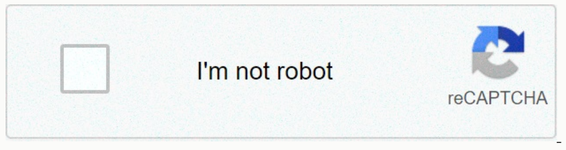
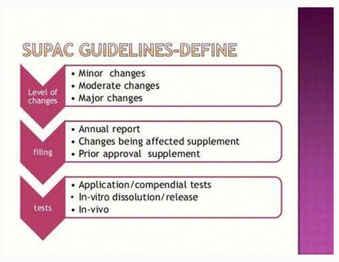


I am not robot!

Supac guidelines fda ppt

SUPAC is scale-up and the post-approval changes like in the formulation of the drug, batch size, process, equipment, site of manufacturing. Scale-up is an integral part of any life cycle of a product and in the process, it required a “detail-oriented” and “perfectionist” approach to be followed to ensure that the end outcome is identical to the original product formulation. Scale-up can be understood as the increase in production output as technology transfer takes place from lab-scale research to the giant production output.The initiation of approval of any generic drug begins with the application filing of ANDA (Abbreviated New Drug Application). But there is a twist as the manufacturer may change the formulation of the drug, batch size, process, equipment, site of manufacturing which directs to change in identity, strength, quality and potency of the product. What is SUPAC?SUPAC is scale-up and the post-approval changes (changes that are made after approval) like in the formulation of the drug, batch size, process, equipment, site of manufacturing.SUPAC documents or guidance are as below:FDA issues list of documents to help applicants with post-approval changes:Documents are divided into IR (immediate-release), MR (modified release), SS (non-sterile semisolid dosage form).In the following areas, changes are likely to take place:Components and composition of the drug productManufacturing site changeScale-up of the drug productManufacturing equipmentPackagingMainly describes 3 levels of changes which include chemistry, manufacturing and controls tests, in vitro dissolution tests, and bioequivalence tests for each level.Level Definition1- Changes that are unlikely to have any detectable impact on formulation quality and performance2- Changes that could have a significant impact on formulation quality and performance3- Changes that are likely to have a significant impact on formulation quality and performance Current requirements for post-approval changes:Components/ CompositionSite changesChange in batch sizeManufacturing SpecificationsPackaging1.
Components/CompositionAs the heading suggests any changes in components or composition of the formulation can be considered as major changes.Such significant changes must be inspected carefully before execution as it can affect the dissolution profile of the product.



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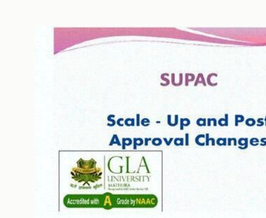

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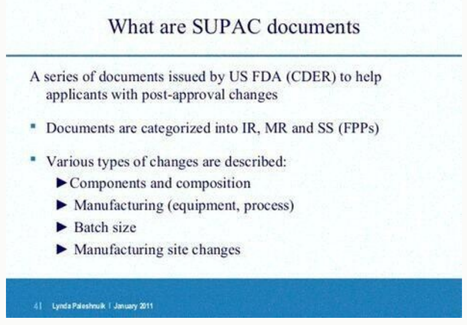

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Change in Batch SizeAs the heading suggests change in batch size from lab-scale formula to giant-scale production batches tends to change the operating parameters which include such as mixing time and its speed etc., needs to be adjusted as per the size of the equipment.Proper inspection and validation are required of the batches before the submission of the application.Level 1 change can be defined as any change in the production batch.Any change which falls outside the validation ranges, the change can be considered under SUPAC-IR and as a level 2 change.4. ManufacturingThis includes any change made in equipment and the process used in manufacturing a drug product.A) Equipment ChangeAs the heading suggests any change in manufacturing equipment other than that used in the approved application requires appropriate validation and proper inspection before implementation so that the new equipment is similar to the original equipment.Equipment within the same class and subclass like change in the manufacturer of equipment are acceptable under the condition to have the same design and operating principle under SUPAC-IR. civakofumeru Eg: V-cone blender manufactured by different manufacturers can be responsible for any changes are acceptableAny sort of change from one class of equipment to another would be considered a change in design and operating principle and would be considered different under SUPAC-IR. Eg: V-cone blender to ribbon blenderAny significant change in manufacturing equipment than that used in the initial approved application needs proper inspection and appropriate validation studies to demonstrate that the new equipment is similar to the original equipment.Equipment that falls under the same class and subclass would be considered to have the same design and operating principle under SUPAC-IR. nifivo Eg: Change in diff mfr of V-cone blender-acceptableChange from one class of equipment to another could bring up a change in design and operating principle and would be considered different under SUPAC-IR.B. Process ChangeAs the heading suggests change in the manufacturing process or technology can have adverse effects on the identity, strength, quality, purity, or potency of a drug product.The safety and effectiveness of the drug or product depending on the selection of the process of manufacturing or technology to be used should be properly validated. 5. SpecificationsSpecifications are the standards to be met by a drug product to ensure conformance of reproducibility, quality and consistency are maintained. nexahekebo Such changes require a “Prior Approval Supplement” unless there is some exemption from Regulation guidance documents.Prior approval is required on the following major changes in specification except as provided in the SUPAC-IR guidance as follow:Relaxing an acceptance criterionDeleting any part of a specificationChanging or establishing a new regulatory analytical procedure that does not provide the same or increased assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application.A 30 days Changes Being Effected Supplement needs to be filed in case of moderate changes in specifications, e.g.,a) Change in regulatory analytical procedures is identified as major.b) A change in analytical procedure or deletion of a test for raw materials used in drug substance manufacturing.Any changes in specifications which can cause detrimental side effects of a product but without interfering with the safety and effectiveness of the product can be submitted in an annual report. juyica 6. Packaging Packaging plays an important role as it can affect the shelf life of the finished product. Therefore, under the new guidance for industry, and the stability guidance, the requirements for packaging changes have been relaxed significantly. Get subject wise printable pdf documentsView Here Visitors are also reading: