

REVIEW ON PHARMACEUTICAL PROCESS VALIDATION OF TABLETS

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Abstract : Validation is the craft of outlining and honing the composed strides alongside recording and documentation. The procedure approval is setting up reported confirmation which give a high level of affirmation that a particular procedure reliably create an item meeting its foreordained determination and quality characteristics. Approval ponders are the basic piece of GMP which are required to be done according to predefined conventions. Process approval additionally underscores the part target measures and factual devices and investigations and underlines information, location, and control of fluctuation and gives affirmation on reliable of value/efficiency all through life cycle of item.

IndexTerms – Good Manufacturing practices, Food and Drug Administration, Research and development.

INTRODUCTION

Validation is the way toward building up narrative proof exhibiting that a system, process, or movement did in testing and afterward creation keeps up the coveted level of consistence at all stages. In the pharmaceutical business, it is imperative that notwithstanding last testing and consistence of items, it is additionally guaranteed that the procedure will reliably deliver the normal outcomes.^[1]

Validation mainly Based on, FDA regulations describing current good manufacturing practice (CGMP) for finished pharmaceuticals are provided in 21 CFR parts 210 and 211.

A wide assortment of methodology, procedures, and exercises should be approved, the field of approval is isolated into various subsections including the accompanying:

- Equipment validation
- Facilities validation
- HVAC system validation
- Process Validation
- Analytical method validation
- Computer system validation
- Packaging validation
- Cold chain validation

Similarly, the activity of Qualification of system and equipment is divided into a number of subsections including the following:

- Design qualification (DQ)
- Component qualification (CQ)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

Process Validation is gathering the information and its examination all through the outline and assembling of an item keeping in mind the end goal to affirm that the procedure can dependably yield results of a decided standard. Administrative specialists like EMA and FDA have distributed rules identifying with process approval.^[2]

Need of Process Validation

- **Assurance of quality of the product-** Item quality can't be guaranteed for a procedure by routine quality control testing due to the confinement of the measurable inspecting and constrained affectability of the completed item testing. Quality variety among units inside a group or among various clumps are only here and there recognized by testing of completed item tests. Approval changes the sufficiency and dependability of a framework or procedure to meet foreordained criteria.^[3]
- **Optimization of the Process-** The enhancement of a procedure for most extreme productivity, while keeping up its quality security and immaculateness, is a result of approval. Exacting significance of word to enhance is "To make as powerful, flawless or helpful as could reasonably be expected". The enhancement of the office, hardware, frameworks, and procedures brings about an item that meets with the foreordained quality or the quality guidelines.
- **Quality requirements at the lowest cost-** The direct financial advantage of approval is a lessening in the cost related with process observing, inspecting and testing. Examination of numerous examples would not be required keeping in mind the end goal to moderate homogeneity for an approved mixing process. The consistency and unwavering quality of an approved procedure to

deliver a quality item give coordinate cost reserve funds coming about because of a reduction or disposal of item dismissals, revamps and retesting. Last arrival of the clump would be sped up and liberated of postponements and intricacies caused by protracted examinations of process, or investigative related fluctuations. Furthermore item quality protestations and potential item reviews would be limited.

- **To reduce the mixups and contaminations**
- **Minimal batch failures, improved efficiently and productivity**
- **Reduction in rejections and reducing the cost and time of reprocessing.**
- **Increasing the output**
- **Avoidance of capital expenditures**
- **Fewer complaints about process related failures**
- **Reduced testing in process and in finished goods**
- **More rapid and reliable start-up of new equipments**
- **Easier scale-up form development work**
- **Easier maintenance of equipment**
- **Improved employee awareness of processes**
- **More rapid automation**
- **Government regulation (Compliance with validation requirements is necessary for obtaining approval to manufacture and to introduce new products)^[4,5]**

Major phases in validation: ^[6-10]

The activities relating to validation studies may be classified into three:

Phase 1: Pre-validation Qualification Phase –This stage typically characterize the business producing in light of information increased through improvement and scale up exercises. It is the action of characterizing the business fabricating process that will be reflected in arranged ace generation and control records.

