	OF HEALTH AND HUMAN SERVICES AND DRUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	10	DATE(S) OF INSPECTION	
10903 New Hampshire Ave - White Oak (Bldg. 51 Rm. 4225) Silver Spring, MD 20993		08/07-11/2017	
Phone: 301-796-3334 email: CDEROSIAB@fda.hhs.gov	, F	EINUMBER	
Industry Information: www.fda.gov/oc/industry		3007719313	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			
TO: LIN Jian Qiu, President			
FIRM NAME	STREET ADDRESS		
Zhejiang Hisun Pharmaceutical Co., Ltd.	46 Waisha Road, Jiaojiang District		
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT IN		
Taizhou, Zhejiang, 318000. CHINA	API/Finished Drug Prod	luct Manufacturer	
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPR OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETER OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURIN YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE	RMINATION REGARDING YOUR COMPLIAN NT CORRECTIVE ACTION IN RESPONSE NG THE INSPECTION OR SUBMIT THIS IN	ICE. IF YOU HAVE AN OBJECTION REGARDING AN TO AN OBSERVATION, YOU MAY DISCUSS THE	
DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:			
OBSERVATION I			
Laboratory records do not always include relevan	nt metadata in order ensure es	tablished procedures are followed.	
Specifically, during our review of historical (201 support of <sup>(b) (4)</sup> API DMF <sup>(b) (4)</sup> and <sup>(b) (b)</sup>	(4) API DMF (b	phy (HPLC) data collected in (4), we found that the integrity	
of data collected and reported could not be fully	verified:		
For example (this list is not exhaustive):			
A) For $^{(b)(4)}$ APl			
<ul> <li>a) The audit trail for stability data collected at the review. According to your analyst, the audit trail</li> <li>b) Data for the 0 and 24 month stability timepoin HPLC systems with no system audit trail or other</li> </ul>	l was not archived and cannot ts for batch <sup>(b) (4)</sup> were co	be retrieved. Illected using stand-alone Agilent	
B) For (6) (4) API			
a) Data for the 0 month stability timepoint for ba system with no system audit trail or other control		ing stand-alone Agilent HPLC ity.	
OBSERVATION 2			
	eaning and maintenance of eq	uipment.	
OBSERVATION 2 Written procedures are deficient regarding the cla SEE	eaning and maintenance of eq		

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CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
Taizhou, Zhejiang, 318000, CHINA	API/Finished Drug	API/Finished Drug Product Manufacturer	
	i i		
Specifically,			
A) During our review of your cleaning validation	n study performed for the	(b) (4) tablet press to be used in	
		ic rationale (e.g. risk assessment)	
justifying the <sup>(b) (4)</sup> sampling points.		(	

Additionally, there are no specific instructions (e.g. diagrams, pictures) available to define where the swabbing was to take place. For example, your validation report states that the <sup>(b)(4)</sup> inner surface" was sampled; however, there is no evidence available to define the sampling location in order to ensure that the worst-case location was sampled.

B) Your firm uses purified water as the solvent during routine cleaning of the <sup>(b) (4)</sup> tablet press following the manufacture of <sup>(b) (4)</sup> tablets, however, there has been no scientific evaluation to justify the use of purified water and evaluate its effectiveness considering the API and excipients used during manufacturing.

C) Your cleaning procedure document H5-SOP-5204 for cleaning of the <sup>(b)(4)</sup> tablet press lacks specific instructions regarding how to disassemble/reassemble the equipment, the temperature of purified water to be used, and the cleaning tools (e.g. brush) and actions to be used.

## **OBSERVATION 3**

Storage conditions for samples retained for testing are not monitored appropriately.

Specifically, your firm's stability chambers' routine monitoring is performed at the locations found to be the highest temperature and humidity during the qualification studies. These locations do not represent the worst-case locations (coldest/lowest humidity) within the chambers.

