Analytical test method validation protocol template

TTPR-002
Issue date

Process Validation Interim / Final Report
(Reference: RSP _____)

[Enter Product Title, Number & Strength]

PRODUCT CODE:

	WRITTEN BY:	REVIEWED BY:
Name:		
Signature:		
Position:		
Date:		

Qualification Status
The qualification of the raw material[item description, item code] as per protocol [enter protocol no] has been completed for the following:

- [enter product name, code and lot no]

All deviations and additional protocol results for the batch are documented in this interim report. All acceptance criteria have been met according to protocol [enter protocol no] and all deviations resolved.

The qualification for the use of [enter raw material item description, item code] in the manufacture of enter product name, code and lot no] has been successfully completed.

or The qualification status of the use of enter raw material item description, item code] in the manufacture of enter product name, code and lot no] is pending. The qualification data has been completed for this study and will be documented in a subsequent report.

REPORT COMPLETION APPROVAL:			
Name:	[Type Name]	[Type Name]	[Type Name]
Signature:			
Position:	Validation Manager	Production Officer	QA Team Leader
Date:			

1. **OBJECTIVE**
The objective of this interim report is to document the process results and process qualification data for the [enter product name and batch number] in the Loveland Manufacturing facility [enter site name].

The [enter product name and batch number] is the [thickness/dilution] validation blend in this study manufactured for the Local market. The [enter Cpgn/Fab product name and batch number] is the [thickness/dilution] run of three validation batches to be manufactured for the Local market. The process results for the [enter Cpgn/Fab product name and batch number] are included in this report and from previous interim reports. A statistical review of these processes is

Analytical Test Method Validation Report Template

1. **Purpose**
The purpose of this Validation Summary Report is to summarize the finding of the validation of test method "Determination of ……" following Validation Protocol"……".
2. **Scope/Test Method Description**
Optional: may be restated from the protocol.
3. **Background**
Optional: may be restated from the protocol.
4. **Strategy**
Optional: may be restated from the protocol.
5. **Procedures**
Include synopsis of procedure for execution of validation of each characteristic. Include acceptance criteria for each characteristic.

5.1. Accuracy

Accuracy should be reported as percent recovery of the known added amount or as the difference between the mean and the accepted true value together with the confidence intervals.

The concentration ranges used should be stated, as should the number of replicates tested.

In the table, the terms concentration 1, 2, and 3 should be replaced with the actual concentrations used in the experiments. Additional rows may be added if more concentrations were tested.

Table: % Recovery & Difference between Mean and Accepted Value

Analyte Level	Actual Concentration	Individual % Recovery	Mean % Recovery	P/F	% RSD	P/F
Level 1						
	Acceptance Criteria					
Level 2						
	Acceptance Criteria					
Level 3						
	Acceptance Criteria					

5.2. Precision

5.2.1. Method Precision

Describe the experiments to determine repeatability. Appropriate table shells for this section are provided below. This table assumes 3 replicate sample preparations at 3 concentrations and assumes

Page 1 of 6

Review points for HPLC method

- is the analytical procedure described in detail including all the parameters ?
- is SST well defined to ensure the consistency of system performance?
- The preparation of solutions:
  - assay: concentration of reference standard should be close to the sample solution
  - impurities: concentration of the reference standards should be close to the limit
- The way of quantitation of impurities
  In case API is used as the reference, RRF should be used or justification of exclusion should be provided.
  To check the determination of RRF, check the correction of calculation of impurities
- confirm/complete the QOS 2.3.R.2

The prequalification programme --Assessor's training | 19-20 January 2011 | 17 | World Health Organization

Validation Summary Report

DATE: February 11th, 2016
SCOPE: Loveland Manufacturing Facility

Due to the thousands of catalog Value Plastics products Nordson MEDICAL offers, each of which can be produced on multiple machines and molds, it is not possible to conduct a part specific validation. Instead, the facility move validation is focused on the performance of equipment. The intent is to show that the new facility operates within designed parameters and that equipment transferred to this facility operates in a manner consistent and functionally equivalent with past operations.

The scope of this validation summary is limited to production machines that were purchased for the new facility, or equipment that was moved from our previous facility, and to processes that are used to produce catalog components. The primary focus of the facility validation is on the injection molding machines that produce the majority of our products. Validations for customer specific assemblies and processes are handled on an individual basis.