This stage is otherwise called process configuration stage concentrating only on capability endeavors. This stage fundamentally covers all exercises identifying with item RnD, definition pilot cluster contemplates, scale-up considers, innovation exchange to business scale groups, building up strength conditions and capacity, and treatment of in-process and completed dose frames, hardware capability, establishment capability, ace item archive, operational capability and process limit. Likewise this the phase in which the foundation of a ground breaking strategy for the procedure control is occurring utilizing gathered information and comprehension of the procedure.

The principle point of this stage is to build up a procedure that will create a result of foreordained quality

1. Building and capturing process knowledge and understanding-

Outlining a methodical procedure with an effective procedure control approach is reliant on process information and understanding got. Plan of examination studies can help to create process learning by devulging relationship, including numerous communications, between the variable information (process parameters) and coming about yield (In process material, semi completed material and completed great).

2. Establishing a strategy for process control- Process information and osmosis is the reason for setting up a way to deal with process control for every single stage and the procedure general. Methodologies for the procedure control can be intended to decrease enter variety, change for input variety amid assembling (thus lessen its effect on the yield), or consolidate the two methodologies.

Phase2 : Process qualification- Amid this stage the procedure which is laid out in process configuration stage is surveyed whether the procedure is equipped for reproducible business fabricating. It affirm that all the set furthest reaches of basic process parameters are legitimate and satisfactory items can be delivered .

This stage has two components initially is Design of offices and gear capability and utilities and second is process execution capability. Amid second stage CGMP protest methodology must be taken after. Effective consummation of stage second is important before business dispersion. Items made amid this stage, if pass as far as possible than cluster can be discharged for business circulation

1. Design of facilities and qualification equipment and utilities- Activities perform to guarantee legitimate offices outline and that the gear and utilities are adequate for their planned utilize and perform appropriately.

2. Process Performance qualification- It include characterizing execution standards and choosing what to gather when, how much information, and proper examination of information. Maker should experimentally characterize reasonable criteria and legitimize it.

Phase 3 : Continued process verification- Continuous affirmation is gotten amid routine creation that the procedure stays in a control state. A framework or frameworks for recognizing spontaneous deviaton from the procedure as configuration is critical to accomplish this objective.

This is known as the Validation Maintenance Phase, it requires visit survey of all records identified with the procedure, including approval of review answers, to guarantee that there have been no progressions, deviations, disappointments and adjustments to the generation procedure and that all standard working methods (SOPs), including change control systems, have been taken after. At this stage, the approval group including people speaking to every significant division likewise guarantees that there have been no progressions/deviations that ought to have brought about requalification and revalidation. A cautious outline and approval of frameworks and process controls can set up a high level of certainty that all parts or bunches created will meet their proposed particulars. It is expected that all through assembling and control, tasks are led as per the rule of good assembling practice(GMP) both when all is said in done and in particular reference to sterile item fabricate.

Planing for Validation

All Validation exercises ought to be arranged before execution. The rule components of an approval program ought to be plainly characterized and archived in an approval end-all strategy (VMP) or equal reports (VMP) or equivalent documents

1. Validation master plan^[11-14]

An Validation ground breaking strategy is a record that embody the general logic, target ways to deal with be utilized for execution sufficiency. It is critical to make summarised archive that will characterize an entire undertaking. This record will for the most part incorporate the capability parts of a task.

Validation when all is said in done requires careful readiness and arranging of the different strides all the while. Notwithstanding be done deliberately as indicated by characterized a standard working methods. All perception must be and where conceivable must be recorded as genuine numerical.

The approval ground breaking strategy ought to give a review of the whole approval task, its hierarchical structure, its topic and arranging. Its fundamental components being the rundown/stock of the things to be approved and the arranging plan. All approval exercises identifying with basic specialized activities, like item and process controls inside a firm ought to be incorporated into the approval ground breaking strategy. It ought to contain all imminent, simultaneous and review approvals and in addition revalidation. The Validation Master Plan ought to be a rundown report and ought to in this manner be brief, short and clear. It ought not rehash data recorded somewhere else but rather should allude to existing archives, for example, approach reports, SOP's and approval conventions and reports.

The organization and substance ought to include:

- Introduction: approval strategy, degree, area and timetable.
- Organizational structure: staff obligations.
- Plant/process/item portrayal :balanced for considerations or avoidances and degree of approval.
- Specific process contemplations that are basic and those requiring additional consideration.
- List of items/forms/frameworks to be approved, outlined in a grid arrange, approval approach.
- Re-approval exercises, real status and
- Key acknowledgment criteria.
- Documentation organize.
- Reference to the required SOP's.
- Time designs of every approval task and sub-venture.

