-Laboratory Close
- 9-Work instruction for liquid batch mixing
- 10-Weigh Right Operations SOP

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- 11-Photo Bicarbonate Concentrate Packaging Area
- 12-Photo of Sealer
- 13-Hopper/Conveyor in Bicarbonate Concentrate Area
- 14-Management Responsibility
- 15-Interoffice memos dtd 7/27/07
- 16-Addendum dtd 8/30/07
- 17-Solution Technologies SOP on LAL Testing
- 18-Solution Technologies SOP on Dextrose Testing
- 19-Weigh Right Validation
- 20A-B Photo Fogg Filler/Filling Line
- 21-In-process Worksheet C-208
- 22-Final Report for Validation of Formulation Tanks 1 & 2
- 23-In-process Worksheet C-208, 7C16-03
- 24-C-208-55, 7C16-03 Batch Release worksheet
- 25-Hemodialysis Water Panel
- 26-Water System Monitoring and Maintenance SOP
- 27-DI Sanitization Process Revalidation dated 8/20/07
- 28-Diagram of Water System
- 29-Photo Production Area/Wall over filling line
- 30-Photo Warehouse Area/Filling Line
- 31-Photo Laboratory Hood
- 32A-E Photo Case Making Equipment/Labeler on Filling Line
- 33A-B Photo Mouth of Mix Tank
- 34A-Nonconformance Log
- 34B-Nonconformance Log
- 35-Complaint 0704S013
- 36-NCR Summary report dated 10/14/07
- 37-Non-conformance/Corrective Action Procedure
- 38-Complaint 0706S007
- 39-Complaint 0710S011
- 40-Complaint 0707S004
- 41-Complaint 0712S015
- 42-Sampling, Testing Release Hemodialysis Concentrate
- 43-Daily DI Water System Data Collection Form dtd 8/23/07
- 44-Water System Sanitization Log
- 45-FiberFlow Fiber Cartridge Filters Info

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46-Proposed Corrective Actions

47-Photo Carbon & DI Tanks

48-Photo Dusty cases of finished product stored in warehouse

49-Photo Ultraviolet Sterilization unit on DI water system

50-Photo Outside Drum Storage

51-Photo Back wall of Warehouse



Claudette D Brooks, Investigator



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