

	VENDOR AND CONTRACT MANUFACTURER AUDIT SUMMARY REPORT		No. : F-PM-08-07
	No.		Rev. : 01
			Effective Date : July 25 th 2017
Date(s) of Audit :			
Vendor/Contract Manufacturer Company Name :			
Address :			
Telephone Number :			
Fax Number :			
Email Address :			
Number of Pharmaceutical Manufacturing Licence :			
Certificate Number GMP/GDP/ISO/..... :			
Type Vendor / Contract Manufacturer :			
Dosage Form (Contract Manufacturer) :			
Material supplied/Product Manufactured :			
Areas to be audited :			
Audit Objectives :			
Vendor		Contract Manufacturer	
<input type="checkbox"/> New Vendor		<input type="checkbox"/> New Contract	
<input type="checkbox"/> Evaluation are not good		<input type="checkbox"/> Addition of dosage form/production facility	
<input type="checkbox"/> Routine Audit		<input type="checkbox"/> Evaluation are not good	
<input type="checkbox"/> Complaints against quality		<input type="checkbox"/> Routine Audit	
		<input type="checkbox"/> Complaints against quality	
Key Personnel		QA :	
		: QC :	
		Production :	
Lead Auditor	:		Department
Auditor	:	1.	Department
	:	2.	Department
	:	3.	Department
Auditee	:	1.	Department
	:	2.	Department
	:	3.	Department
	:	4.	Department
	:	5.	Department
General Company Information			

2. Previous Audit Results
 Initial Audit Follow Up Audit

Previous audit results, see list of CAPA No. :

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3. Status CAPA

No	NonConformities	CAPA	Status	Timeline	Corrective Action and Preventive Action Evidence

4 NonConformities and Opportunities for Improvement

No.	NonConformities	Category

5. Suggestion

- 1.
- 2.
- 3.
- 4.
- 5.

6. Audit Summary and Conclusion

a. Number of NonConformities

Critical :
 Major :
 minor :
 Total :

b. Therefore, based on audit results : Vendor Contract Manufacturer Recommended : CAPA is necessary, see List of CAPA No. CAPA is unnecessary Not Recommended**7. Authorization**

Auditor	Name	Position	Signature
Lead Auditor			
Auditor	1.		
	2.		
	3.		
	4.		
	5.		

Bekasi,.....

Approve by

Quality Assurance Manager