DRM FDA 483	(9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	Page 2 of 5
REVERSE OF THIS PAGE	PED PP	Peter E. Baker, Investigator Parul Patel, Investigator	08/11/2017
SEE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10903 New Hampshire Ave - White Oak (Bldg. 51 Rm. 4225) Silver Spring, MD 20993 Phone: 301-796-3334 email: CDEROSIAB@fda.hbs.gov Industry Information: www.fda.gov/ac/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: LIN Jian Qiu, President FEM NAME STREET ADDRESS Zhejiang Hisun Pharmaceutical Co., Ltd. 46 Waisha Road, Jiaojiang District GTY.STREAN 2/P CODE Type of ESTABLISHMENT INSPECTED Taizhou, Zhejiang, 318000, CHINA APU/Finished Drug Product Manufacturer Records are not completed contemporaneously. Specifically, during my inspection of your microbiology laboratory on 08/08/17, 1 observed your microbiologist preparing to load the purified water and form of the incubator for samples collected and prepared earlier that day. However, the sample preparation worksheets for these samples were either partially completed or blank. OBSERVATION 5 Laboratory records do not include complete data derived from microbial limit testing to ensure established procedures are followed. Specifically, 1. During our review of the microbial limits test method validation for for failed for main and form for sample scales: a) The weight of product sample used is not documented. b) The initials and/or signature and date of the analyst are not documented on microbial test record sheets. c) There is no documentation to demonstrate when and who performed the following discrepancies: 2. Our review of historical stability data for form Tablets for may and form for for form for form for form for form for form for form form			ALTH AND HUMAN SERVICES RUG ADMINISTRATION	
10903 New Hampshire Ave - White Oak (Bidg. 51 Rm. 4225)       08/07-11/2017         Silver Spring. MD 20993       Phone: 301-79-6334 email: CDEROSLAB@/dta.hhs.gov       30/07719313         NAME AND ITTLE OF NORMOUNT TO WHOM REPORT IS ISSUED       30/07719313         TO:       LIN Jian Qiu, President       STREET ADDRESS         Zhejiang Hisun Pharmaceutical Co., Ltd.       46 Waisha Road, Jiaojiang District         CITY, STATE AND 2P CODE       TYPE OF ESTABLISHMENT INSPECTED         Taizbou, Zhejiang, 318000, CHINA       API/Finished Drug Product Manufacturer         Records are not completed contemporaneously.       Specifically, during my inspection of your microbiology laboratory on 08/08/17, 1 observed your microbiologist preparing to load the purified water and <sup>BUM</sup> plates into the inclubator for samples collected and prepared earlier that day. However, the sample preparation worksheets for these samples were either partially completed or blank.         OBSERVATION 5       Laboratory records do not include complete data derived from microbial limit testing to ensure established procedures are followed.         Specifically,       1. During our review of the microbial limits test method validation for <sup>BUM</sup> and <sup>BUM</sup> transfer between incubators.         2) Our review of historical stability data for <sup>BUM</sup> and <sup>BUM</sup> and <sup>BUM</sup> and <sup>BUM</sup> and <sup>BUM</sup> transfer between incubators.         2) Our review of historical stability data for <sup>BUM</sup> and <sup>BUM</sup> and <sup>BUM</sup> and <sup>BUM</sup> transfer	DISTRICT OFFICE			