2. Validation protocol^[15-16]

In the wake of planning VMP, the subsequent stage is to set up an approval convention. The substance of the approval convention is:

Point by point convention for exucuting approvals are imperative to guarantee that the procedure is sufficiently approved. Process approval conventions ought to incorporate the accompanying components:

- Objectives, extent of scope of the approval think about.
- Validation group enrollment, their capabilities and obligations.
- Type of approval: forthcoming, simultaneous, review, re-approval.
- Number and choice of clusters to be on the approval contemplate.
- A rundown of all hardware to be utilized; their typical and most pessimistic scenario working parameters.
- Outcome of IQ, OQ for basic gear.
- Requirements for adjustment of all estimating gadgets.
- Critical process parameters and their particular resiliences.
- Process factors and traits with plausible hazard and counteractive action will be caught.
- Description of the handling steps: duplicate of the ace reports for the item. Testing focuses, phases of inspecting, strategies for examining, examining plans
- Statistical apparatuses to be utilized as a part of the investigation of information.
- Training necessities for the preparing administrators.
- Validated test strategies to be utilized as a part of inprocess testing and for the completed item.
- Specifications for crude and bundling materials and test strategies.
- Forms and diagrams to be utilized for archiving comes about
- Format for introduction of results, recording conclusions and for endorsement of study comes about.

Table no.-1-Index of a VMP

S. No	Subject
1.0	Protocol preparation and Approval
2.0	Objective
3.0	Scope
4.0	Validation Team
5.0	Responsibility
6.0	Batch Under Process Validation
7.0	Training Need
8.0	Equipment Summary

9.0	Batch details
10.0	Approved vendor list
11.0	Reference Specification raw & packing materials
12.0	Process flow Diagram
13.0	Sampling plan
14.0	Sampling procedure and schematic Diagram of sample location
15.0	Brief of Manufacturing process & Control points
16.0	In-process check & Specification
17.0	Intermediate & finished product Specification
18.0	Deviation & Change Control
19.0	Batch output details
20.0	Documentation & reporting
21.0	Summary Report
22.0	Attachment
23.0	Abbreviations

Type of process validation:^[17-20]

Validation can be prospective, concurrent, retrospective or revalidation, it depends on when is performed.

1. Prospective validation – It is executed amid improvement organize by the mean of hazard examination of the creation procedure, which is separated into steps, these means are than tried based on past involvement to disclose whether they prompt basic circumstances.

Basic circumstances are recognized, hazard assessment is finished. All the potential causes are investigated and evaluated for likelihood and expand, the preliminary designs are drawn up, and needs are set. The general appraisal is made by performing and assessing every one of the preliminaries. On the off chance that toward the end the outcomes are agreeable, the procedure is attractive, if the procedure is unacceptable it ought to be changed and enhance until the point when it is approved them to be tasteful. This type of approval is fundamental so as to restrict the danger of blunders happening on the generation scale.

2. Concurrent validation – It is executed amid improvement organize by the mean of hazard examination of the creation procedure, which is separated into steps, these means are than tried based on past involvement to disclose whether they prompt basic circumstances.

Basic circumstances are recognized, hazard assessment is finished. All the potential causes are investigated and evaluated for likelihood and expand, the preliminary designs are drawn up, and needs are set. The general appraisal is made by performing and assessing every one of the preliminaries. On the off chance that toward the end the outcomes are agreeable, the procedure is attractive, if the procedure is unacceptable it ought to be changed and enhance until the point when it is approved them to be tasteful. This type of approval is fundamental so as to restrict the danger of blunders happening on the generation scale.

This careful monitoring of the first three production batches is sometimes treated as prospective validation. Concurrent validation together with a trend analysis including stability should be carried out to an appropriate extent throughout the life of the product.

3. Retrospective validation- It includes the testing of past involvement of generation on the supposition that piece, methods, and hardware stay unvarying; such experience and the consequences of in-process and last control tests are then assessed. Recorded obstacles and disappointments underway are analyzed to decide the points of confinement of process parameters. A pattern examination might be directed to decide the degree to which the procedure parameters are inside the admissible range.

