INDOFARMA	CHECKLIST OF VENDOR AUDIT (RAW MATERIAL PRODUCER)	No. : F-PM-08-10 Rev. : 00 Valid date : 21 March 2016

This check list filled by :	
Name	:
Position	:
Department	:
Date of audit	:
Sign	:

Name of Manufacturer	:
Address	:
No. Telephone	:
No. Fax	:
Email	:
Raw material produced (used by PT Indofarma)	:

Please fill in the following questions and/or circle one of answer choice, "Yes" or "No". Circle N/A if the question is not irrelevant

A. Quality Management System				
1	Whether the company has implemented a quality management system (example : ISO)	Yes	No	N/A
	If Yes, then describe the quality management system is implemented along with the certificate number, valid date, expiry date their certificate:			
2	Have the authorized institutions audit/inspected the manufacturing facility in the last 5 years?	Yes	No	N/A
	If Yes, please specify who conduct the audit/inspection, when and how is the results			
3	Is the audit conducted by other pharmaceutical companies in the last 2 years?	Yes	No	N/A
	If Yes, please specify who conduct the audit/inspection, when and how is the results			
4	Does the company has a Site Master File?	Yes	No	N/A
5	Does the company implement risk management systems, especially at the production stage?	Yes	No	N/A
6	If yes, is there a procedure to manage the risk management system?	Yes	No	N/A
7	How does the definitions of lot or batch ?			
8	How does the system of lot number or batch ?			
9	Are all procedures documented and approved ?	Yes	No	N/A
10	How long documents/records that associated with the production was stored ?			
11	Are there retained samples for each batch of product ?	Yes	No	N/A
	If yes, how long the retained samples storage?			
12	Does the expiration date or retest date defines for all material came in and producing?	Yes	No	N/A
	If yes, please specify in detail:			

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13	Are available a list of approved suppliers for the material used in the production?	Yes	No	N/A
14	Does the company carry out audits to suppliers?	Yes	No	N/A
15	Do all the products have Material Safety Data Sheet?	Yes	No	N/A
16	How does the system of handling customer complaints/claims?			
	Is there any deadline for giving respond of customer complaints/claims?	Yes	No	N/A

B. Personnal				
1	Is there a company organizational structures? (If yes, please copy attached)	Yes	No	N/A
2	Who is the responsible person for the sections below:			
	a. Quality Assurance :			
	b. Quality Control :			
	c. Production :			
3	How much the employees/workers:			
	a. All :			
	b. Quality Assurance :			
	c. Quality Control :			
	d. Production :			
4	How many shifts of work are implemented?			
5	Who is responsible for communication with PT Indofarma related the things below?			
	a. Quality :			
	b. Administration and another technical matters :			
6	Is the entire production personnel have qualified?	Yes	No	N/A
7	Is there a training program?	Yes	No	N/A
8	Is the training program that have finished been evaluated and approved?	Yes	No	N/A
9	Is there employees training records?	Yes	No	N/A

C. Production Facilities and Equipments				
1	Is the plant used to produce materials used by PT Indofarma "dedicated" or "multipurpose" type?			
	If the multipurpose plant, what are any other material which is produced at the unit / plant them?			
2	Are the production facilities and equipment was sufficient to produce quality components?			
	a. Production building	Yes	No	N/A
	b. Machines	Yes	No	N/A
	c. HVAC	Yes	No	N/A
	d. Water System	Yes	No	N/A
	e. Environmental Control	Yes	No	N/A
3	Are the facilities used to produce materials used by PT Indofarma already qualified :			
	a. HVAC, is there any report?	Yes	No	N/A
	b. Water System, is there any report?	Yes	No	N/A
4	Is the machinery, equipment and critical instrument has been calibrated?	Yes	No	N/A
5	Is the machinery, equipment and critical instrument has been qualified?	Yes	No	N/A
6	Is the log book of machines and production equipment provided?	Yes	No	N/A
7	Are there cleaning procedures for machinery and production equipment? Whether it has been validated?	Yes	No	N/A
8	Is the pipes in the production room labeled?	Yes	No	N/A

