DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 N. Central Expy., ste. 300 Dallas, TX 75204 214 253-5200	06/05-08/2007 FEI NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: George Carlisle Birdsong, Corp. President MAXOR / IVSolutions of Lubbock

FIRM NAME	STREET ADDRESS
IVSolutions of Lubbock	3712 20th Street
CITY, STATE AND ZIP CODE Lubbock, TX 79410	TYPE OF ESTABLISHMENT INSPECTED Compounding Pharmacy

DURING AN INSPECTION OF YOUR COMPOUNDING PHARMACY I OBSERVED:

The following apply to the compounding and supporting operations for *Colistimethate Sodium for Inhalation, (USP 75mg/3ml)* in respule units.

1. The product is not routinely or periodically tested for sterility to demonstrate process control and the consistent ability to perform aseptic fill operations.

2. The above referenced product is not tested for potency of the active ingredient.

3. The pharmacy is currently assigning a ninety day expiration date for the product based on contract lab sterility test results on the "test batch". There is no formal approved Stability Test protocol describing the stability testing requirements and specifications for the product.

4. There are no records / documents, e.g., preparation worksheet and compounding records for the "test batch". As a result there is no lot number information or traceability for the Colistimethate API or diluent solutions (b) (4) and (b) (4)(b) (4) used to compound the "test batch".

5. Only (b) (4) The stability/ test batch comprised of only (b) (4) respule units which is not representative of routine batch sizes which can typically range from (b) (4) respule units. The pharmacy has compounded (b) (4) batches since January 2007.

6. Activities and movement with-in the sterile products preparation room is directed by Policy # PP-21, Title: Sterile Products Preparation Room. A review of the referenced policy revealed the following: There are no statements or requirements addressing the opening and closing of the wooden entry door during aseptic fill operations. The opening of the door has the potential to disrupt air-flows with-in the ante-room and the laminar flow work station(s). The appropriate air-flows are necessary to maintain the required air classifications/environmental control during aseptic fill operations. Additionally, The referenced policy indicates stock supplies may not be stored in the preparation (fill) areas. Unused bags containing respules are routinely stored in the laminar work station.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
		David M. Beltran, Investigator	June 8, 2007

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Lubbock, TX 79410	Compounding Pharmacy

7. During aseptic filling of Colistimethate Sodium for Inhalation, USP 75mg/3ml batch number C75/306012007, the technician performing the fill operations was observed sanitizing (b) (6) gloved hands with an agent ((b) (4) Antiseptic Hand Sanitizer: containing ingredients which include but are not limited to (b) (4) that is contrary to sterile applications for drug products.

8. Labeling for Colistimethate Sodium for Inhalation, USP indicates Keep Refrigerated (2 – 8°C) storage requirements. While the product is shipped using ice-paks, shipping studies have not been performed nor are any documented controls in place to assure the product was not exposed to extreme temperature conditions during shipment which could adversely affect the safety and efficacy of the drug product upon receipt by the end user.

9. Not all patient complaints are documented in a complaint log and/or investigated per requirements specified in Policy number PP-18, Title: Patient Grievance Procedures. E.G., the Pharmacist in Charge described instances when patients would call and complain about melted Ice-Paks in the shipping container upon receipt. The communication from the patients regarding this issue were not documented or investigated.

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