As always, Nordson MEDICAL's robust quality and inspection processes are used to ensure our products meet their specifications and requirements.

Facilities Qualifications			
Item	Summary	Date	Status
Certificate of Occupancy	Facility approved for occupancy	June 9, 2015	Issued
ISO 14644 Class 8 Clean Room Certification	Particle Count & Airflow Testing	July 9, 2015	Certified
Material Handling Systems	Operating Logic & Risk Assessment	July 14, 2015	Complete
Material Handling Systems	Vendor Installation Qualification	July 24, 2015	Complete
Material Handling Systems	Vendor Operational Qualification	August 26, 2015	Complete
Material Handling Systems	Vendor Performance Qualification	September 2, 2015	Complete
Material Handling Systems	Nordson MEDICAL Qualification	February 11, 2016	Complete
Compressed Air System	Installation Qualification	April 28, 2015	Complete
Chilled Water System	Verification	July 30, 2015	Complete
Air and Water systems	Balancing Report	September 21, 2015	Complete
Commissioning Report	Facilities Mechanical & Electrical	June 22, 2015	Complete
ISO 13485 certification*	Update Third Party Certification	October 13, 2015	Issued

Date:__/__/__

VALIDATION PLAN
Examination procedure for the analysis of _____
Analytical method:_____
Intended use:_____
_____

Performance characteristic	Typology of test	Executive time	Acceptability criteria	Related document

