(b) (4) This latter method for simulating the sterile filling of SEE REVERSE OF THIS PAGE		DEPARTMENT OF HEAD		BERVICES	
Derror, CO. 80225-0087 TERMEN 3031 236-3000 Faxi (303) 236-3100 TERMEN Max Montro Steposite Weekeers Mase To: Darby C. Brown, Owner/President/CEO Terment Max Man for Steposite Weekeers Mase To: Darby C. Brown, Owner/President/CEO Terment Max Man for Steposite Weekeers Mase To: Compounding Center, Inc. T3796 Compare Mase Englewood, , CO. 80112 Producer of Sterile Drug Products This document lists observations and to they the IDA representative(s) during the inspection of your failing. They are inspectional observation, and do not represent failad Agenedet derivation in repronse to an observation, and do not represent failad Agenedet derivation in the PDA at the eddress above. If you have any questions, please costset FDA at the phone number and address above. DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Assptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (10) (1) in June/July of 2014 indicate microbial failures in ISO 5 hoods where sterile filling of product occurs. Your film continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent rooms. Mon to beserved, the pressure differentials is the condition. There are no written procedures or criteria for assuring	DISTRICT ADDRESS AND PHONE NUMBER	TOOD AND DRU	6 ADMINISTRATION	DATE(S) OF INSPECTION	
13031:236:3000 3010894019 100101211 3010894019 100101211 3010894019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 100101211 1001094019 10010111 1001094019 10010111 1001094019 10010111 1001094019 10010111 1001094019 10010111 1001094019 10010111 1001094019 10010111 1001094019 <t< th=""><th></th><th></th><th></th><th></th><th>2014*</th></t<>					2014*
Industry Information: www.fdd.gov/oc/industry Divexation of the second base second and the					
TO: Darby C. Brown, Owner/President/CEO Distribution Income's Compounding Center, Inc. 13796 Compark Blvd, # 100 Orgenate Section Prestautowets Englewood, , CO 80112 Prestautowets This document lists observations and by the FDA representative(s) during the inspection of your facility. They are inspectional observation, or have inplemented, or plant in any other of an observation, or your may discuss the adjection or eaction with the TDA representative(s) during the inspection or submit This information to FDA at the address above. If you have any questions please context FDA at the phone number and address above. DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: OBSERVATION 1 Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (10) (10) in June/July of 2014 indicate microbial failures in ISO 5 hoods where strife filling of product occurs. Your firm continued to produce in the sapetic processing room and adjacent orons. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 incles water gauge, with the adjacent Vial Washing Room at 0.14 (ISO 8). The pressure differentials between the aseptic production or otherwise. Viable active air monitoring is scheduled to be performed only (1) (2) and not during each duily production shift. Likewise, nor-wiable particulates are not monitored during each production. Pressure and periodic an shift, but are measured per a (1) (2) (3) are nonitoring is not compone hallway is not known or monitored. No documentation of pressure differentials is recorde	Industry Informat	ion: www.fda.gov/oc/indu	strv	2010024012	
Improver Senter Assess Deriver is Compounding Center, Inc. 13796 Compark Bivd, # 100 Contrast, Proceedanty Producer of Sterile Drug Products This document lists observations made by the FDA representative(s) during the impection of your Assesses Drug Producer of Sterile Drug Products This document lists observations and by the FDA representative(s) during the impection of your Assesses During the impection of your Assesses observation, and do not represent a final Agency determinion regarding your compliance. If you have an objection or adverted to an observation, or have implemented, or plan to impediate 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: OBSERVATION 1 Asseptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor There are no written procedures or criteria for assuring pressure differentials between the asseptie processing room and adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent Vial Washing Room at 0.14 (ISO 8). The pressure differentials is recorded during sterile production or halfway is not known or monitoring is scheduled to be performed only (19) and not during each dialy production or halfway is not known or monitoring is scheduled to be performed only (19) and not during each dialy production shift. Likewise, now-viable partinduring durent forms and personnel anononinting is not comonon hal				L	