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9	Whether valves and pipes of production related area does not leak ?	Yes	No	N/A
10	Is the ceiling and walls of the room in good condition to prevent possible contamination from the paint peeling?	Yes	No	N/A
11	Is there a maintenance program on the buildings and production facilities?	Yes	No	N/A

D. Production and Production In Process Control				
1	Does the manufacturer have more than one plant?	Yes	No	N/A
2	If yes, whether the materials used by PT Indofarma is produced in more than one plant?	Yes	No	N/A
	If yes, describe the system identify the plant where the product is produced:			
3	Do subcontractors is used to process or critical stages/significant in the manufacture of materials used by PT Indofarma ? (Subcontractors including contract analytical testing laboratory or factory toll manufacturing)	Yes	No	N/A
	If yes, mention subcontractors used and explain:			
4	Is the product (specially used by PT Indofarma) produced using intermediate product purchased from other manufacturers?	Yes	No	N/A
	If yes, please explain the detail:			
5	Are there health and hygiene procedures?	Yes	No	N/A
6	Is the production personnel using personal protective equipment according to regulations?	Yes	No	N/A
7	Is the product during the manufacturing process is given a clear identity?	Yes	No	N/A
8	Is the manufacturing process follows the flow of the appropriate production records ?	Yes	No	N/A
9	Does every process stage verify by the 2nd personnel?	Yes	No	N/A
10	Is the critical process has been validated?	Yes	No	N/A
11	Is the cleaning process has been validated?	Yes	No	N/A
12	Are the production process documentations included:			
	a. Process instructions	Yes	No	N/A
	b. Amount of materials used	Yes	No	N/A
	c. Cleaning record	Yes	No	N/A
	d. Line readiness	Yes	No	N/A
13	Is there a in process control systems?	Yes	No	N/A
14	Are there procedures associated with change control ?	Yes	No	N/A
15	Are there procedures associated with deviation control ?	Yes	No	N/A
16	Is investigation carried out properly if any deviations occur during the production process?	Yes	No	N/A
17	Are there procedures for taking action in the event of failure of the batch?	Yes	No	N/A
18	Do reprocess/rework allowed?	Yes	No	N/A
	If yes, is it available procedure for products handling that reprocessed/reworked?	Yes	No	N/A

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E. Packaging				
1	Is the packaging process separate from the process of production?	Yes	No	N/A
2	Is the packaging area is labeled in accordance with the packaged product?	Yes	No	N/A
3	Whether used containers are reused?	Yes	No	N/A
4	Is the cleaning procedure available in the packaging area?	Yes	No	N/A
5	Are there procedures in the use of labels and labeling process?	Yes	No	N/A
6	Is the label details checked before use?	Yes	No	N/A
7	Is there procedure for label reconciliation?	Yes	No	N/A
8	Are there procedures for disposal of unused labels?	Yes	No	N/A
9	Are all the products have the original label on each container? (Include: Name of the plant, product names, logos factory, hazard symbol, date of expiry/retest date?	Yes	No	N/A
10	How to make container seal?			
11	Was the entire material be clearly labeled, including waste and rejected material?	Yes	No	N/A

F. Product Release				
1	Are there procedures for sampling and testing of the finished product?	Yes	No	N/A
2	Do the results of the testing and final inspection documented?	Yes	No	N/A
3	Is there a final review of production documentation?	Yes	No	N/A
4	Is investigations conducted properly if irregularities are found in the final review?	Yes	No	N/A
5	Whether the decision to pass/reject a product made by a person/functions that are independent of the production?	Yes	No	N/A
6	Apakah status akhir produk didokumentasikan?	Yes	No	N/A
7	Is the final status of product documented?	Yes	No	N/A
8	Is the release certificate signed by QA?	Yes	No	N/A
	If not, who is Jika tidak, who signed the certificate?			
9	Is the shelf life , retest date or the expiration date stated on CoA or CoC?	Yes	No	N/A
10	Whether there is a product recall procedure?	Yes	No	N/A
11	Is there a system for handling rejected products?	Yes	No	N/A
12	Is there a system to handle returned products from customers ?	Yes	No	N/A