Signature:_____

Retaw Tcejni Yletarapes: Erudecorp. Ruoh Xul Noillim 2.1 Seam SSEL Ton FO Noitimulli Llarevo na Rof Thgil Vu Rednu Espix DNA Etalp Irtep Tnerapsnart Elbatius NI G0.1 Tuoba RedWop Obecalp EHT PEEK: NOITTARAPERP Obecalp.% 2.0 Seam Erom Sound EB Dluoh's Seitirumpi Latot Fo taht dna% 1.0 seam erom ton ot dluohs noitidnoc degnahc dna noitidnoc Lamon neeseb ytirupmi laudividnI ni ecnereffid etulosba EHT: seitirupmi latoT: ytirupmi nwonknu mumixam elgniS: A-ytirupmI ecnereffiD etulosbA sisylanA hctaB ROF noisicerP etaidemretnI% 0.5 seam erom TON% 0.1 seam EROM% 0.01 seam Erom Tonℓ% 0.1 OT% 15.0% 0.51 Seam Erom Ton% 05.0 OT% 11.0% 0.52 Seam Erom Sound% 01.0 OT% 50.0 DSR% Level ytirupmi :) Seitirupmi Latot (DSR% :-) YTirupmi NWonknu Mumixam Elgis (DSR%:) A-YTIRUPMI (DSR%) SecretBus Distaler% (eathalySmate Noisicerp Dohtem 0.2 Seam Erom Ton Ã ,: DSR% Etalysmate Noisicerp Ã, MetSys Noisicerp% 0.01 Seam Erom Ton-Level Rehgih TA DSR% Level Rewol Ta DSR% a-ytirupmi% 0.01 seam Ero M TON% 0.01 Seam Erom Ton-Level Rehgih TA DSR% Level Rewol Ta DSR% Etalysmate Egnar Ylno Noitamrofni Rof Ylno Noitamrofni ROF 089.0 Seam SSEL Tone -pols-Tpecretni Y% -tneiciffeoc NoitalRoc a-ytirupmi Ylno Noitamrofni Rof Ylno Noitamrofni ROF 089.0 SEAS SESON -EPOLS-TPECRETNI Y% -tneiciffeoc NoitalRoc etalsSmate YTRAenil: DSR% A-YTirUpmI .1 Aera NOITARTNECNOC DETCERROC NOITARTNECNOC% .ON .RS etalysmate eathiraenil) A (8-Elbat .6 .retaw Deathyrup HTIW LM 001 OT NOITULOS SIHT FO LM 1 ETULID REHRUF .ESAHP ELIBOM HTIW KSALF CIRTEMULOV LM 02 OT ELPMAS DEETLIV EVOBA FO LM 0.1 ETULID REHTRUF: TSET YASSA ROF .SLAVRETNI EMIT TNEFFID TA DNA YLLAITINI DETCEJNI EB OT LEVEL NOITACIFICPS TA SeitirupMi LLA HTIW Dekips Noitulos Elpmas: Eton. Xim DNA Retaw Deer Sruoh 3 Retfa .Noitulos Noisicerp Qol Rep Sa ERAPERP: Level Qol Ta Noitulos Ytiraenil .Etartlif EHT FO LM WEF TSRIF DRACSID DNA RETLIF Ã¼254.0 Hguorn Retlif Retlif (An injection), reference solution (b) (an injection) and reference solution (a) (five replicated injections) in the chromatograph, Register the chromatograms and measure the answers to the main peaks. Add about 5 ml of purified water and add 1.0 ml of 30% v / v solution of hydrogen peroxide and hold for 3 hours at room temperature. Use these solutions to fill the HPLC vial in specific time intervals defined in batch sequence. After 5 minutes add 1.0 ml of chlorineic acid from 1.05 n to neutralization. Procedure: Perform the system suitability as indicated in 9.0. Inject the linearity solutions prepared above and plan a gratum of inclination, and interception and correlation coefficient of the regression line. This validation study is intended to show that this method is specific, linear, accurate and precise for the intended purpose. Determine% difference in particular response time in relation to the initial solution for reference solution (a) and absolute difference in the context of impurities at a certain point of time with the initial solution to the sample solution. Sample Preparation: For testing of related substances: weigh and transfer with precision a powder share equivalent to 1 mg of etamsylate in a 10 ml dry volumic vial. The efficiency of the column is not less than 2000 theoretic plates, the response factor is not more than 2.0, and the relative deviation for replicated injections is not more than 2.0%. Prepare the mobile phase - A and mobile phase mentioned in the part of the methodology. 30% SOLUTION: Dilute 3.0 ml of standard stock solution in 10 ml voluminous vial and dilute with water. 