Itcourt's Compounding Center, Inc. 13796 Compark Blvd, # 100 Producer of Sterile Drug Products This document lists observations and by the FDA representative(3) during the inspection of your facility. They are inspectional observation, and do not represent a final Agency determination regarding your compliance. If you have an objection or granding an observation, and the inducement, correctly eaction in response to an observation, or your my discuss the objection or action with the FDA representative(3) 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: OBSERVATION 1 Asseptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (b) (b) (c) (c) (c) (c) (c) (c) (c) (c) (c) (c		wn, Owner/President/CEO	STDEET ANNDERS		
Control Englewood, , CO 80112 The estimation of sterile Drug Products This document list observations made by the FDA representative(s) during the inspection of sterile Drug Products This document list observations, and they the FDA representative(s) during the inspection of symmetry of the inspection of sterile Drug Products Discretion, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection 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: OBSERVATION 1 Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criterin for assuring pressure differentials between the asptic processing room and adjacent rooms. Also, the pressure in the Aseptic Room (ISO 7) where filling coorn from a common halways is to known or monitored. No documentation of pressure differentials is recorded during sterile production or otherwise. Viable active air monitoring is scheduled to be performed only [1][1][2][4] and not during each daily production with the algicerst formed only strike as analy each and the during sterile production or otherwise. Viable active air monitoring is scheduled to be performed only [1][4][4][6][6][6][6][6][6][6][6][6][6][6][6][6]	- <u>A</u> 1922 - VAL.	ng Center, Inc.		rk Blvd. # 100	
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observation, or have implemented, or plan to implement, corrective action in reagonase to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or abusing this information to FDA at the address above. If you have any questions, please contact FDA is the phone number and address above.	CITY, STATE, ZIP CODE, COUNTRY	ing concorr mor	TYPE ESTABLISHMENT INS	PECTED	
observations, and do not represent a final Agency determination regarding your compliance. If you have no disjection regarding an observation, you may discuss the objection or action with the FDA representative(5) 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: OBSERVATION 1 Asceptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (D) (4) in June/July of 2014 indicate microbial failures in ISO 5 hoods where sterile filling of product occurs. Your firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent rooms. When observate, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) super filling occurs was 0.13 inches water gauge, with the adjacent rooms. Also, the pressure differentials between the aseptic processing room and adjacent rooms. When observed, the pressure of the pass room/box area separating the filling room from a common hallway is not known or monitoring is scheduled to be performed only by (D) (4) and not during each daily production shift. Likewise, non-viable particulates are not monitored during each production stress in the ISO 5 area is only scheduled to be performed only where gloved hands are tested using contact plates. OBSERVATION 2 Proceclures designed to prevent mi	Englewood, , CO	80112	Producer of	Sterile Drug Produc	ts
OBSERVATION 1 Asceptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (b) (4) in June/July of 2014 indicate microbial failures in ISO 5 hoods where sterile filling of product occurs. Your firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent vial Washing Room at 0.14 (ISO 5). The pressure of the ISO 7 Aseptic Room is not shown positive to all adjacent vial Washing Room at 0.14 (ISO 5). The pressure of the ISO 7 Aseptic Room is not shown positive to all adjacent vial Washing Room at 0.14 (ISO 5). The pressure of the ISO 7 Aseptic Room is not shown positive to all shown or monitored. No documentation of pressure differentials is recorded during each daily production shift. Likewise, non-viable particulates are not monitored during each production shift, but are measured per a (D) (4) as well, and is not associated with daily sterile production. Personnel monitoring is not conducted on employees during aseptic filling operations. Microbiological personnel surfaces annalies (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring to be sterile do not include adequate validation of the sterilization process. OBSERVATION 2 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. SEE REVERSE Michael A. Charles, Investigator Michael A. Charles, Investiga	observations, and do not repr observation, or have implem action with the FDA represent	resent a final Agency determination reg ented, or plan to implement, corrective ntative(s) during the inspection or subm	arding your complia action in response to it this information to	ace. If you have an objection rega	arding an the objection or