Silver Spring, MD 20993 Phone: 301-796-3334 email: CDEROSIAB@dda.hhs.gov Industry Information: www.fl.agev/cofindustry MME AND THE OF REVIEWOULD SerVerT IS ISSUED TO: LIN Jian Qiu, President FRM NME Zhejiang Hisun Pharmaceutical Co., Ltd. Zhejiang Historical Stability data for Pharmaceutical Pharmaceutical Colorement Historical Stability data for Pharmaceutical Colorement Historical Colorement Historical Stability data for Pharmaceutical Colorement Historical Colorement Historical Stability data for Pharmaceutical Colorement Historical Colorementation Color				
Phone: 301-796-3334       email: CDEROSIAB@fda.hhs.gov       3007719313         Industry Information: www.fda.gov/oc/industry       3007719313         NAME AND TITLE OF NONDOLA TO WHOM REPORT IS ISSUED       3007719313         TO:       LIN Jian Qiu, President       STREET ADDRESS         Zhejiang Hisun Pharmaceutical Co., Ltd.       46 Waisha Road, Jiaojiang District       The No.MEE         TRY, STATE AND ZIP CODE       TYPE OF ESTABLISHMENT INSPECTED       API/Finished Drug Product Manufacturer         Records are not completed contemporaneously.       Specifically, during my inspection of your microbiology laboratory on 08/08/17, 1 observed your microbiologist preparing to load the purified water and for plates into the inclubator for samples collected and prepared earlier that day. However, the sample preparation worksheets for these samples were either partially completed or blank.         OBSERVATION 5       Laboratory records do not include complete data derived from microbial limit testing to ensure established procedures are followed.         Specifically,       1. During our review of the microbial limits test method validation for for for the microbial test record sheets.         a) The weight of product sample used is not documented.       Tablets (0) mg, we noted the following discrepancies:         a) The weight of product sample used is not documented.       Tablets (0) mg, we noted the following discrepancies:         a) The weight of product sample used is not documented.       Tablets (0) mg, we noted the following discrepancies:	Silver Spring, MD 20993 Phone: 301-796-3334 email: CDEROSIAB@fda.hhs.gov		08/07-11/2017	
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b) There is no documentation to demonstrate when and who performed the $^{(b)(4)}$ and $^{(b)(4)}$ and $^{(b)(4)}$ .	2. Our review	of historical stability data for (b) (4)	Tablets $\binom{(b)}{(4)}$ mg, we noted the following	discrepancies:
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EMPLOYEE(S) SIGNATURE         EMPLOYEE(S) NAME AND TITLE (Print or Type)         DATE ISSUED	CONTRACTOR OF T	Carlor and	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS Peter E. Baker, Investigator	REVERSE	PEB	Peter E. Baker. Investigator	
PAGE M Parul Patel, Investigator 08/11/2017		M		08/11/2017
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE INSPECTIONAL OBSERVATIONS Page 3 of 5	FORM FDA 483 (9/	08) PREVIOUS EDITION OBSOLETE	NSPECTIONAL OBSERVATIONS	Page 3 of 5

