
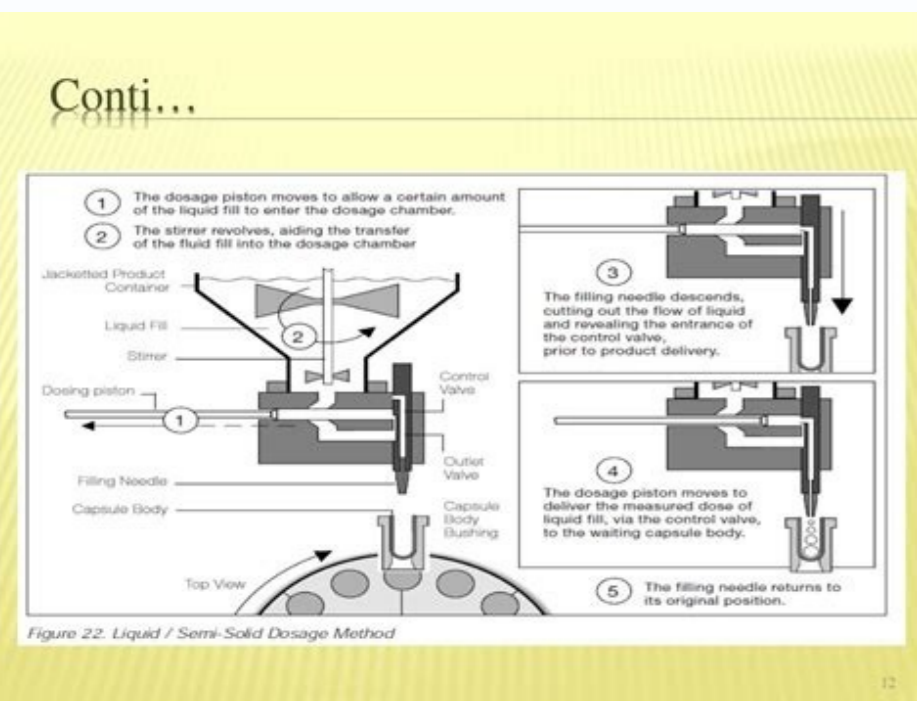


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Qualification of capsule filling mac



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Automatic Encapsulator Automatic encapsulator is a capsule filling machine that is developed and designed to automatically fill empty hard gelatin capsule with powders and granules. Its simple design and robust construction (which ensures long life and trouble-free operation), the use of stainless steel and non-corrosive approved materials in the construction of contact parts (which eliminates contamination and facilitates easy cleaning after use) make the machine suitable for filling powders and granular materials in the pharmaceutical and health food industries. Types of capsule filling machines Various types of encapsulation machines are available and these machines are selected based on the requirement of the manufacturer/nature of the capsule (hard capsule or soft capsule).The quantity of capsule to be manufactured. This protocol is specific to the Capsule Filling Machine and related instrumentation and equipment. How a manual capsule filling machine works Semi-automatic encapsulators As the name implies, semi-automatic encapsulators (semi-automatic capsule filling machines) combine both manual and automatic methods of capsule filling, thus can be said to be partially automated. EncapsulatorsA Used in encapsulation of hard gelatin capsule can be classified or said to be of three types. Sandwich of cap and body rings are positioned under rectifier to receive the empty capsule and the caps are separated from the body by pulling the vacuum from beneath the sings.The body rings are then positioned under the foot of the powder hopper for filling process.The cap and body rings are rejoined and positioned in front of pins which push the bodies to engage of pins which push the bodies have been filled.The plate is then swung aside and the pins are used to eject the closed capsule. The stages are:1) Capsule feed (w/relative automatic selection via optional unit)2) Capsule orientation, positioning and opening (equipped of deddA stenopmC 30-200d5004 :gniwarD 31.5tinU gninaeC 11-120d1144 :gniwarD 21.5tinU noiucejE eluspaC 11-020d0144 :gniwarD 11.5etalprenuoC gnisoC dna tinU gnitroS tcejE 1R 910d9044 :gniwarD 01.5tinU noiucejE redwoP/noisserpmoC 70-810d8044 :gniwarD 9.5tinU gnideeF redwoP 10-710d7044 :gniwarD 8.5tinU gnineP dna gnideeF eluspaC 11-510d5044444444444444 :warD 7.5tinU etalP 50-410d4044 :gniwarD 6.5tinU nruteR launaM 51-310d3044 :gniwarD 5.5tinU redwoP 11-210d2044 :gniwarD 4.5tinU noitmoC itamienik 82-110d1044 :gniwarD 3444444 :gniwarD 3444444 :gniwarD 4444444444444444 :gniwarD 