STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Approval & Release of Batch (Finished Product)	**Effective Date:**
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1.0 OBJECTIVE:

To lay down the procedure for approval and release of batch (Finished product).

2.0 SCOPE:

This procedure is applicable to all batches (Finished products) manufactured in ……..

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3.0 RESPONSIBILITY:

Executive – Quality Assurance

Head – Quality Assurance

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Receive the BMR and BPR from production department, which are completed.

5.2 Ensure that the analytical reports are available in batch record.

5.3 Ensure that the control samples are collected and also ensure that stability samples are collected as applicable.

5.4 Scrutinize all the documents and list the various faults in the 'Batch Review Record' (Refer Annexure-I).

5.5 Categorize the faults as Critical and Minor faults as given below:

5.5.1 Critical Faults:

5.5.1.1 These are those faults that have a direct impact on the quality of the product which give rise to batch reprocessing/rejection.

5.5.1.2 These faults must be brought to the notice of the Head Quality Assurance.

5.5.1.3 These faults may arise from a failure to carryout GMP/GLP in some form or another. All critical faults observed shall be corrected in consultation and agreement with Head Production and Head Quality Assurance.

5.5.1.4 Some of the critical faults are listed below:

- Line or area clearance from the QA for any manufacturing process, is missing completely.
- Checking of the weights for the active ingredient and its addition is not recorded.
- Documents filled in advance to the actual operation/ process.
- Any process deviations carried out without formal approval of authorized persons.
- Inability or discrepancies to carry out product and packing material reconciliation with exception to material such as Roll labels, foils rolls, straps, BOPP tape etc.
- Missing entries such as humidity, temperature, QC results etc.
- Missing signatures of operators for critical activities such as dispensing, blending, mixing, drying, lubrication, compression, coating, filling, packing etc.
- Failure to carry out cleaning procedure such as cleaning of processing equipment, area, AHU's etc.
- No explanations for the addition/deletion of extra/required ingredients.
- Addition of drug substances without checking the quantity to be added without calculation based on the potency and /or water content.
- Specimen of labels, foils, cartons, catch covers, overprinted material etc. duly signed by production and QA taken at the time of each processing step of the manufacturing or packing process.
- All in process weight labels duly checked at each stage of processing by the production and QA executives.

5.5.2 Minor Faults:

5.5.2.1 These are less serious faults and do not affect the quality of the product.

5.5.2.2 These can be rectified with the consultation of the QA and production personnel.

5.5.2.3 Some of the Minor faults are described below:

- One of the signatures missing.
- Missing date in a sequential flow.
- Over writing entries.
- Error due to transcription of entries.
- Leaving blank spaces instead of striking out the area or writing 'NIL/'NA'.

- Check of one ingredient is present and other is missing from the BMR.
- Missing ancillary documents that are found later.
- Omission of date of start and end of processing.
- Control sample entry missing in the register.

5.6 After checking and reviewing the documents and records, send them to the relevant production sections for any minor rectification to be completed immediately.

5.7 QA Executive shall check the corrections made and check their appropriateness and adequacy.

5.8 Make entries in the 'Batch Audit Checklist' (Refer Annexure-II).

5.9 Head- QA or his designee shall prepare a 'QA Batch Release Intimation slip' (Refer Annexure-III). Before release Head QA or his designee shall check batch audit checklist for kind of minor or critical observations.

5.10 Send a copy of 'QA Batch Release Intimation slip' to Finished Goods Stores for dispatch.

5.11 Put all the documents in a file and store in the document room.

6.0 ABBREVIATION(S):

AHU : Air Handling Unit
BMR : Batch Manufacturing Record
BPR : Batch Packaging Record
GLP : Good Laboratories Practice
GMP : Good Manufacturing Practice
QA : Quality Assurance

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure – I: Batch Review Record
Annexure – II: Batch Audit Checklist
Annexure – III: QA Batch Release Intimation slip

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9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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Annexure I