		ENT OF HEALTH AND HUMAN SERVICES DOD AND DRUG ADMINISTRATION		
DISTRICT OFFI	ICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTI	DATE(S) OF INSPECTION	
10903 New Hampshire Ave - White Oak (Bldg. 51 Rm. 4225) Silver Spring, MD 20993 Phone: 301-796-3334 email: CDEROSIAB@fda.hhs.gov				
		gov	FEI NUMBER	
	ormation: www.fda.gov/oc/industry	3007719313		
O: LIN Jia	an Qiu. President			
IRM NAME		STREET ADDRESS		
Zhejiang His	sun Pharmaceutical Co., Ltd.	46 Waisha Road, Jiaojiang District		
ITY, STATE AN		TYPE OF ESTABLISHMENT INSPECTED		
faizhou. Zh	ejiang, 318000, CHINA	API/Finished Drug Product Manufacturer		
locumente	ed under VC- <sup>(b) (4)</sup> -1602 and VC <sup>(b)</sup>	" changes to the <sup>(b) (4)</sup> API manufacturi 1603. There was no risk assessment or aken to monitor the acceptability/effectiveness	other scientific	
DBSERVA Process val	ATION 7 lidation studies do not contain a his	tom of all relevant data		
Specifically	y, during our review of your in-prod	cess control <sup>(b) (4)</sup> data collected dur	<b>.</b>	
pecifically alidation	study for <sup>(b) (4)</sup> API perform	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie	<b>.</b>	
Specifically alidation		cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie	<b>.</b>	
Specifically alidation s A) Origina B) During what appea our printe	study for <sup>(b) (4)</sup> API perform and in-process electronic data is not ave our review of the printed <sup>(b) (4)</sup> ars to be an <sup>(b) (4)</sup> peak in the start and <sup>(b) (4)</sup> traces are only ava	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie vailable for review. for in-process <sup>(b) (4)</sup> $pf^{(b) (4)}$ neak summary table at $p^{(b)}$	we identified (4) Howeve	
Specifically alidation ( A) Origina 3) During (	study for <sup>(b) (4)</sup> API perform al in-process electronic data is not ave our review of the printed <sup>(b) (4)</sup> ars to be an <sup>(b) (4)</sup> peak in the star ed <sup>(b) (4)</sup> traces are only ave (e.g. samples) could	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencies vailable for review. for in-process <sup>(b) (4)</sup> $pf^{(b) (4)}$ ndard <sup>(b) (4)</sup> peak summary table at $\gamma^{(b)}$ ailable up to <sup>(b) (4)</sup> The presence of this	we identified (4) Howeve	
Specifically validation s (A) Origina (A) During ( vhat appea your printe emaining ( (DBSERVA	study for <sup>(b) (4)</sup> API perform al in-process electronic data is not ave our review of the printed <sup>(b) (4)</sup> ars to be an <sup>(b) (4)</sup> peak in the star ed <sup>(b) (4)</sup> traces are only ave (e.g. samples) could	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie vailable for review. for in-process <sup>(b) (4)</sup> $pf^{(b) (4)}$ ndard <sup>(b) (4)</sup> peak summary table at ~ <sup>(b)</sup> ailable up to The presence of this <sup>(b)</sup> d not be determined.	we identified (4) Howeve	
Specifically alidation ( A) Origina (A) During ( what appea our printe emaining ( DBSERVA The final A pecifically	study for (b) (4)       API perform         I in-process electronic data is not avon our review of the printed (b) (4)       ars to be an (b) (4)         our review of the printed (b) (4)       peak in the start or avon of the printed (b) (4)         ars to be an (b) (4)       peak in the start or avon of the printed (b) (4)         ars to be an (b) (4)       peak in the start or avon of the printed (b) (4)         (ars to be an (b) (4)       (e.g. samples) could (e.g. samples) could (for a constrained for a constrained constrained for a constrained for a constrain	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie vailable for review. for in-process <sup>(b) (4)</sup> of <sup>(b) (4)</sup> ndard <sup>(b) (4)</sup> beak summary table at ~ <sup>(b)</sup> ailable up to <sup>(b) (4)</sup> The presence of this <sup>(b)</sup> d not be determined.	we identified (4) Howeve (4) peak in the	
pecifically alidation s b) Origina c) During bat appea our printe emaining DBSERVA The final A pecifically	API perform API perform and in-process electronic data is not ave our review of the printed <sup>(b) (4)</sup> ars to be an <sup>(b) (4)</sup> peak in the star dr <sup>(b) (4)</sup> traces are only ava (e.g. samples) could ATION 8 API storage areas are not maintained y, on August 9, 2017 during my wa	cess control <sup>(b) (4)</sup> data collected dur ned in 2010, we found the following deficiencie vailable for review. for in-process <sup>(b) (4)</sup> of <sup>(b) (4)</sup> ndard <sup>(b) (4)</sup> beak summary table at ~ <sup>(b)</sup> ailable up to <sup>(b) (4)</sup> The presence of this <sup>(b)</sup> d not be determined.	we identified (4) Howeve (4) peak in the	

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ISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S)	OF INSPECTION	
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Silver Spring, MD 20993 Phone: 301-796-3334 email: CDEROSIAB@fda.hhs.gov		FEINUMBER	
ndustry Information: www.fda.gov/oc/industry	30077	3007719313	
AME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			
o: LIN Jian Qiu, President			
	STREET ADDRESS		
Chejiang Hisun Pharmaceutical Co., Ltd.	TYPE OF ESTABLISHMENT INSPECTE	Road, Jiaojiang District	
faizhou, Zhejiang, 318000. CHINA	API/Finished Drug Product M		
(4) API was stored in room $102$ , (b) (4)	API was stored in room 104 and <sup>(b)</sup>		
bom 105.			
	8		
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or 1	Type) DATE ISSUED	
SEE REVERSE OF THIS			
PAGE But later	Peter E. Baker, Investigator Parul Patel, Investigator	08/11/2017	