Review approval is certifiably not a quality affirmation measure in itself, and ought to never be connected to new procedures or items. It might be utilized as a part of uncommon occurrence just, e.g. at the point when approval prerequisites are first presented in an organization. Review approval may then be valuable in setting up the needs for the approval program. On the off chance that the aftereffects of a review approval are certain, this demonstrates the procedure need prompt consideration and might be approved as per the ordinary timetable. For tablets which have been compacted under individual weight delicate cells, and with qualified hardware, review approval is the most critical trial of the general assembling procedure of this measurements frame. Then again, it ought not be connected in the make of sterile items.

Revalidation- It is required when we require to guarantee that adjustments simultaneously as well as in the process condition, regardless of whether deliberate or inadvertent, don't unfavorably influence process properties and item quality.

- Revalidation may be divided into two categories:
- Revalidation after any change having a course on item quality. Periodic revalidation did at booked interims.

Revalidation after changes. Revalidation must be executed on foundation of any progressions that may influence the assembling or potentially standard strategy having a heading on the built up item execution attributes. Such changes may incorporate those in beginning material, bundling material, producing forms, gear, in-process controls, fabricating zones, or emotionally supportive networks (water, steam, and so on.). Each such change seeked ought to be inspected by a qualified approval gathering, which will choose whether it is sufficiently critical to legitimize revalidation and, assuming this is the case, its degree.

Revalidation after modification might be founded on the execution of an indistinguishable tests and exercises from those utilized amid the first approval, including tests on substages and on the hardware concerned. Some normal changes which require revalidation incorporate the accompanying:

- Changes in the beginning material(s). Changes in the physical properties, for example, thickness, consistency, molecule estimate circulation, and gem compose and alteration, of the dynamic fixings or excipients may influence the mechanical properties of the material; as a result, they may unfavorably influence the procedure or the item.
- Changes in the bundling material, e.g. supplanting plastics by glass, may require changes in the bundling method and along these lines influence item security.
- Changes simultaneously, e.g. changes in blending time, drying temperature and cooling administration, may influence ensuing procedure steps and item quality.
- Changes in hardware, including estimating instruments, may influence both the procedure and the item; repair and support work, for example, the substitution of significant gear parts, may influence the procedure.
- Changes in the creation territory and emotionally supportive network, e.g. the revision of assembling regions as well as emotionally supportive networks, may bring about changes all the while. The repair and upkeep of emotionally supportive networks, for example, ventilation, may change the ecological conditions and, as a result, revalidation/requalification might be fundamental, for the most part in the make of sterile items.
- Unexpected changes and deviations might be seen amid self-assessment or review, or amid the consistent pattern investigation of process information.

Periodic revalidation. It is notable that procedure adjustment may happen continuously regardless of whether experienced administrators work accurately as per built up strategies. Essentially, hardware wear may likewise cause continuous changes. Subsequently, revalidation at booked circumstances is fitting regardless of whether no progressions have been intentionally made. The choice to present occasional revalidation ought to be construct basically in light of an audit of verifiable information, i.e. information created amid in-process and completed item testing after the most recent approval, went for confirming that the procedure is under control. Amid the survey of such authentic information, any pattern in the information gathered ought to be assessed. In a few procedures, for example, cleansing, extra process testing is required to supplement the recorded information. The level of testing required will be obvious from the first approval.

Furthermore, the accompanying focuses ought to be checked at the season of a planned revalidation:

- Have any adjustments in ace recipe and strategies, clump estimate, and so on., happened? Assuming this is the case, has their effect on the item been surveyed?
- Have alignments been made as per the set up program and time plan?
- Has preventive support been performed as per the program and time plan?
- Have the standard working systems (SOPs) been appropriately refreshed?
- Have the SOPs been executed?
- Have the cleaning and cleanliness programs been done?
- Have any progressions been made in the expository control strategies?

Basic Concept of Process Validation

Pharmaceutical Process Validation is the most vital and perceived parameters of cGMPs. The prerequisite of process approval shows up of the quality framework (QS) control. The objective of a quality framework is to reliably deliver items that are fit for their proposed utilize [21].

