



Raw Material Evaluation

(Ref. [SOP VAL-105](#))

	Change Control No.	Evaluation No.
1.0 PROCUREMENT		
	Change Description	
	Current Material	Proposed Material
Item Number		
Trade Name		
Material Classification		
Material Function		
Manufacturer		
Supplier		
Shelf-life		
Storage Condition		
Packaging		
Compendia Ref. / Version No.		
Reason for Change		
Products Affected	Product Code	Product Name
Additional Comments		
2.0 COMPLIANCE		
2.1 Assessment of Affected Markets		
Identify affected markets		



Raw Material Evaluation

(Ref. [SOP VAL-105](#))

2.2 Assessment of Existing Material

Current Raw Material Specification Test Report has been verified to be compliant to applicable current - monograph.

YES NO

Comment:

2.3 Proposed Material Assessment

Certificate of Analysis (CoA) of proposed material has been verified and are compliant with current applicable monograph and existing material RMSTR.

YES NO

Record existing Material RMSTR Number _____ Version: _____

Comments:

RMSTR of proposed material created and are compliant with current applicable monograph and existing material RMSTR.

YES NO

Record Proposed Material RMSTR Number _____



Raw Material Evaluation
(Ref. [SOP VAL-105](#))

Comments:

Does this change require a Product Change Proposal (PCP)/ Product Change Request (PCR)?

YES NO

If NO, go to Section 2.4.
If YES, go to Section 2.3.4.

Enter when available the following information:
PCP/PCR Number _____

And attach supporting information as required.

PCP/PCR has been verified. It is closed and completed.

YES NO

Comments:

Section 2.1 — 2.3 completed by:			
Name	Position	Signature	Date

2.4 Stability Assessment

Stability study requirement has been verified against market requirements and recorded

YES NO



Raw Material Evaluation
(Ref. SOP VAL-105)

Markets	Stability Study Requirements	
1	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
2	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
3	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
4	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
5	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
6	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
7	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
8	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
9	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths
10	<input type="checkbox"/> Accelerated <input type="checkbox"/> 3 mths <input type="checkbox"/> 12 mths	<input type="checkbox"/> On going Stability Protocol No.: _____ <input type="checkbox"/> 6 mths <input type="checkbox"/> 9 mths <input type="checkbox"/> 18 mths <input type="checkbox"/> 48 mths <input type="checkbox"/> 60 mths

Section 2.4 completed by:

Name	Position	Signature	Date

3.0 QUALITY ASSURANCE

Manufacturer and/or Supplier Audit



Raw Material Evaluation (Ref. [SOP VAL-105](#))

The manufacturer and/or supplier of the proposed material has been audited for manufacturing and/or supplying the proposed material. The following details have been recorded and the Memorandum of Quality Assurance Audit Report has been attached.

YES NO If NO, provide comments in the Comments section below.

	Manufacturer	Supplier
Date of Audit		
Audit Rating		
Date of Next Audit		
Report Number		

Comments:

Section 3.0 completed by:			
Name	Position	Signature	Date

4.0 THIRD PARTY CONTRACT MANUFACTURING QUALITY ASSURANCE GROUP

4.1 The proposed material has been verified to be used by Third Party Contract Manufacturer.



Raw Material Evaluation
(Ref. [SOP VAL-105](#))

YES NO

If **YES**, list Produce Code, Product Name and Quantity of the proposed material used.

Product Code	Product Name	Quantity Used (% W/W)

4.2 The proposed material has been verified to be used in Semi-finished goods followed by further processing by Third Party Contract Manufacturer.

YES NO

If **YES**, list Product Code, Product Name and Quantity of the proposed material used.

Product Code	Product Name	Quantity Used (% W/W)

If answered YES for either 4.1 or 4.2, complete the following section.

4.3 The products affected have been verified to require validation by the Third Party Contract Manufacturer and the requirement has been communicated.

YES NO

Number of Batches Required	
Concurrent/Prospective Validation	

4.4 The products affected have been verified to require stability study by the Third Party Contract Manufacturer and the requirement has been communicated.

YES NO



Raw Material Evaluation
(Ref. [SOP VAL-105](#))

Stability Requirement :			
Section 4.0 completed by:			
Name	Position	Signature	Date
5.0 QC RAW MATERIALS LAB			
5.1 Testing Requirements			
Three batches of proposed material have been tested by Quality Control Laboratory as per relevant RMSTR and all test specifications have being met. Test results are attached.			
<input type="checkbox"/> YES <input type="checkbox"/> NO			
Comment:			



Raw Material Evaluation
(Ref. [SOP VAL-105](#))

Section 5.0 completed by:			
Name	Position	Signature	Date
6.0 ENVIRONMENTAL HEALTH AND SAFETY CONSIDERATION			
6.1 Workplace Risk characterization			
Workplace Risk characterization has been completed or updated <input type="checkbox"/> YES <input type="checkbox"/> NO			
Comment:			
6.2 Assessment of Hazard			
Is the proposed material is hazardous substance? <input type="checkbox"/> YES <input type="checkbox"/> NO			
If YES is it listed as a highly hazardous substance? <input type="checkbox"/> YES <input type="checkbox"/> NO			
If YES, it is indicated as: (tick all that apply) <input type="checkbox"/> Carcinogen <input type="checkbox"/> Highly Toxic <input type="checkbox"/> Highly Reproductive hazard <input type="checkbox"/> Volatile Lachrymator			
6.3 Estimated annual usage: _____			
6.4 Group approval required: <input type="checkbox"/> YES <input type="checkbox"/> NO			
6.5 Dangerous Goods Information:			
6.5.1	Class		
6.5.2	Subsidiary risk		
6.5.3	Packing group		
6.5.4	UN No.		
6.5.5	Proper shipping name		
6.6 Process Safety Impact Assessment Required: <input type="checkbox"/> YES <input type="checkbox"/> NO			
Comment:			



Raw Material Evaluation
(Ref. [SOP VAL-105](#))

Section 6.0 completed by:			
Name	Position	Signature	Date
7.0 VALIDATION / TECHNICAL SERVICES			
7.1 Qualification / Validation assessment has been completed <input type="checkbox"/> YES <input type="checkbox"/> NO			
Qualification/validation required? <input type="checkbox"/> YES <input type="checkbox"/> NO			
If YES , list product code and product name that require qualification/validation.			
Product Code	Product Name		
Comment:			
Section 7.0 completed by:			
Name	Position	Signature	Date



Raw Material Evaluation

(Ref. [SOP VAL-105](#))

8.0 RECOMMENDATIONS			
8.1	Validation will be performed as per the relevant protocol for the products identified in Section 8.1.1 of this raw material evaluation.	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
8.2	Stability studies will be performed on validation batches by the QC laboratory as per the market requirements and the relevant stability protocols identified in Section 2.4.1 of this raw material evaluation.	<input type="checkbox"/> YES	<input type="checkbox"/> N/A
Comment:			
Section 8.0 completed by:			
Name	Position	Signature	Date
9.0 CONCLUSION			
9.1	The raw material evaluation study indicated that the proposed material is comparable / not comparable (choose either one) to the existing material and is deemed suitable / not suitable for use at the site <u>for the drug products listed in Section 1 of this raw material evaluation.</u>		
Comment:			
Section 9.0 completed by:			
Name	Position	Signature	Date