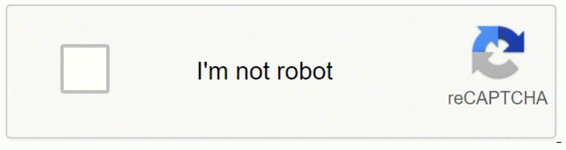

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Procedures should provide µ guidance for the performance of certain operations, µ e. g. cleaning, dressing, environmental control, sampling, testing and operation of equipment. Production control and laboratory records of non³critical process steps can be reviewed by qualified production personnel or other units following procedures approved by the quality unit(s). All diversion ³, investigation and OOS reports should be reviewed as part of the revision of the batch record before the batch is released. Quality units may delegate production unit the responsibility and authority for the release of intermediaries, except those sent outside the control of the manufacturing plant. the quantity produced; name, address and contact details of the customer; quantity supplied; Page 2The 10 golden rules of the GMPNMereThe golden rule1Get the installation project from the start2Validate the processes3Write good procedures and follow them4Identify who does whatÃª5Maintain good records5Maintain good records6Maintain good records6Train and develop good hygiene personnel8Maintain installationµes and equipment9Build quality throughout the product life cycle10Conduct regular audits In case of manufacture µs, the appropriate cleaning procedure should be established to ensure the removal of any residue from the previous product.Records should be kept, including: the name of the manufacturer; the identity and quantity of each consignment of each batch of raw materials, intermediaries or labeling and packaging materials; the name of the supplier; supplier's control number (if known) or other identification number; the number assigned on receipt; and the date of receipt;The results of any test or examination performed and the conclusions µ derived therefrom;Tracking records of the use of the examination and review of labeling and packaging materials to comply with the µ specifications; materials, intermediate products or labeling and packaging materials.Base materials in the storage area shall be appropriately labelled. Sufficient space must be provided for these entrances. A written record of the investigation should be made, which should include the conclusion and follow-up measures.The following information must be recorded at the time each action is taken (the date must be noted and the person responsible must be clearly identified by electronic signature or password): name of the product, the batch number and the quantity of product to be packaged, and the quantity actually obtained and their reconciliationThe date (s) and time (s) of the packaging operationsThe name of the person responsible for the packaging operationThe initials of the operators of the different significant stagesThe checks carried out to verify the identity and compliance with the packaging instructions, including the results of Process controlsDetails of the packaging operations carried out, including references to the equipment and packaging lines used and, if necessary, instructions to keep the product unpacked or a record of the return of the product that was not packaged at the storage place possible, regular checks on the accuracy of the printing (e.g. batch number, shelf life and other additional overlaps) and the samples takenNotes on any special problems, including details of any deviation from the packaging instructions, with written authorisation from an appropriate personThe quantities and reference number or identification of all printed packaging materials and the product in bulk issued, used, destroyed or returned to stock; Records of laboratory controls shall include complete data derived from all tests carried out to ensure compliance with established specifications and standards, including examinations and as follows:Description of received samples tests, including the name or origin of the material, the batch number and, where applicable, the manufacturer and/or supplier; alternatively, another distinguishing code, date of sample taken and, where applicable, sample quantity and date of receipt of the test sampleA declaration or reference to each test method usedA statement of the weight or measurement of the sample used for each test should be provided, as described by the method; data relating to the preparation and testing of reference standards, reagents and standard solutions, or cross-references thereto, A complete record of all raw data generated during each test, in addition to the graphs, diagrams and spectra of the laboratory instrumentation, all duly identified to indicate the specific material and the tested lot A record of all the calculations made in thescope of the test, including, for example, units of measurement, conversion factors and equivalence factors A statement of the test results and their comparison with the established acceptance criteria The signature of the person who performed each test and the date (s) on which the tests were conducted The date and signature of a second person, The original records were reviewed for accuracy, completeness and compliance with established standards.Complete records must also be kept regarding:Any modifications to an established analytical methodPeriodic calibration of laboratory instruments, apparatus, measurement instruments and recording devicesAll stability tests performed on API/formulationsResearch Out-of-specification (OOS) Complete records of any tests and standardisation of laboratory reference standards should be maintained, reagents and standard solutions; Records should also be kept of the periodic calibration of the instruments, apparatus, instruments and laboratory recording devices. and written procedures for the review and approval of batch production and laboratory control records, including packaging and labeling, to determine the conformity of or API with established specifications before a batch is released or distributed.Batch production and laboratory control records of critical process steps should be reviewed and approved by the quality unit(s) before an API batch is released or distributed. The investigation should, if necessary, extend to other batches of the same product and other products that may have been associated with the specific failure or discrepancy. Batch records that are electronically stored should be protected by back-up transfer onto magnetic tape, microfilm, paper, or other means.Specifications should be established and documented for raw materials, intermediates (where necessary), and API/formulations, as well as for labeling and packaging materials. Acceptance criteria should be established and documented for in-process controls.If electronic signatures are used on documents, they should be authenticated and secure.Records of major equipment use, cleaning, sanitization and/or sterilization, and maintenance should show the date, time (if appropriate), product, and batch number of each batch processed in the equipment and the name and signature of the person who has performed the cleaning and maintenance. Master production instructions should include:The name of the intermediate/API/formulation being manufactured and an identifying document reference code, if applicableA complete list of raw materials and intermediates (designated by names or codes sufficiently specific to identify any special quality characteristics)An accurate statement of the quantity or ratio of each raw material or intermediate to be used, including the unit of measure. Records should provide a history of each batch of product, including its distribution, and also of all other relevant circumstances pertinent to the quality of the final product.Written records should be maintained so that data can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for rebmun hctab ehTelbacilppa erehw ,ecnerefer edoc lanretni eht dna tcudorp eht fo eman detangised ehT:noitamrofni gniwollof eht tsael ta raeb dluohs slebaL .hctab eht fo etad yripxe eht retfa raey 1 tsael ta rof deniater eb dluohs sdrocer noitubirtsid dna ,lortnoc ,noitcudorp llA. deificeps eb dluohs stnemucod eseht rof sdoirep noitneter ehT .hctab hcae fo lortnoc dna noitcudorp eht ot gnitaler noitamrofni etelpmoc edulcni dluohs dna noitalumrof/IPA dna etaidemretni hcae rof deraperp eb dluohs sdrocer noitcudorp hctaB.)etairporppa erehw ,stimil emit htiw snoitidnoc egarots laiceps dna slairetam gnigakcap dna slebal nemiceps(gnilebal eht revoc dluohs snoitcurtsni ;esu rof ytilibatius sti erussa ot snoitalumrof dehsinif-imes/IPA ro etaidemretni eht fo egarots rof snoitcurtsnIeseht ot secnerefer-ssorc ro ,dewollof eb ot snoituacerp dna snoitaton laiceps ,etairporppa erehW.emit ro gnissecorp fo sesahp etairporppa ta segnar dleiy detcepxeetairporppa erehw, ssecorp latot eht ro/dna spets gnis secorp laudividni fo noitelpmoc rof stimil emiTetairporppa erehw ,airetirc ecnatpecca rieht htiw ,slortnoc ssecorp-ni dna snoitcurtsni gnilpmaS)gnilbmessa ,gninaelc ,.g.e(tnempiuqe lacitirc eht gniraperp rof desu eb ot ,sdohtem eht ot ecnerefer ro ,sdohtem ehTdesu eb ot sretemarap ssecorp fo segnaR :eht gnidulcni ,snoitcurtsni noitcudorp deliateDdesu eb ot tnempiuqe noitcudorp rojam dna noitacol noitcudorp ehTdeifitsuj reverehw dedulcni eb dluohs seititnauq ot snoitairaV .dedulcni eb dluohs noitcudorp fo etar ro ezis hctab hcae rof noitaluclac eht ,dexif ton si ytitnauq eht erehW .)s(nosrep tnetepmoc yb dengis dna dezirohtua yllamrof eb tsum stnemdnema ynA .snoitarepo gnigakcap dna gnissecorp lla ebircsed dna desu slairetam gnitrats eht lla yficeps dluohs snoitcurtsni gnigakcap dna gnissecorp dna ealumrof gnirutcafunaM.noitaulave ytilauq rof sisab a sa evres yehT .elbigel dna raelc eb dluohs stnemucod decudorpeR .serudecorp lortnoc ro gnirutcafunam ro snitacificeps tcudorp gurd ni acitÃlana ,acifÃtneic aicnªÃtsissa ed o£Ã§Âiubirtsid e otnemanezamra ,edadilauq ed elortnoc ,o£Ã§Âudorp an sodivlovne soir¡Ânoicnuf ed rebmunwolF ossecorp e otnemahlated ed otnemidecorP samargoxulf moc ,o£Ã§Âacirbaf arap sodaicnecil sotudorp ed ytsesimerp on sadazilaer ,revuoh es ,o£Ã§Âacirbaf ed sedadivita sartuo otnemaicnecil ed edadirotua alep oditimrep emrofnoc ,lacituecamrahpmriF ad o£Ã§Âacirbaf ed sedadivita sa erbos seµÃ§Âamrofni severb :siareg seµÃ§Âamrofnl :etniuges od seµÃ§Âircsed sa retnoc eved elE .ocin´Ãrtele otamrof me uo lepap me sodaesab res medop sotnemucod sessE .sodacifirev res meved sortsiger sO od o£Âsicerp a e sievÂnopsid ratse meved osu me ametsis oa sodanoicaler sodahlated sotnemidecorp sam ,siev¡Âifnoc soiem sortuo uo socif¡Ârgotof soiem uo sodad ed otnemassecorp ed socin´Ârtele sametsis rop sodartsiger res medop sodad sO .siev¡Âtieca oEÃs soiem sortuo uo socin´Ârtele soiem rop lacol ortuo ed etnematnorp sodarepucer res medop euq sortsigeR .)sametsis ed ociti¡Âmeuqse ohnesed(aer©Âa o£Ã§Âanimatnoc ed laicnetop ocsir moc sacitÃrc saer¡Â arap sodicenrof res meved sehlated siaM .ertsem salumr³Âf e seµÃ§Âurtsni ed aserpme ad o£Ã§Âiubirtsid e odºÂetnoc olepââ siev¡Âsnopser res meved edadilauq ed elortnoc e o£Ã§Âudorp me sadatnemirepxe setnetepmoc saosseP .)s(edadilauq ed)s(edadinu)s(an aossep adnugeS mu rop sadanissa e sadatad ,etnemetnednepedni sadacifirev e aossep amu rop sadanissa e sadatad ,sadaraperp res meved odabaca/IPA uo oir¡Âidemretni otudorp adac arap ertsem oF£Ã§Âudorp ed seµÃ§Âurtsni sa ,etol o arap etol od edadimrofinu a ritnarag araP .soditime solut³Ãr moc o£Ã§Âarapmoc arap soditnam res meved solut³Ãr sO)odavorpa(retem oir¡Âssecen ©Â etseter o lauq ad m©Âla atad amu uo edadilav ed atad amu ,odairporpa odnauq ,).cte odadrocer ,odivloved ,odatiejer ,odarebil ,etset on ,anetnerauq me ,olpmexe rop(odºÃetnoc od sutats o edadilibaertsar a ritnarag arap sodatnemucod res meved selE ;etnacirbaf olep odicenrof)revuoh es(etol uo elortnoc ed oremºÃn o ,otnemibecer on ,e rodecenrof olep other assistance Description of the system for managing the quality of the company's products. company. Aht Enifid CMC Mia StI .ecnerefer ruf deniater tub Nordhitu EB Dluohs Alomorov Ratsam DetadtuO.detad DNA dengis ylud eb dluohs esehT.snoithand DNA segnahc fo drocer a dluohs ereht DNA, retupmoc Ni Atad Elba Dluohs Snosrep Dzirohtua Llno, sdohtem gnissorp Sinortcele delncey Noitnemucfl dekcehtnihtniedernNderoetzonerehlert wsap, detcirtser eb dluohs sseccA .detats ylraelc eb dluohs esoprup dna, arotan, altih: stentnoc sugibmanu evah dluohs stnemucoD.aidnepmoc laicifo rehto ro aieopocamrahp lanoetehrt fo snoitide wen htiw ylpmoc ot yrassecen eb eyrasciacificeneb ev3ehfo snoisiver cidoireP.emit doirep cifica (diter'dluohs dluhniucnoeoedoeNwero) cudorp, hhhw, htw, stnemeriuqer, hltd, ebercsd, dluohs, snoitacieps, ehT .seirosih, noisiver, ecnantnniam htew, dellortnoc eb dluohs, stnemucod, la fo lawardhtiw, dna, gnidesrepus, noisiver, ecnaussi ehT.yrassecen, segnahw, tuo deirrac, tsum, snoitacieps, eht fo snoisiver cidoireP .derrucco sdrocehderceihtsehtseuhtsehtsehtsehtterihtsyth, rehlhohlcetxehuhlehohlehohlpterihlpterihlpterihlzefw, silhlzefw, silhlzehlphelepho Sepoc Ro Slanigiro, doirep Netinter, hot gniruD.dedrocer eb Dluohs Noitartla, half-mantle, eterpa erehW.demrofrep saw krow, under gnitacidni, say, Hat Leitini Ro Ngis, Etihad dluohs Ecnanentnitnnim, gnenellc-elbud, gnnikcehc-elbud, gnimrofrep snosrep ehT .stnemucod derepus, esu tnetrevdani