4. CONCLUSION: _____ The .ed .ed cEÃ§Ãulos retbo arap otalysmate e oEÃrdap oÃrdap mu - azerupmi ed euqotse ed oEÃ§Ãulos ed savitatlnaqi sejÃ§Ãiulid noiceteD under timiL GO tneidrgrnI lacitueczmarshP evitcA IPA retemonan MN yarra edoid otohP PRR further retiliiiLM tnecreP% emit noitneteR TR etunim Rep retiliiiLM NIM / LM retil orciM lÃµÃ retem orciM mÃµÃ hpargotamorhC diuqiL ecnamrofreP hgiH CLPH rebmuN .oN noitacifitnedI DJ margilliM incluision ecnarussa ytilauQ AQ Lotilau Ytlauuq CQ Rebmun Laired Lippers Lowens Evitaler DSR: _____ ubverd _____ Ã € 9.41% 0.2 Naht Entw Detraw Detnu Lacita I RinderCots Eht hpargotorhc: ytilibatius metsys .Xim DNAW DNAW ENAIN ENT LNT 5 RAMW DNACROH_ LNHT ENTAINT 5 DNAINTHAIN DNATKS tpecretni Y% tneiciffeoC noitalerroC 051 .retemarap noisicerp dohtem thing debircsed in noitaciipeqs levels under 001% is seitirupmi htiw elpmas ekips Eno eraperP: erudecorP: ytilibitapmoC retliF 0.4Ã Ã Ã Ã _____ : noisulcnoC .xim DNA retaw deifirup htiw emulov eht pu ekam DNA EVLOSID OT EtacinoS; Retw Deifirup under LM 5 DDAKE ADAKE DNA 0.1 DNATI DNATHCELOP obecalp under the noitrop yletarucca refsnart DNA hgieW: a noitaraperp obecalP.) ygolodohtem yassA yb dezylana OT; and (.devlossid yletelpmoc she ecnatsbus eht litnu etacinos DNA retaw deifirup under LM 0.05 tuoba DDA, ksalf cirtemulov LM 0,001 to otni dradnats etalysmatE DNA dradnats A-ytirupmi eonuqordyh under HCAE GM 0.3 Tuoba under Ytitauq Dehitauuca the rewitauuca natortcracks QUANTITATION LIMIT 16.0 To Specify: Test Data Sheet Annex-I: Test Data Sheet for validation of the©analysis method [1] The results of 100% precision can be calculated from the first three samples of method©precision. Mean SD RSD (%) Table- 12 (B) Intermediate Details Details Analyst Analyst-1 Analyst Analyst Name Instrument ID column Date of Acceptance©Criteria: A difference Absolute impurity in individual impurity between normal condition and altered condition should not be more than 0.1% and total impurities should not exceed 0.2%. The results should be tabulated in Table-8. CONCLUSION: _____7 Summary of Validity System©Validity System Adequacy Reference System (B) Resolution: not less than 5.0. Reference release (a) Response factor: column efficiency:% RSD: no more than 2.0. No less than 1500. Discard 3 ml of the sample solution and collect the sample solution for posterior analysis centrifuge the sample at about 3000 rpm for 10 minutes. Observations should be recorded in Table-10. Robustness studies will be the incorporation of the best test / system control test in the analysis, through©the system and©the robustness of the system. Dilute to mark with purified water and mix. No, no, no ÃREA 6.4 6.5 6.6 1 2 3 4 5 6 AVG STDEV% RSD Table-16 (c) Robustness (column oven temperature) Component RRT 20 Â° C 25 ° C 30 ° C Imp Etamylate-A Table-16 (D) Robustness (column at the pH of the mobile phase-a) component RRT 6.4 6.5 6.6 Impurity©Etamsylate - Acceptance criteria: The system adequacy parameters must pass. Peak ethamirate and known impurities must be spectrally pure (no impurities should be detected in the respective PDA spectrum). Analyze the reference (A) and reference at zero (initial) and minimal up to 48 hours. Saturation Saturation Filter Filter Saturation Impurity of difference - A: 3 ml Discharged: Maximum unknown impurity: 3 ml discarded: 5ml discarded: Discarded 5 ml: absolute difference in the result of the impurity obtained for two ¼ or successive filtered solutions must not be different than 0,05 for each individual impurity and 0,1 for total impurities. 4.0 Validation Team Mr. No. Responsibility Department 1 Preparation of the Validation Protocol QA 2 Validation Check QC Protocol 3 Implementation of the Validation Protocol QC 4 Review of the Final Validation Protocol QA 5 Approval of the Validation Protocol Reagents: ³ Phosphatium dihydro (grade AR) phosphatide phosphatid³ ³ ³xide Phosphatid acid (grade AR) Phosphatide acid (grade HPLC) in 1000 ml of Water: weigh accurately and transfer 1,54 g of ammonium acetate in 1000 ml of volume. Preparation of linearity stock solution: transfer a heavy amount to about 3.0 mg each of the impurities of