G. Storage (Warehouse)				
1	Is the storage facilities by lease system?	Yes	No	N/A
	If yes, please explain in detail :			
2	Is the admission process and expenditures well documented?	Yes	No	N/A
3	Are there clear identification and separation of the product released or rejected?	Yes	No	N/A
4	Are the rejected products handle properly?	Yes	No	N/A
5	Whether the product is handled and stored properly to avoid damage?	Yes	No	N/A
6	Is the storage conditions (temperature, humidity, etc.) are compliant with the product its stored ?	Yes	No	N/A
7	Is the storage temperature controlled and documented?	Yes	No	N/A
8	Is the storage humidity controlled and documented ?	Yes	No	N/A
9	Is the stock items are checked periodically?	Yes	No	N/A
10	Which does the system used, FIFO or FEFO?			

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H. Laboratory and Quality Control				
1	Do laboratories have an adequate facilities and equipment?	Yes	No	N/A
2	Are all instruments qualified?	Yes	No	N/A
3	Are all instruments calibrated?	Yes	No	N/A
4	Is the log book of instruments/equipment provided?	Yes	No	N/A
5	Is there a maintenance program to the instrument?	Yes	No	N/A
6	Are there procedures related to:			
	a.Sampling	Yes	No	N/A
	b.Sample handling	Yes	No	N/A
	c.Sample labeling	Yes	No	N/A
	d.Resampling/retest	Yes	No	N/A
	e.Specification determination	Yes	No	N/A
	f. Method of analysis determination	Yes	No	N/A
	g.Control and review of the method of analysis	Yes	No	N/A
	h.Investigation of material rejected	Yes	No	N/A
	i. Product complaint	Yes	No	N/A
	j. Handling of out of specification test result	Yes	No	N/A
7	Do manual calculations verified by the 2nd?	Yes	No	N/A
8	Do data transcription is verified by the 2nd?	Yes	No	N/A
9	Was the entire raw data (primary data) stored ?	Yes	No	N/A
10	Is analytical methods validated?	Yes	No	N/A
11	Is the entire test/inspection documented properly?	Yes	No	N/A
12	Is the stability testeing for material and/or product conducted?	Yes	No	N/A
13	Is the annual review of the product done?	Yes	No	N/A
14	Does the QC have color standards for the finished product? (Specific to the dye, the coating material, or capsule)	Yes	No	N/A
15	Is the correctness of print (for capsule) checked each lots againts the specification approved?	Yes	No	N/A
16	Does the technical drawings? (Special capsule) verified each lot?	Yes	No	N/A

I. Transportations				
1	Is there an approved transportation/expedition list?	Yes	No	N/A
2	Are there vehicle inspection procedure before being used to send the product?	Yes	No	N/A
3	Is controlled temperature during shipping?	Yes	No	N/A
	If yes, is temperature monitoring records evaluated and stored?	Yes	No	N/A

J. Others				
1	Does the company have a certificate in accordance with the needs of PT Indofarma (GMP, FDA, COS approval, ISO, TGA, Halal certificate, PIC, WHO, etc.)?	Yes	No	N/A
2	Are there self-inspection program and internal quality audits?	Yes	No	N/A
3	re there pest control program and the accompanying procedures?	Yes	No	N/A
4	Is there a waste disposal system?	Yes	No	N/A
5	Are there wastewater treatment plant?	Yes	No	N/A
6	Is the waste water is checked periodically?	Yes	No	N/A
7	Are there solid waste management of toxic and hazardous substances?	Yes	No	N/A