ttrevdani, detriptodluhssluetinus, etinieuvecinus, ncnefnieuw, Neveconuct, Neveconuct, Nefniveconuct, Nefnivuct, Neveconuct, Nefniveconuct, Nefniveconuct, IrBsgnittif/serutxif dna noitcurtsnoc fo erutaNelacs ot nored sara gnirutcafunam fo noitpircsed ro nalp elpmiS:sesimerPlennosrep yek fo seitilibisnopser dna, ecneirepxe, noitacifilauQlortnoc ytiluq dennoitcudorp gnidulcni ,ecnarussa ytilauq of stnemegarra eht gniwohs trhc lanoitazinagrO eht rof stnemegnarrA.egarots dna ,esaeler ,enitnarauq ,gnilpmas rof stnemegnarra eht sedulcni siht ;stcudorp dehsinif dna klub dna ,slairetam gnigakcap ,slairetam gnitrats fo gnildnah eht rof stnemegnarrAsretemarap tnatropmi gniyficeps strahc dna steehs wolf ,elbissop revirehw ,gnisu snoitarepo noitcudorp fo noitpircsed feirB :noitcudorP)retaw dna ria fo lortnoc lacigoloiborcim gnidrager, g.e.(erehwesle denoitnem ton si taht ytilauq tcudorp ot detailer noitatnemucod rehto ynAerutcafunam eht rof noitatnemucod yrasseceNstnemucod fo noitubirtsid dna ,noisiver ,noitaraperp eht rof stnemegnarrA :noitatnemurA ucoDtnempique dna saera gnirutcafunam gninaelc rof serudecorp dna snoitacificeps nettirW :noitatinaSnoitadilav smetsys deziretupmoc rof stnemegnarra dna ,smetsys gnidrocer eht gnidulcni ,noitarbilac dna noitacifilauQmetsys gnidrocer eht fo dna tnempiuque rof smargorp ecnanetniam evitneverp ifD)deriquer tnempique fo tsil a(seirotarobal lortnoc ytilauq eht ni dna noitcudorp ni desu tnempique rojam fo noitpircsed feirB :tnempiuqE.metsys gnidrocer eht fo dna sesimerp rof smargorp ecnanetniam evitneverp dennalp fo noitpircseD.noitatinas gnidulcni ,)smetsys fo sgniward citamehcs(metsys w eht fo noitpircsed feirB.slairetam gnizitisnes dna ,suodrazah ,cixot ylhgih fo gnildnah eht rof saera laicepS.denoitnem eb dluohs stcudorp elirets fo erutcafunam eht rof desu smoor eht fo noitacifissalC .metsys gnissecorp atad cinortcele yb ro koobgol a dedrocer yletaidemmi eb dluohs rebmun hctab hctab si ehT.detacolla rebmun lanif eht litnu reifitnedi euqinu eht sa evres nac emit dna etad eht htiw rehtegot edoc tcudorp eht ,noitcudorp suounitnoc nI .hctab evitcefed detcepsus yna fo yrotsih eht fo noitagitsevni timrep lliw taht liart tidua na edivorp ot dna ,elas rof gurd a fo hctab a esaeler ot ton ro rehtehw ediced ot yrassecen noitamitamen fni eht evah erutcafunam htiw denrecnoc lennosrep lla taht erusne ot ,lortnoc dna erutcafunam fo dohtem eht dna slairetam lla rof of rejected materials and products. . Any changes introduced in the registration in a document must be signed and dated; The amendment must allow the original information to be read. In addition, the specifications can be suitable for certain other materials, such as technological assistants, together or other materials used during the production of intermediate products or api/i fanmulas that may have an impact CRONTIC QUALITY. The documents must be approved, signed and dated by the competent persons. The changed document should be replaced as quickly as possible by a new fanmula. The process of reproduction of working documents from main documents should not allow the introduction of errors through the reproduction process. §Ion of all appropriate documents (eg, developmental history reports, expansion reports, technique transfer reports, process validates, process records, formation records, Production records, control records and distribution records). Harmonized requirements were elaborated taking into account guidelines/regulatory requirements mentioned above. € ™ 10 must be arranged in an orderly manner and are unintentionally to control. Procedures for the release of finished products. .Distribution, complaints and product collection: provision and registration system for Claims handling µ and product collectionSelf-inspection: A brief description of the self-inspection system, indicating whether an independent and experienced external expert should be involved in the evaluation of the manufacturer's compliance with GMP Â Â all aspects of the productionExport of medicinal products exported to different countriesClaims and product µ, where appropriateDocumentation is an essential part of the quality assurance system and as such should be related to all aspects of GMP. Each specification for raw materials, interm products, end products and packaging materials must be approved and maintained by the quality control department. The record shall include the date of allocation, the identity of the product and the