Process approval is a key component in guaranteeing that these standards and objective are met. The procedure approval is institutionalization of the approval records that must be submitted with the accommodation petition for showcasing approval. The procedure approval is planned to help producers in understanding quality administration framework (QMS) necessities concerning process approval and has general appropriateness to assembling process. As indicated by FDA, Assurance of item quality is gotten from cautious and foundational consideration regarding various significance factors, including: choice of value process through in-process and finished result testing [22].

The basic principle for validation may be stated as follows: ^[23-26]

Installation Qualification (IQ)

Setting up by target confirm that every single key part of the procedure gear and auxiliary framework establishment hold fast to the maker's endorsed detail and that the suggestion of the provider of the hardware are appropriately considered.

IQ contemplations are:

- Equipment configuration highlights (i.e.material of development clean ability,etc.)
- Installation conditions (wiring, utility, usefulness, and so forth.)
- Calibration, protection support, cleaning plans.
- Safety highlights.
- Supplier documentation, prints,drawings and manuals.
- Software recorded.
- Spare parts list.
- Environmental conditions (such asclean room requirements,temperature, and dampness).

Operational Qualification (OQ)

Setting up by target confirm process control cutoff points and activity levels which result in item that every single foreordained prerequisite. OQ contemplations include:

- Process control limits (time, temperature, weight, line speed, setup conditions, and so forth.)
- Software parameters.
- Raw material determinations
- Process working methodology.
- Material dealing with prerequisites.
- Process change control.
- Training.
- Short term strength and ability of the procedure, (scope studies or control graphs).
- Potential disappointment modes, activity levels also, most pessimistic scenario conditions.
- The utilization of measurably legitimate strategies, for example, screening analyses to upgrade the procedure can be utilized amid this stage.

Performance Qualification (PQ)

Building up by target confirm that the process, under foreseen conditions, reliably delivers an item which meets every single foreordained necessity.

PQ contemplations include:

- Actual item and process parameters and strategies set up in OQ.
- Acceptability of the item.
- Assurance of process capacity as set up in OQ.
- Process repeatability, long haul process steadiness.

Strategy for industrial process validation of tablet dosage Form^[27-28]

The methodology chose for process approval ought to be Simple and straight forward.

The accompanying five focuses gives methodology for mechanical process approval:

1. The utilization of various loads of crude materials ought to be incorporated i.e., dynamic medication substance and major excipients.
2. Clusters ought to be kept running in progression and on various days and movements (the last condition, if fitting).
3. Groups ought to be made in the hardware and offices assigned for possible business generation.
4. Basic process factors ought to be set inside their working extents and ought not surpass their upper and lower control limits amid process task. Yield reactions ought to be well inside completed item particulars.
5. Inability to meet the necessities of the Validation convention as for process info and yield control ought to be subjected to process requalification and consequent revalidation following an intensive investigation of process information and formal exchange by the approval group.

The regulatory basis for process validation^[27-30]

Directing the procedure approval is just an administrative necessity, yet in addition make a lot of sence from building and in addition a business perspective. It is clear that pharmaceutical organizations that are knowledgeable in leading procedure approval have an upper hand over the individuals who are not.^[31]

Process approval is required, in both general and particular terms, by current great assembling hones control for completed pharmaceuticals, 21CFR sections 210 and 211.^[32,33]

The idea of process approval from its beginnings in the mid 1970s through the administrative viewpoints related with current great assembling practice (cGMP) directions and the application thereof to different logical, quality confirmation, pilot plant, creation, and sterile item and strong measurements frames considerations. In the mid 1990s, the idea of preapproval review (PAI) was conceived and had as one of its essential fundamentals the confirmation that endorsed approval conventions and timetables were being created and that exhaustive advancement, scale-up, and biobatch and business group approval information were required so as to accomplish an effective administrative PAI review. There are a few vital explanations behind approving an item or potentially process. First, producers are required by law to fit in with cGMP directions. Second, great business directs that a producer keeps away from he plausibility of rejected or reviewed bunches. Third, approval guarantees item consistency, reproducibility and quality. Although the first focal point of approval was coordinated towards doctor prescribed medications, the FDA Modernization Act of 1997 extended the organization's power to assess foundations fabricating over-the-counter (OTC) drugs to guarantee consistence with cGMP. Once the idea of having the capacity to foresee process execution to meet client prerequisites advanced, FDA administrative authorities set up that there was a lawful reason for requiring process approval. A definitive legitimate specialist is Section 501(a)(2)(B) of the FD&C Act, which expresses that a sedate is regarded to be debased if the strategies utilized as a part of, or the offices or controls utilized for, its fabricate, handling, pressing, or holding don't adjust to or were not worked or administrated in congruity with cGMP. The cGMP controls for completed pharmaceuticals, 21CFR 210 and 211, were proclaimed to authorize the prerequisites of the demonstration. FDA has the expert and obligation to assess and assess process approval performed by makers. The cGMP controls for approving pharmaceutical (tranquilize) fabricating require that medication items be delivered with a high level of confirmation of meeting every one of the credits they are expected to have (21 CFR 211.100(a) and 211.110(a)).