BATCH REVIEW RECORD

Product Name	
Batch No.	
Name of Reviewer	
Checking of Documents	

Categories of faults:	
Critical faults:	
Line clearance from QA for any manufacturing or packing stage is completed	Yes/No
Checking of weight for the active ingredient and its addition is recorded	Yes/No
Documents filled in advance to the actual operation/ process.	Yes/No
Any process deviations carried out without formal approval of authorized persons.	Yes/No
Inability or discrepancies to carry out product and packing material reconciliation with exception to material such as Roll labels, foils rolls, straps, BOPP tape etc.	Yes/No
Missing entries such as humidity, temperature pH, QC results etc.	Yes/No
Missing signatures of operators for critical activities such as dispensing, blending, mixing, drying, lubrication, compression, coating, filling, packing etc.	Yes/No
Failure to carry out cleaning procedure such as cleaning of processing equipment, area, AHU's etc.	Yes/No
No explanations for the addition/deletion of extra/required ingredients.	Yes/No
Addition of drug substances without checking the quantity to be added without calculation based on the potency and/or water content.	Yes/No
Specimen of labels, foils, cartons, catch covers, overprinted material etc. duly signed by production and QA taken at the time of each processing step of the manufacturing or packing process.	Yes/No
All in process weight labels duly checked at each stage of processing by the production and QA executives.	Yes/No
Observation: Critical faults are observed/ not observed in Batch Record	
Minor faults:	
One of the signatures missing.	Yes/No
Missing date in a sequential flow.	Yes/No
Over writing entries.	Yes/No
Error due to transcription of entries.	Yes/No
Leaving blank spaces instead of striking out the area or writing 'NIL' / 'NA'.	Yes/No
Check of one ingredient is present and other is missing from the BMR.	Yes/No
Missing ancillary documents that are found later.	Yes/No
Omission of date of start and end of processing.	Yes/No
Control sample entry missing in the register.	Yes/No
Observation: Minor faults are observed / not observed in Batch Record	

Signature of reviewer (QA)/Date

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If any discrepancies are observed in BMR/BPR/Analytical report. Inform to Production/QC through QA Manger and intimate for corrective action or action taken as per given following format.

From	QUALITY ASSURANCE	Date:
To	PRODUCTION/QC	
Subject	Discrepancies observed in the Batch Manufacturing Record, Batch Packing Record & Analytical Records.	

Product

Batch no.

Observations

Signature of reviewer (QA)/Date

From	PRODUCTION/QC	DATE:
To	QUALITY ASSURANCE	
Subject	Actions taken:	

Signature of Production
Manager/QC Manager/Date

Minor/ Critical Observations reviewed and batch is released/ rejected

Signature of QA

Head/ Date

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Annexure II

BATCH AUDIT CHECKLIST

Product Name:

Batch No. :

S.No.	DOCUMENTS	AVAILABLE	NOT AVAILABLE
1.	Manufacturing Record		
2.	Packaging Record		
3.	In-process checks document		
4.	Analytical reports		
5.	Control samples collection record		
6.	Specimen of foils, labels, cartons		
7.	Deviation records, if any		
8.	Weight cards at each stage of processing		

MANUFACTURING RECORD

S.No.	DOCUMENTS	SATISFACTORY	NOT SATISFACTORY
1.	Batch details (Batch No., Mfg. date, Exp. date etc.)		
2.	Bill of materials entry details		
3.	In-process reports		
4.	Analytical reports		
5.	Temperature and humidity records		
6.	Stage wise reconciliation		
7.	Deviation records, if any		
8.	Weight cards at each stage of processing		
9.	Line clearances		

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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PACKAGING RECORD

S.No.	DOCUMENTS	SATISFACTORY	NOT SATISFACTORY
1.	Batch details (Batch No., Mfg. Date, and Exp. Date etc.)		
2.	Packing materials entry details		
3.	In process approvals for coding, overprinting etc.		
4.	Analytical reports		
5.	Temperature and humidity records		
6.	Stage wise reconciliation		
7.	Deviation records, if any		
8.	Weight cards at each stage of processing		
9.	Line clearances		
10.	Finished goods transfer note		

Reviewed By
(Sign/Date)

Approved By
(Sign/Date)

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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ANALYTICAL DOCUMENTS

Product: **AR No.**

Batch No:

S.No.	DOCUMENTS	SATISFACTORY	NOT SATISFACTORY
1.	Intimation slip/GRN attached		
2.	FG data sheet attached		
3.	Batch details (Batch No., Mfg. Date, Exp. Date etc., A. R. No.)		
4.	HPLC/GC Chromatogram & mobile phase preparation sheet attached		
5.	KF/IR/UV/SOR graph attached		
6.	TLC Plate and microbial report attached, If any		
7.	External Party Testing report attached, if any		
8.	In process Data & Reports		
9.	Sampling remark sheet attached		
10.	Certificate of analysis attached		
11.	Any other Information		
12.	Total number of pages + COA		

Reviewed By
(Sign/Date)

Approved By
(Sign/Date)

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Annexure III

QA BATCH RELEASE INTIMATION SLIP

Date:

To: Finished Goods Store – Dispatch Section

From: Quality Assurance Department

The following batch is approved and can be dispatched

S.No.	PRODUCT	BATCH No.	PACK	QUANTITY

Sign/Date
(HEAD – Quality Assurance)