3444 :gniwarD 3 warD 3444454554454 :caM esaB 73-010d0044 :gniwarD 2.5 ylbmessA enihcaM gnillif eluspaC 00-420004 :gniwarD 1.5stnemucOD ecnerefeR 0.5.tem erew airetic ecnatpecca lia dna yltcrooc detelpmoc saw locotorp detucexe eht gnitaicdni ,locotorp siht htiv detaicossa trosa lanif eht evorppa lliw HIN ,noitucexe eht gniwolloF 1.2.4)IS(htlaeF fo setutitsnI lanoitaN 2.4.locotorp siht etucexe ot SPQ fo ytilibisnopser eht si tl 2.1.4.locotorp siht etirw ot SPQ fo ytilibisnopser eht si tl 1.1.4.CLL ,snoituloS ssecorP noitacifilauQ 1 seililbisnopser 0.4riA)4wk 5.1 V 084 rewoP)3gk 0501 thgieW)2L mm 0412 x H mm 0761 x W mm0002 :noisemiD)1F6 isanaZ eht ot ylppa stremarap lareng gniwollof ehTgulp noisnetxe cirtceE)81notub hsup pots ycnegrem 1 legats lartneC)61tinu gnisoD diuqIL)51tinu noiuceles eluspaC)41tinu gnisoC eluspaC)31tinu noiuceles eluspaC)11tinu gnisoD telleP ro redwoP)11tinu gnisoD telbar ro telleP)01lorlnoc gnilevel dna reyal redwoP)9tinu deef redwoP)8slorlnoc launaM revoegnac secorp rof strap egnaic-eziS)6lenap lorlnoc dna tenbae cirtceE)5dooh avoidectorP)4strap gnivoM)3noitazirotoM)2esab)1:stnemele rojam gniwollof eht fo desirable pmoc si enihcam gnillif eluspaC eht)noitazerges lif laitrap dna ytme citamotua(noiuceles eluspaC)8noitceje eluspaC)7erusote dna tsemgila eluspaC)6citamotua(noiuceles eluspaC)5gnillif tucdorp eluspaC)4gnillif-erp noitarapes eluspaC)3seagats 8 etsed oEASAcucexe an sodilovne soir)Anoicmf so sodot ed oEASAtaieca ed sailaieritC 3.7,oxena oir;Alumrof on atad e siaicini ,arutansa ,aserpme ,ohutA, emon rop adacifitnedi res eved aossep adaC ,sodassecorp siairetam sod edadilaug ed sotubirta so uo / e ametsis od oEASArepo a ,Aratefa ohnepmesed ojuc seleuqa omoc sodinifed oEAS sotnemurtsnI acitArC oEASAtnemurtsnI acitArc oEASAtnemurtsnI 1.6sejASAnifed 0.6strec sotnemapiuqe e edadimrofnoC ed edadimrofnoC ed oEASAnetunam ed oEASAnetunam :odniulcni ,aluspiAc ad otnemihcne ed aniuqiAm a arap oEASArepo e oEASAlatsni ed launaM 40M17053 :otnemucOD 73.5tnalP rIA oEASArripsA 10 :930C044 :ohneseD 63.5tnalP rIA odmirpmoC 330C044 :ohneseD 53.5samargorp ed megatsil 1V2S-F :otnemucOD 43.5acirt©Ale oEASAsoper ed saSAep ed atsil 86.44 EI :otnemucOD 33.5citamehcS lacirtceE 86.44 ,ajes uo :ohneseD 23.5dooh aSAAnarugeS 73-463D8244 :ohneseD 13. 5 osepe mes sodanoicida setnenpmoC 20-363D0444 :ohneseD 03.50F)Ap me megasod ed otnemapiuqe 30-651d9104 :ohneseD 92.54F)Ap ed megasod ed otnemapiuqe 30-451d9104 :ohneseD 82.53F)Ap me megasod ed otnemapiuqe 30-351d9104 :ohneseD 72.52F)Ap ed megasod ed otnemapiuqe 30-251d9104 :ohneseD 62.51F otnemapiuqe)Ap me megasod 30-151D9104 :ohneseD 52.50F edadinU sotnemapiuqe eluspaC stellep /)Ap 60-641D5004 :ohneseD 42.54F edadinU eluspaC telleP / redwoP 60-441D5004 :ohneseD 32.53F edadinU eluspaC telleP / rewoP 60-341D5004 :ohneseD 22. 