PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Handling of Product Hold Time	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1. **Purpose:** The purpose of this SOP is to describe the systematic procedure to handle the hold batches at semi-finished as well as finished stage

2. **Scope:** This procedure is applicable to:
   2.1 In process, semi-finished as well as finishes product handling at ……

3. **References , Attachments & Annexures:**
   3.1 **References: ……..**
   3.2 **Attachments:**
      3.2.1 Attachment 1: Hold Time Sampling Register
      3.2.2 Attachment 2: Hold Time soft copy logbook(template)
   3.3 **Annexures:** NA

4. **Responsibilities:**
   4.1 **Quality Assurance:**
      4.1.1 To collect the hold time in process samples as per hold time study.
      4.1.2 To send duly filled "Test Requisition Cum Report" to QC department.
      4.1.3 To maintain hold time register.
      4.1.4 To maintain the soft copy of hold days record (Attachment 2).
      4.1.5 To investigate in case of failure/discrepancies.

   4.2 **Quality Control:**
      4.2.1 To make entry of the sample as per defined procedure.
      4.2.2 To analyze the sample as per defined procedure.
      4.2.3 To share the report
      4.2.4 To investigate in case of failure/discrepancies.

   4.3 **Production:** To prepare the Test Requisition cum report.
      4.3.1 Intimate QA for sampling.

   4.4 **Regulatory Affairs, Quality Head and Plant Head:**
      4.4.1 To review and approve the SOP

5. **Distribution:**
   5.1 Quality Assurance
   5.2 Quality Control
   5.3 Production

6. **Abbreviations & Definitions of Terms:**
   6.1 **Abbreviations:**
      6.1.1 QC: Quality Control
      6.1.2 QA: Quality Assurance

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6.1.3 HDPE: High density Polyethylene

6.2 **Definitions of Terms:** NA

7. Procedure:

7.1 Hold time study shall be performed in one batch, which shall represent the respective product.

7.2 The hold time study for tablet and capsule shall be performed up to :

For Tablet:

a) Hold blend for 30 days (sample send to QC at Initial, end of 15 & 30 days)
b) Hold core tablet for 60 days (sample send to QC at Initial, end of 30 & 60 days)
c) Hold coating suspensions for 48 hours (sample send to QC at initial, end of 24 & 48 hours)
d) Hold Coated tablets for 60 days

For Capsules:

a) Hold blend for 30 days (sample send to QC at Initial, end of 15 & 30 days)
b) Hold filled capsules for 60 days (sample send to QC at Initial, end of 30 & 60 days)

7.3 In case of New Product, the Hold time period for tablet and capsule are given below:

a) Blend should be compressed/filled within 15 days
b) Core tablet should be coated/packed within 30 days from the date of compression.
c) Coating suspension should be used before 24 hrs from the preparation of coating suspension
d) Coated tablet should be packed within 30 days from the date of coating.
e) Filled capsule should be packed within 30 days from the date of filling.

7.4 The handling of Hold time samples of In-process and finished products for tablets and capsule manufacturing), should be done as follows:

7.5 **Hold time samples(Blends, Core tablets, Coated tablets & Coating Suspensions) handling during tablet manufacturing:**

7.5.1 **Blend Stage:**

7.5.1.1 QA person shall collect the required quantity of the sample of blend or granules as per the protocol or as specified in BMR/MPS and stored in the HDPE container in blend Quarantine.

7.5.1.2 The entry of hold time samples collected should be made in the hold time sampling register.

7.5.1.3 On completion of hold time, 'Test Requisition Cum Report' should be filled by QA and send to QC along with the sample.

7.5.2 **Compression Stage:**

7.5.2.1 QA person shall collect the required quantity of the sample of core tablet as per the protocol and stored in the HDPE container in tablet Quarantine.

7.5.2.2 The entry of hold time samples collected shall be made in the hold time sampling register.

7.5.2.3 On completion of hold time, 'Test Requisition Cum Report' shall be filled by QA and send to QC along with the sample.

7.5.3 **Coating Stage:**

7.5.3.1 QA person shall collect the required quantity of the sample of coated tablet as per the protocol and stored in the HDPE container in tablet Quarantine.