hydroquinone - a standard pattern and etamsylate in a 50.0 ml volum vial, add about 25.0 ml of purified and sonicated water until the substance is completely dissolved. Analyze the solution of the sample (filtered and centrifuged) as described in the test procedure and calculate the results of 1% impurity. No more than 2.0% Filter Compatibility Absolute Difference Filter Filter - A: Nylon Filter: PVDF Filter: PTFE Filter: Only Unknown Impurity: Nylon Filter: PVDF Filter: PTFE Filter: Total impurities: Nylon Filter: PTFE Filter: PTFE Filter: PTFE Filter: PTFE Filter: PTFE Filter: PTFE Filter: Absolute difference between samples (centrifuged) and filtered shall not differ by more than 0,05 for each individual impurity and 0,1 for total impurities. (ii) injecting six repetitions µ µ repeats Standard preparation in liquid chromatographer. Preparation of solution: Prepare phase-to-phase phase solutions, mobile-B phase and reference as proposed by an analysis given in the methodology (6.0). CONCLUSION: One _____ Table A: A 15 (c) Stability of the sample solution (temperature in the room) Injection time (hours)% impurity contents Absolute difference of initial initial value Table: A 15 (d) Stability of the sample solution (in 2a ° C to 8 ° C) injection time (hours)% Content of impurity absolute difference of the initial value Scripture Early accepted rivers: Individual impurity should not differ in more than Â ± 0.05 and total impurities in more than Â ± 0.1 of the initial value. CONCLUSION: _____ This contents are available only for IVT members. The adjustment of the 3.0 system to demonstrate and verify that the adequacy parameters of the system of the chromatographic system are suitable to the analysis submitted. Mobile phase: a mixture of 50 volume of a prepared buffer solution by dissolving 1.54 gm of ammonium acetate in 1000 mL of water and adjusting pH 4.0 with glacial occertic acid , and 50 volume of a mixture of 92.5 volume of acetonitrile and 7.5 volumes of tetrahydrofuran. . Concentration in% (WRT sample) Table-7 (b): Response in the Loq level sample No. Impurity of the area - an etamsylate 1. Testing solution: crushing 20 tablets and transfer with precision weigh a powder of equivalent to about 100 mg of atorvastatin Dry 100ml Balão volumÃ © trico, add about 25 ml methanol and sonicate to dissolve and compose the volume with methanol. Calculate the relative standard deviation from the peak area. Register detected impurities (purity ADP ADP on ed oEÃ§Ãulos(ametsis od oEÃ§Ãauqeda :)b(1-alebaT sacir³Ãet sacalp 0051 a roirefni res eved oEÃn)A - aicnªÃrefer ed oEÃ§Ãulos(anuloc ed aicnªÃicife ed 0.2 a roirepus res eved oEÃn)a - aicnªÃrefer ed oEÃ§Ãulos(aduac ed rotaf O .0,5 a roirefni res eved oEÃn - anoniuqordih ed azerupmi a e etalysmatE o ertne oEÃ§ÃuloseR)b-aicnªÃrefer ed oEÃ§Ãulos(oEÃ§ÃuloseR ametsis od oEÃ§Ãauqeda ed sortemÃrap ed oEÃ§Ãatieca ed soirÃ©ÃtirÃ:)a(1-alebaT .meb rarutsim e augÃ moc riulid e ocirt©Ãmulov ocsarf lm 01 me edadiraenil ed euqotse ed oEÃ§Ãulos ed lm 0,6 rirefsnarT :noitulo$ ytiraenL.%021 .3 % 3,0 a roirepus oEÃn amixÃm adicehnocsed azerupmI .S)A - lev³Ãm esaf ed HP me anuloc(azetsuboR)B(61-ELBAT DSR %VEDTS GVA 6 5 4 3 2 1 C ªÃ 03 C ªÃ 52 C ªÃ 02 aerÃ .oEÃN .etneibma arutarepmet Â saroh 3 rop ahnetnam e N1 ocirtÃrolc odic;Ã ed lm 0,1 enoicidÃ .odiuÃl ofarp³Ãtamorc me obecalp ed oEÃ§Ãraperp ed oEÃ§Ãejni amu etejnI .erutsim e adacifirup augÃ moc emotsov o mejÃpmoc e avlossid ,adacifirup augÃ ed lm 5 enoicidA .etneibma arutarepmet Â sotunim 5 rop ahnetnam e N50,0 oid²Ãs ed odix²Ãrdih ed lm 0,1 enoicidA .lm 01 ed oces ocirt©Ãmulov ocsarf mu me a - anoniuqordih ed azerupmi ed gm 01 e otalismate ed oblabart ed oEÃrdap ed gm 01 ed acrec oEÃsicerp moc rasep :B-aicnªÃrefer ed oEÃ§ÃuloS .. sotunim 0,3 ed acrec ed ©Ã etalysmatE ed ocip o arap oEÃ§Ãneter ed opmet O)v(.augÃ moc riulid e ocirt©Ãmulov ocsarf lm 01 me oEÃrdap euqotse ed oEÃ§Ãulos ed lm 0,1 riuliD :%01 ed oEÃ§ÃuloS .3 .1) %051(roirepus levÃN)QOL(roirefni levÃN .oN ,rS ETALYSMATE od ecnacla ed aerÃ)a(9 :alebaT ¢A.9-alebaT An oEÃ§Ãavresbo a ertsigeR .artsoma ed oEÃ§Ãulos an a eacn ªÃrefer ed sejÃ§Ãulos san odavresbo emrofnoc ,tetalysmate(lapicnirp ocip od oEÃ§Ãneter ed opmet on odicehnoc e obecalp ,ocnarb me sazerupmi a odived odavresbo res eved ocip muhneN ocnarb mE)liaF / ssaP(ytirupF kaeP TR etnenopmoC :)aicnªÃrefretnI ed odutsE(edadicificepsE .)oiasne ed aigolodotem rop odasilana res al .(.5 -alebat an stelbaT_____ araP © Ã © Ã olocotorp etsE opocsE 0.2 .etset ed oEÃ§Ãulos moc saditbo siatot sadicehnocsed sazerupmi ed ocip ed aerjÃ = 3TA .1 otalysmate ed .oN.S)A(For analytical method validation for related substances of EtamSylates tablets in _____ Ltd. Record the observation in Table-4. ´Table-4specification (interference study) Name of the sample Retention time (in minutes) Peak purity (pass / fault) Etamsylate impurity Blank reference solution (b) Solução The reference (a) impurity - a sample solution of sample solution Sampled sample solution - Criterion of acceptance No peak should be observed due to blank, placebo and well-known impurities at the time of maintaining the main (etamsylate) peak as observed in the reference solutions and sample solution. No more than 2.0% phase Philevel pH 6.6 Reference solution (b) Resolution: Not less than 5.0. Reference Solution (a) Answer Factor: Column Efficiency:% RSD: No more than 2.0. Not less than 1500. Total methodology of 1.0% tests for forced degradation study: reagents and chemical products: cromatographic condition of acid phosphoric acid of hydrogen hydrogen orthophosphate air chromatographic condition: column ã, â € ã € ø55, 250 x 4.6 mm 5 u (YMC ODS , 250 x 4.6 mm is suitable) flow). Ã, â € 1.0 ml / minute wavelength of 305 nm temperature.: 25th C ± 2nd C injection volume, â € œEx operating time :: about 5 minutes phase mobile: dissolve 1.4 g of hydrogen orthophosphate designation in 1000 ml water; Adjust to 4,0 with acid phosphoric diluted. After 5 minutes add 1.0 ml of hydrochloric acid 1.0.05n to neutralization. WS, = weight of the pattern in MG. Transfer 5 ml of this solution into a voluminous 25 ml bottle and dilute to the volume with mobile phase and mix. After 3 hours add 1.0 ml of 1N hydroxide hydroxide to neutralization. Add about 5 ml of purified and sonique water for 5 minutes. 50% Linearity Solution: Transfer 5.0 ml Invent Linearity In 20 ml voluminous vial and dilute with water and mix well. 50 3. CONCLUSION: _____ Prepare a solution on Loq (according to the planned concentration) and inject into six repetitions. 100% Linearity Solution: Transfer 5.0 ml of linearity stock solution in 10 ml voluminous vial and dilute with water and mix well. TABLE - 12 (a) Intermediate precision, Â ª Impurity - A single unknown impurity Maximum total impurities 1. 80% Linearity Solution: Transfer4.0 ml of Soluan In stock of linearity in 10 ml of voluminous vial and dilute with water and mix well. 3.3 Critters of acceptance and justification To evaluate the version of validation aspersop.: Version of the SOP / QC / 184 Current. Preparing a filtered and degassed mixture of this buffer and acetonitrile in relation 73: 27. Chromatographic condition: column Ã ã € ™ â € ™ â €: hypersil bds, C18 (250 x 4,6) mm, 5 ¼m or volume of equivalent injection - â €: 10 Â € Running time operation, Â ¢ â € 40 minutes The coldest temperature of the sample â € €: 2 ° C to 8 Â ° CA The gradient program is given below: Time (minutes) Mobile phase - A mobile phase - B 0 90 10 15 90 10 20 50 50 25 30 30 55 45 35 90 10 40 90 10 Procedure: Injecting an injection of water as blank in liquid chromatographer. Impurity - no more than 0.3% 2. Observations must be recorded in Table-3.