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Cleanroom Certification conducted by contractor (b)(4) in June/July of 2014 indicate microbial failures in ISO 5 hoods where sterile filling of product occurs. Your firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent Vial Washing Room at 0.14 (ISO 8). The pressure of the ISO 7 Aseptic Room is not shown positive to all adjacent rooms. Also, the pressure differential of the pass room/box area separating the filling room from a common hallway is not known or monitoring is scheduled to be performed only (b)(4) and not during each daily production shift. Likewise, non-viable particulates are not monitored during each production shift, but are measured per a (b)(4) as well, and is not associated with daily sterile production. Personnel monitoring is not conducted on employees during assectiations. Microbiological personnel surface samples (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring of employees is conducted during (b)(4) of sterile filling performed on-site. One is a sterile filling of employees is conducted filling of (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) This latter method for simulating the sterile filling of (b)(4) This latter method for simulating the sterile filling of (b)(4) This latter method for simulating the sterile filling of (b)(4) This latter method for simulating the sterile filling of (b)(4) This latter method for simulating the sterile filling of (b)(4) This latter met	DURING AN INSPECTION C	DF YOUR FIRM WE OBSERVED:			
Cleanroom Certification conducted by contractor (b)(4) in June/July of 2014 indicate microbial failures in ISO 5 hoods where sterile filling of product occurs. Your firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent Vial Washing Room at 0.14 (ISO 8). The pressure of the ISO 7 Aseptic Room is not shown positive to all adjacent rooms. Also, the pressure differential of the pass room/box area separating the filling room from a common hallway is not known or monitored. No documentation of pressure differentials is recorded during sterile production or otherwise. Viable active air monitoring is scheduled to be performed only (b)(4) and not during each daily production shift. Likewise, non-viable particulates are not monitored during each production shift, but are measured per a (b)(4) eschedule. The measurement of microbial contamination on work surfaces in the ISO 5 area is only scheduled to be performed (b)(4) as well, and is not associated with daily sterile production. Personnel monitoring is not conducted on employees during aseptic filling operations. Microbiological personnel surface samples (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring to be sterile do not include adequate validation of the sterilization process. There are (b)(4) of sterile filling performed on-site. One is a sterile fill into (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4	OBSERVATION 1				
hoods where sterile filling of product occurs. Your firm continued to produce in these hoods without sufficient frequency of environmental monitoring to assure an acceptable operating condition. There are no written procedures or criteria for assuring pressure differentials between the aseptic processing room and adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent rooms. Also, the pressure differential of the pass room/box area separating the filling room from a common hallway is not known or monitored. No documentation of pressure differentials is recorded during sterile production or otherwise. Viable active air monitoring is scheduled to be performed only (D) (4) and not during each daily production shift. Likewise, non-viable particulates are not monitored during each production shift, but are measured per a schedule. The measurement of microbial contamination on work surfaces in the ISO 5 area is only scheduled to be performed (D) (4) as well, and is not associated with daily sterile production. Personnel monitoring is not conducted on employees during assplic filling operations. Microbiological personnel surface samples (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring of employees is conducted during (D) (4) where gloved hands are tested using contact plates. OBSERVATION 2 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. There are (D) (4) of sterile filling performed on-site. One is a sterile fill into (D) (4). This method has a Media Fill program to simulate. The other filling method involves (D) (4). (D)	Aseptic processing areas	are deficient regarding the system f	or monitoring envi	ironmental conditions,	