7.5.3.2 The entry of hold time samples collected should be made in the hold time sampling register.

7.5.3.3 On completion of hold time, 'Test Requisition Cum Report' should be filled by QA and send to QC along with the sample.

7.5.4 **Coating Suspension:**

7.5.4.1 QA person shall collect the required quantity of coating suspension as per the protocol and stored in the S.S container in the tablet Quarantine.

7.5.4.2 The entry of hold time samples collected should be made in the hold time sampling register.

7.5.4.3 On completion of hold time, 'Test Requisition Cum Report' should be filled by QA and send to QC along with the sample.

7.6 **Hold time samples (Blends, Capsules) handling during capsule manufacturing:**

7.6.1 **Blend Stage:**

7.6.1.1 Follow the procedure as described in serial no 7.5.1

7.6.2 **Capsule Filling Stage:**

7.6.2.1 QA person shall collect the required quantity of filled capsule as per the protocol and stored in the HDPE container in the tablet/capsule Quarantine.

7.6.2.2 The entry of hold time samples collected should be made in the hold time sampling register.

7.6.2.3 On completion of hold time, 'Test Requisition Cum Report' should be filled by QA and send to QC along with the sample.

7.6.3 The blend, uncoated tablets, coated tablets, capsules shall be stored by wrapping in double polyethylene bag lined by cleaned High Density Polyethylene container.

7.6.4 The in process and finished product samples shall be stored under controlled environmental condition.

7.6.5 If the hold time period of the product is exceed from the predefined period then fill the deviation and give the proper justification.

7.7 **Hold time(Tablets/capsule/sachets/bottle/pouch)handling at packing stage :**

7.7.1. For Tablets/capsule/sachets/bottle/pouch which kept in factory premises at specified storage condition beyond the hold time data specified, shall be send to QC for analysis before release of batch.

7.7.2. Head QA/Quality head shall recommend the testing parameter for re-testing ,Preferably stability indicating test shall be consider for retesting (Assay, Ave. Wt. ,Fill wt, RS (impurities) description etc.).

7.7.3. "Test requisition cum report" slip shall be prepared by packing officer and shall be forwarded to IPQA officer for collection of sample.

7.7.4. IPQA officer shall be reviewed the soft copy (PDF) data of hold time which shall be available in "K" drive QA—IPQA Packing—Hold time analysis data for referencing the previous hold time of products.

7.7.5. For chemical testing 50 units for tablet/capsule and for bottle/sachets 50 gm or as per QC requirement.

7.7.6. For microbiology testing required 10 gm. Or as per micro. requirement from each dosages form separately shall be send to QC.

7.7.7. Certificate of analysis of Hold time stage receive from QC department shall be attached with respective BMR/BPR and no. of hold time shall be updated in soft copy for future reference as attachment-2 and soft copy shall be password protected by concerned IPQA officer.

7.7.8. Batch will be transferred only after ensuring the compliance of QC result.

7.7.9. The retest result shall be considered the valid for 30 days from the date of last release report form QC and batches shall be released of the hold time is less than the total hold time.

e.g. Previous established hold time is 80 days,

A current "XX" batch hold up to 110 day, then the releasing criteria will be 80 days +30 days(grace period)=110 days.

The total hold time of "XX" is 109 days, which is less than net hold time allowed i.e.110 days, this can be released without any retesting, however the retesting can be critical further compression of obtained retest results with initial result to be done prior to batch release, if any objectionable result reported shall be reported to QA/Quality Head for decision.

7.7.10. In case a batch /product in retested and result found the complying then the existing hold time shall be updated accordingly for the future reference.

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Attachment – I

Hold Time Study Sampling Register

S.No	Date	Product Name	Batch No	Stage	Sampled Quantity	Location	Initial sample send to QC	Sample submitted by	IInd sample send to QC	Sample submitted by	IIIrd sample send to QC	Sample submitted by	IVth sample send to QC	Sample submitted by	Remarks

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Attachment – 2

Hold Time study data logbook (Template)

S.No.	PRODUCT NAME	ITEM CODE	FNISHED PRODUCT HOLD DAYS	TYPE (STRIP/BLISTER etc.)	EFFECTIVE BATCH No./DATE

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8. History:

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