



STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES



WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE  CHANGE LOC  NEW  CURRENTLY NOT OPERATING  CHANGE OWNER

File # 6254

Insp # 123201

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT ANAZOHEALTH CORP		PERMIT NUMBER 15735	DATE OF INSPECTION 12/5/2013
DOING BUSINESS AS		DEA NUMBER BG5703740	PRESCRIPTION DEPARTMENT MANAGER DAVID STEWART JOSEPH
STREET ADDRESS 5710 HOOVER BLVD		TELEPHONE # (813) 882-4500	EXT.
CITY TAMPA	COUNTY 39	STATE/ZIP 33634	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 17564
COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE	COMPOUNDING PERSONNEL	MEDIA FILLED TEST DATE
See attached			
SATISFACTORY    N/A    YES    NO			

High-Risk Level CSPs

1	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i)4.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2	Personnel authorized to compound high-risk-level CSPs completed a media-filled test with high-risk test kit within the past 6 months (semiannually). [64B16-27.797(1)(i), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3	High risk sterile compounded preparations greater than 25 units have antimicrobial testing prior to dispensing [64B16-27.797(7)(a)3., F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Medium and Low-Risk Level CSPs

4	Medium-risk and low-risk preparations must pass sterility testing OR preparations are properly stored and do not exceed time periods specified in rule. [64B16-27.797(1)(n)4.; (o)4.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Personnel authorized to compound medium or low-risk level CSPs completed a media-filled test with medium-risk test kit within the past 12 months. [64B16-27.797(1)(n), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Barrier Isolator or Compounding Environment

6	All sterile compounds prepared in barrier isolator which has been certified as ISO 5 by independent contractor. [64B16-27.797(5)(e), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Compounding environment appropriate for Risk Level (certification by independent qualified organization). Semi-annually for high risk, annual for medium and low-risk.	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	a) Anteroom/Ante area maintained within ISO class 8 [64B16-27.797(1)(a), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	b) Buffer area (clean room) maintained within ISO class 7 (separate room required for high-risk) [64B16-27.797(1)(f); (5)(a), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	c) Laminar Air Flow Hood(s) or class100 ISO room maintained within ISO class 5 [64B16-27.797(1)(k), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Antineoplastic Drugs (Cytotoxins)

9	Spill kits for antineoplastic agent spills. [64B16-27.797(5), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	All cytotoxic preparations are compounded in a vertical flow, Class II, biological safety cabinet in a negative pressure room. [64B16-27.797(6), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

General Requirements

12	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
13	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
14	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16	Current reference material, hard copy or readily available online, are maintained. [64B16-27.797(5)(d), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
17	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
18	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
19	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation and protective apparel for cytotoxins. [64B16-27.797(5)(6), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
20	Documented on-going quality assurance program with audits at regular planned intervals. [64B16-27.797(7), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
21	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
22	Compounding records properly maintained [64B16-28.140(4), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
23	Quantity of compounded drug is reasonable considering the intended use and nature of the practitioner's practice [64B16-27.700(3)(b), F.A.C.]	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Remarks: Anterooms, buffer rooms and LAWFS certified by Medrep June 11, 2013.  
One pharmacist and one technician media fill out of date for high risk compounds.  
Thoroughly reviewed compounding records.  
PDM is Sabeen Hasni PS39363

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Sabeen Hasni

*Sabeen Hasni*

Institutional Representative  
INV 797 Revised 12/12, 12/11 Created 8/11

12-05-2013  
Date

*[Signature]*  
Investigator/Sr. Pharmacist Signature

ID oi129



**STATE OF FLORIDA  
DEPARTMENT OF HEALTH  
INVESTIGATIVE SERVICES  
COMMUNITY PHARMACY**



WWW.DOH.STATE.FL.US

File # 12193

Insp # 119227

ROUTINE  CHANGE LOC  NEW  CURRENTLY NOT OPERATING  CHANGE OWNER

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT ANAZOHEALTH CORP				PERMIT NUMBER 20156				DATE OF INSPECTION 12/5/2013				
DOING BUSINESS AS				DEA NUMBER BG8914182				PRESCRIPTION DEPARTMENT MANAGER				
STREET ADDRESS 5710 HOOVER BLVD				TELEPHONE # (800) 995-4363			EXT. 237	DAVID STEWART JOSEPH				
CITY TAMPA			COUNTY 39	STATE/ZIP 33634			PRESCRIPTION DEPARTMENT MANAGER LICENSE # 17564					
PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN				LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. See attached				
Open	7:30	7:30	7:30	7:30	7:30	X	X	2.				
Close	8	8	8	8	8			3.				
								SATISFACTORY		N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6 Prescription department is clean and safe, has sink/running water convenient to prescription department and adequate equipment as is necessary to the professional practice of pharmacy. [64B16-28.102, F.A.C.]										<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
12 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
13 All controlled substance prescriptions contain information required. [893.04, F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
14 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.]										<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
15 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]										<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
16 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
17 DEA 222 order forms properly completed. [893.07, F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
18 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
19 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
20 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
21 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
22 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
23 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
24 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
25 Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
26 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
27 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
28 Preparation time does not exceed 1 hour when preparing, and administration begins not later than 1 hour following start of immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
29 Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
30 Compliant office use compounding agreement between practitioner and pharmacy available for review. [64B16-27.700 (3)(d)]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
31 Complete office use compounding records available for review. [64B16-27.700 (3)(e)]										<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

\* Note: If establishment is engaged in sterile compounding, a separate inspection form should be completed.

Remarks: Biennial inventory 6-1-2012  
PDM is Sabeen Hasni PS39363

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Sabeen Hasni

*Sabeen Hasni*

12-05-2013

Date

*Joseph*

Investigator/Sr. Pharmacist Signature

ID oi129