adjacent rooms. When observed, the pressure in the Aseptic Room (ISO 7) where filling occurs was 0.13 inches water gauge, with the adjacent Vial Washing Room at 0.14 (ISO 8). The pressure of the ISO 7 Aseptic Room is not shown positive to all adjacent rooms. Also, the pressure differential of the pass room/box area separating the filling room from a common hallway is not known or monitored. No documentation of pressure differentials is recorded during sterile production or otherwise. Viable active air monitoring is scheduled to be performed only (b)(4) and not during each daily production shift. Likewise, non-viable particulates are not monitored during each production. Personnel monitoring is not conducted on employees during aseptic filling operations. Microbiological personnel surface samples (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring of employees is conducted during (b)(4) The result of the sterilization process. Description of the sterilization process. There are (b)(4) of sterile filling performed on-site. One is a sterile fill into (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) (b)(4) This method has a Media Fill program to simulate. The other filling of (b)(4) This method has a Media Fill program to simulate. The other filling of (b)(4) Thas alter the other filling the ste	hoods where sterile filling	g of product occurs. Your firm conti	inued to produce in		
Likewise, non-viable particulates are not monitored during each production shift, but are measured per a schedule. The measurement of microbial contamination on work surfaces in the ISO 5 area is only scheduled to be performed (b)(4) as well, and is not associated with daily sterile production. Personnel monitoring is not conducted on employees during aseptic filling operations. Microbiological personnel surface samples (such as fingers, forearm, chest, etc.) are not taken with association of sterile drug production at all. The only surface monitoring of employees is conducted during (b)(4) where gloved hands are tested using contact plates. OBSERVATION 2 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. There are (b)(4) of sterile filling performed on-site. One is a sterile fill into (b)(4) This method has a Media Fill program to simulate. The other filling method involves (b)(4) EXERCISES OF THIS PAGE Michael A. Charles, Investigator	adjacent rooms. When ob with the adjacent Vial Wa adjacent rooms. Also, the	served, the pressure in the Aseptic 1 ashing Room at 0.14 (ISO 8). The p pressure differential of the pass roo	Room (ISO 7) who ressure of the ISO om/box area separa fferentials is record	ere filling occurs was 0.13 incl 7 Aseptic Room is not shown ating the filling room from a co ded during sterile production o	nes water gauge, positive to all common hallway or otherwise.
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process. There are (b) (4) of sterile filling performed on-site. One is a sterile fill into (b) (4) This method has a Media Fill program to simulate. The other filling method involves (b) (4) (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of SEE REVERSE OF THIS PAGE Michael A. Charles, Investigator 08/11/2014	Likewise, non-viable part schedule. The measureme (b) (4) as well, an employees during aseptic are not taken with associa	iculates are not monitored during ex ent of microbial contamination on w d is not associated with daily sterile filling operations. Microbiological	ach production shi ork surfaces in the production. Perso personnel surface I. The only surfac	ft, but are measured per a e ISO 5 area is only scheduled onnel monitoring is not conduc samples (such as fingers, fore e monitoring of employees is o	(b) (4) to be performed eted on arm, chest, etc.) conducted
adequate validation of the sterilization process. There are (b) (4) (b) (4) This method has a Media Fill program to simulate. The other filling method involves (b) (4) This method has a Media Fill program to simulate. The other filling method involves (b) (4) This method has a Media Fill program to simulate. The other filling method involves (b) (4) This latter method for simulating the sterile filling of SEE REVERSE OF THIS PAGE Michael A. Charles, Investigator O8/11/2014	OBSERVATION 2				
(b) (4) This method has a Media Fill program to simulate. The other filling method involves (b) (4) (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) This latter method for simulating the sterile filling of (b) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4			on of drug product	s purporting to be sterile do no	ot include
SEE REVERSE OF THIS PAGEMichael A. Charles, Investigator08/11/201408/11/2014	(b) (4) <mark>.</mark> This	method has a Media Fill program to (b) (4	o simulate. The oth	her filling method involves	(b) (4) ing of
SEE REVERSE OF THIS PAGE Isabel Y. Espinosa, Investigator 08/11/2014				12	-DATE ISSUED
	SEE REVERSE	아이는 정말 가슴다는 정말 방법을 들었다. 것이 가지 않는 것이 집에 가장 하는 것이 가지 않는 것이 많이 가지 않는 것이다.	22~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		08/11/2014
FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS PAGE 1 OF 3 PAGE	FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSP	ECTIONAL OBSER	VATIONS	PAGE 1 OF 3 PAGES