Process Validation and Quality Assurance^[34]

The relationship of value affirmation and process approval goes well past the obligation of any quality confirmation (QA) work. In any case, it is a reasonable for say that procedure approval is a QA device, since it sets up a quality standard for the particular process. Quality confirmation in pharmaceutical organizations epitomizes the push to guarantee that items have the quality, immaculateness, security and viability spoke to in the organization's new medication application (NDA) filings. Albeit quality confirmation is typically assigned as a departmental capacity, it should likewise be a vital piece of an association's exercises. At the point when process approval turns into a general goal of the specialized and operational gatherings inside an association, it moves toward becoming the main impetus for quality

gauges being developed work, designing exercises, quality confirmation, and generation. The quality affirmation related with the pharmaceutical improvement exertion incorporates the accompanying general capacities:

- To guarantee that a substantial detailing is assigned.
- To qualify the procedure that will be scaled up to creation measure groups.
- To help the outline of the approval convention.
- To make the bio groups for the clinical program, which will end up being the question of the FDA's preapproval freedom.
- To work with generation and building to create and complete the capability program for creation hardware and offices/process frameworks.
- To create approved investigative techniques to permit:
 - The dependability program to be done.
 - The testing of crude materials and completed item
 - The advancement of discharge details for the crude materials and completed item.
 - The testing of handled material at certain predetermined stages.

Quality confirmation is the exertion taken to guarantee consistence with government directions for the frameworks, offices, and faculty required with assembling items. QA reviews will be very fluctuated in extension to accomplish this confirmation. These obligations incorporate clump record surveys, scrutinizes of item configuration, process approval movement, and, possibly, reviews of different offices activities.

Documentation ^[35]

“Palest ink is better than sharp memory”

Documentation at each phase of the procedure approval lifecycle is imperative for viable correspondence and comprehension in complex, and multiskilled ventures. Documentation is vital so information got about an item and process is reachable and understandable to others engaged with each phase of the lifecycle. Data clearness and openness are key statute of the logical strategy. They are additionally fundamental to empowering hierarchical units capable and responsible for the procedure to make educated, science-based choices that at last help the arrival of an item to business. The kind of documentation and degree required by CGMP change amid the approval lifecycle. Documentation necessities are most prominent amid Stage 2, process capability, and Stage 3, proceeded with process check. Concentrates amid these stages must conform to CGMPs and must be affirmed by the quality unit as per the directions. Viral and pollution leeway considers, notwithstanding when performed at little scale, additionally require quality unit oversight.

CGMP archives for business fabricating (i.e., the underlying business ace bunch generation and control record and supporting strategies) are key yields of Stage 1, process outline. The rule suggest that organizations procedure stream chart for the full-scale process. Process stream graphs ought to depict every single unit activity, its situation in the general procedure, checking and control focuses, and the part, and additionally other preparing material sources of info (e.g., handling helps) and expected yields (i.e., semi completed materials and completed item). It is likewise helpful to deliver and safeguard process stream outlines of the different scales as the procedure configuration advances to encourage examination and basic leadership about their likeness.

Conclusion

Approval is the most broadly utilized word in the field of medication improvement, assembling and determination of completed items. The consistency and dependability of an approved procedure to deliver a quality item is the critical for an industry. Pharmaceutical Process Approval is the most critical and perceived parameters of c-GMP. The procedure approval is planned to help producers in understanding quality administration framework (QMS) prerequisites concerning process approval and has general appropriateness to assembling process.

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