52F tinU tnepmiupqe eluspaC telleP / redwoP 60-241D5004 :ohneseD 12.51F otnemapiuqe ed edadinU aluspiAc telleP /)Ap mE 60-141D5004 :ohneseD 02.5CPS mes etuhC aluspiAc 21-090D0144 :ohneseD 91.5knaT yratoR oa sodanoicida setnenpmoC 30-820D2044 :ohneseD 81.5acis;Ab aniuqiAm A sodanoicida setnenpmoC 50-400d004 :ohneseD 61.5acis;Ab aniuqiAm A sodanoicida setnenpmoC 50-400d004 :ohneseD 51.5 acis;Ab aniuqiAm A sodanoicida setnenpmoC 70-400D2004 :ohneseD 41.5enihcaM must be present.8.0 Test FunNumber two: Test equipment (Annex # 2) 8.1 Objective to verify and document all equipment 8.2 Procedure 8.2.1 Complete a list of all the instruments required for conducting OQ testing.8.2.2 Verify that the test equipment/instruments are calibrated and the reference standards are traceable to National Institute for Standards and Technology (NIST) or other approved standard.8.2.3 Complete the applicable attachment, indicating the equipment description, ID/serial number, calibration date, re-calibration date 8.3 Acceptance CriteriaAll equipment required for execution shall be calibrated with copies of calibration records attached.9.0 Test Functi Operating principles of a capsule filling machine Capsule filling machines should all have the following operating principles in common. They are used in the large scale production of capsule. These machines are used to fill empty soft or hard gelatin capsules of various sizes with powders, granules, semi-solids or liquids substances containing active pharmaceutical ingredients or a mixture of active drug substances and excipients. Manual /hand operated capsule filling machine.Semi-Automatic capsule filling machine.Automatic capsule filling machine. Critical instruments are calibrated and certified using standards that are traceable to NIST (National Institutes of Standards and Testing).6.2 Non-Critical Instrumentation Instrumentation provided for indication or convenience purposes only.7.0 Test Function Number One: OQ Signature Verification List (Attachment #1)7.1 ObjectiveTo identify and document all personnel involved in executing this protocol.7.2 Procedure Verify that each person who executes this protocol signs Attachment # 1. The output of the filler is adjustable with a maximum production rate of 6000-6120 capsules/hr dependant upon process selection.The filler is an alternate movement capsule filling machine provided with a rotary stage that provides clockwise axis centered slip stick motion to transport capsules thru 8 process stages. Automatic Filling machines are extremely durable 4 e 0

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