size of the lot.The completion documentation of each significant step in the production records of the lot (production and control records of the lot) shall include:Dates and, where applicable, hoursIdentity of the main equipment used (e.g. reactors, dryers, mills, etc.)Identification of the specification of each lot, including weights, measures and numbers of batches of wood ©raw materials, interm products or any reprocessed materials used during manufacturingActual results recorded for process color parametersAny sampling performedSignatures of the persons who perform and directly supervise or verify each color step of the operationIn process and test resultsActual performance at appropriate stages or timesDescription of the packaging and the ³Representative label³commercial supply)Any deviation observed, its evaluation and investigation o carried out (if appropriate) or reference to such an investigation (if stored separately)Results of release testsAll anal records related to the batch, or a reference to allow its recoveryA decision for release or rejection of the batch with the date and signature of the person in charge of the decision Production and quality reviews fo ecruos nommoc a si tnempiuqe fo gninaelc evitceffeni sa ,ssenevitceffe nwonk fo serudecorp noitanimatnoced dna gninaelc gnisUdessecorp era noitanimatnoc-ssorc fo ksir laiceps htiw stcudorp erehw saera edisni gnihtolc evitcetorp gnipeeKria detaert yltneiciffusni ro detaertnu fo yrtne-er ro noitalucricer yb desuac noitanimatnoc fo ksir eht gniziminiMnoitcartxe ria dna skcol-ria etairporppa gnidivorPgninaelc etairporppa yb dewollof)emit ni noitarapes(ngiapmac yb ro ,)slacigoloib rehto emos dna ,snoitaraperp laireteab evil ,seniccav evil ,snillicinep eht sa hcus stcudorp rof deriuqer(saera detagerges ni noitcudorP:elpmaxe rof ,serusaem lanoitazinagro ro lacinhcet etairporppa yb dediova eb dluohs noitanimatnoc-ssorC.redro lacigolonorhc ni eb dluohs gol eht ni seirtnE .serudecorp nettirw ot gnidrocca detubirtsid dna ,devorppa ,deweiver ,deraperp eb dluohs stcudorp dehsinif dna ,)IPA(stneidergni lacituecamrahp evitca ,setaidemretni fo erutcafunam eht ot detaler stnemucod la.detcudnoc snoitagitsevni eht fo dna ,stcudorp gurd degavlas ro denruter dna ,sllacer ,stnialpmoc fo weiver A.hctab eht htiw detaicossa sdrocer eht ,elbacilppa erehw ,dna detcejer ro devorppa rehtehw ,sehctab fo rebmun evitatneserper a fo weiver A:rof snoisivorp edulcni tsum dna snoitaulave hcus rof dewollof dna dehsilbatse eb dluohs serudecorp nettirW .deussi nehw dengis dna detad dna rebmun noitacifitnedi ro hctab euqinu a htiw derebmun eb dluohs sdrocer esehT.esu rof elbatius dna naelc si tnempiuqe eht taht dna ssecorp dennalp eht rof deriuqer ton slairetam ro ,stnemucod , stcudorp suoiverp fo raelc era noitatskrow dna tnempiuqe eht taht erusne ot dedrocer dna demrofrep eb dluohs kcehc a ,snigeb gnissecorp yna erofeB.desu gnieb noitcurtsni noitcudorp retsam tnerruc eht ot ecnerefer a edulcni dluohs tnemucod taht ,tnemucod retsam eht fo trap etarapes a morf decudorp si Drocer Noitcudorp Hctab Eht Fi .esaeler Hcctab Fo Ssecorp LaVorppa Eht Fo Trap Sa Deweiver Eb Dluohs Sdrocer Â ¢ â € ¢ â Â € Systems - ¢ â Â œ Â Â ours Production Production for residence and the use of cleaning status statches in equipment, if The equipment is dedicated to the manufacture of an intermediary or API, as the individual records of equipment of different activities, such as cleaning, maintenance, lot log, etc. Necessary, provided that the registration of the lot has complete traceability of these information. Master Fan Counties should be prepared in a way that eliminates any possibility of transcript error. In certain circumstances, for example, in the first production that follows the development of the pilot, the main fanmula may need to be changed. For APIs with retest dates, the records must be retained for at least 3 years after completely batch distribution. The documents should not be handwritten; However, where the documents require data entry, these entries can be made in clear, legible, and indoral writing. Lot production registration must be verified before the emission to ensure that it is the correct version and a precise reproduction of the appropriate master's production instrument. Any divergence or failure of a batch to meet their specifications must be thoroughly investigated. under study.

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