DEPARTMENT OF HE	ALTH AND HUMAN	
DISTRICT ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087)		07/28/2014 - 08/11/2014*
Denver, CO 80225-0087		FEINUMBER
(303) 236-3000 Fax: (303) 236-3100		3010894019
Industry Information: www.fda.gov/oc/in-	dustry	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED		
TO: Darby C. Brown, Owner/President/CE	0	
FIRM NAME	STREET ADDRESS	
Brown's Compounding Center, Inc.	13796 Comp	ark Blvd. # 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT IN	ISPECTED
Englewood, , CO 80112	Producer o	f Sterile Drug Products
Betamethasone Inj does not have a Media Fill performed.		

Also, there are no established procedures for conducting documented smoke studies (e.g., review/conclusion whether

acceptable) under dynamic conditions in order to show proper design and control in preventing turbulence and stagnant air in aseptic processing areas.

There are no written procedures for stopper cleaning (conducted manually), nor are stoppers (used in the sterile filling of Betamethasone Injection) being tested for endotoxins.

The water produced from your **(b)** (4) has not been sampled and tested/analyzed, and there is no established monitoring program for this water manufacturing. Validation of this manufacturing process has not been performed. There is no documentation to show that this water is not a microbiological and endotoxin source. Water of unknown quality from this system is used to wash vials and stoppers used as containers/components in sterile filling of Betamethasone Injection.

OBSERVATION 3

Control procedures are not established which monitor the output and 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.

Validation for the sealing process of plastic bags used in the packaging of materials for autoclave sterilization was not performed. Prior to autoclaving, stoppers and vials are placed into plastic bags and then sealed with a twist tie. There is no documented evidence that this process can produce a seal effectively so that packaged items remain sterile as they are taken from the **b** (4) Neither has

seal (package) integrity testing been performed. These vial and stopper components are used in the sterile filling of Betamethasone Injection.

OBSERVATION 4

The written stability program for drug products does not include reliable, meaningful, and specific test methods.

There is analytical data to support the potency of drugs produced, but analytical methods used for assay analyses of drugs are not validated (i.e., the accuracy, sensitivity, specificity, and reproducibility of test methods have not been established), neither is sterility nor endotoxin testing performed at the claimed shelf life to support the expiration dating.

FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 2 OF 3 PAGES
SEE REVERSE OF THIS PAGE	Michael A. Charles, Isabel Y. Espinosa,	Investigator	08/11/2014
	EMPLOYEE(S) SKONATURE		DATE ISSUED

	FOOD AND DRU	LTH AND HUMAN SERVICES IG ADMINISTRATION	
DISTRICT ADDRESS AND PHON	ENUMBER	DATE(S) OF INSPECTION	10.01.1.
6th & Kipling Denver, CO 8	St. (P.O. Box 25087)	07/28/2014 - 08/11 FEI NUMBER	/2014*
	0 Fax:(303) 236-3100	3010894019	
Industry Info	rmation: www.fda.gov/oc/indu	stry	
	Brown, Owner/President/CEO		
FIRM NAME		STREET ADDRESS	
Brown's Compo	unding Center, Inc.	13796 Compark Blvd, # 100	
Englewood, ,		Producer of Sterile Drug Produ	cts
		1	
OBSERVATION	5		
Reports of analysis	from component suppliers are accepted in	lieu of testing each component for conformit	with all
		t one specific identity test on each component	
		alidation of the supplier's test results at approp	
Duria componente a	manufact based on the manufacture of	- tifi-to - four large (O - f A) and up trating h	
		ertificate of analysis (C of A), and no testing b is no sampling and testing of incoming materi	
		on and review, such as a cursory examination	
Analysis, is conduc	ited.	· ·	
* DATES OF INSPI			
07/28/2014(Mon), 07	/29/2014(Tue), 07/30/2014(Wed), 07/31/2014	(Thu), 08/06/2014(Wed), 08/11/2014(Mon)	
	EMPLOYEE(S) SIGNATURE		DATE ISSUED
SEE REVERSE	Michael A. Charles, Investi Isabel Y. Espinosa, Investi	.gator	08/11/2014
OF THIS PAGE	Teaper 1. Esbruosa, ruvesci	galve	00/11/2014

FORM	FDA 4	83 (09/0	8)	

.

INSPECTIONAL OBSERVATIONS