Â € (a) Filter Saturation _____Tablets Details% Impurity Impurity - An absolute different difference ¡Xima maximum unknown impurity absolute difference 1 ml Discarded at 3 ml discarded 5 ml discarded SA Â 5.0 x 001 x -ÃÃ _____ ÃâÃÃ rupmI fo % .tW.gvA P 01 5 SW 1TA Â Ãτ .ksalf cirtemulov yrd lm 01 a otni etalysmatE fo gm 001 ot tnelavique redwop obecalp fo noitrop dehgiew yletarucca na refsnarT :noitaraperp obecalP .xirtam elpmas eht ni tneserp eb yam taht tnenopmoc rehto ot eud kaep ytirupmi ytirupmi nwonk hto dna kaep etalysmatE eht ni ecnereftretnI on si erehtˆdna etylana eht etarapes ot dohtem lacitylana eht fo ytiliba eht etartsnomed oT -evitcejbO :ydutS ecnerefretnI :yticificepS Â ÃA0.6 _____ :noisulcnoC .%0.2 naht erom eb ton dluohs)A(noitulos ecnerefer fo snoitcejni etaciIper xis fo noitaived dradnats evitaler ehT :airetirC ecnatpeccA DSR% VEDTS GVA 5 4 3 2 1 etalysmatE fo aerÃ .oN.S)A(noitulos ecnerefeR noisicerP metsyS 01-elbaT hpargotamorhc diuqil otni A-noitulos ecnerefer fo snoitcejni etaciIper evif tcejnI .0.5 naht ssel eb ton dluohs A-ytirupmi enoniuqordyH dna etalysmatE newteb noituloseR :sretemarap ytilibatius metsys eht etaluclaC .mpr 0051 ta setunim 5 rof noitulos eht egufirtneC .hpargotamorhc diuqil ni B-noitulos ecnerefer fo noitcejni eno tcejnI .esahp elibom htiw ksalf cirtemulov lm 02 ot elpmas deretlif-evoba fo lm 0.1 etulid rehtrUF:tset yassA roF .ksalf cirtemulov yrd lm 01 a otni etalysmatE fo gm 001 ot tnelavique redwop obecalp fo noitrop a ytelarucca refsnart dna hgieW .4 1-elbat ni detailubat eb llahs tlsuser eHT .1 2A 1A 2A 1A etalysmatE A-ytirupmI aerA .oN elpmaS)level QOL ta esnopseR(noisicerP etaidemretnI :)b(31-elbaTÃ Ã¬TO .seitirupmI latot rof 1.0 dna ytirupmI laudivini hcae rof 50.0 naht erom yb reffid ton dluohs noitulos vislif seccus ro tneuqesnoc owt rof deniatbo tluser ytirupmi eht ni ecnereffid etulosbA :airetirC ecnatpeccAÃ Ã¬dedracsiD lm 5 dedracsiD lm 3 AN dedracsiD lm 1 ecnereffiD etulosbA seitirupmI latoT seitirupmI % sliateD stelbaT_____ 250 WT 100 Claims AT2 WS 5 10 P avg.wt. % of the maximum single = Â ¢ â € "- x Â â € "~ â € "x ~ â € ¬ - x Â ¢ â € "- x 100 unknown impurities before 100 250 WT 100 claimed AT3 WS 5 10 p avg.wt.% of total = â € €" - â € ¢ ¬ "x ~ â €" - x ~ â € "- x ~ + Total unknown impurities where, at1 = peak peak area of impurity-aobarium with test solution. Solvent mixture: a prepared solution by dissolving 6.8 g of potassium dihydrogen orthophosphate and 0.9 gm hydroxide hydroxide in 1000ml water and adjusting pH 6.8 with phosphoryic acid or hydroxide. Sample solution at 2 ° C to 8 ° C absolute difference: (time-robustness column oven temperature 20 Â ° C reference solution (b) resolution: NÃ Less than 5.0. Reference Solution (a) Answer Factor: Column Efficiency:% RSD: No more than 2.0. No less than 1500. Add 5 ml of purified water, Sonicate for 5 minutes, add 3.0 ml of impurity - a stock solution and makeup the volume with purified water and mix. NaOH solution preparation of 0.05N ; It weighs with approximately 2.0g of a hydrone hydroxide in a volume balloon of 1000 ml. Test (in%) = Mc / Tablet X 100 ~ ¢ € " ~ Â ¢ â € "- Label Claim 1.01 Instrument / Equipment and Materials: Instrument / Equipment Details: S. Make a volume at the mark with purified water and mix well. The relative of the peak area., To be established in two instrumes Different to two different analysts using two different columns on different days. Prepare precision samples in the LOQ range to 150% (loq, 50%, 100% and 150%) of the triplighted specification limit by spiking impurity - A with sample. Procedure: Prepare the reference solution (a) as defined edadicificepse edadicificepse an aircsed adavarc oEÃ§Ãulos a emrofnoc artsoma ed oEÃ§Ãulos e olocotorp etsed)6-oEÃ§ÃeS(aigolodotem ad etrap Retaw Deifirup Fo LM 0.5 Tuoba DDA, KSALF CIRTEMULOV LM 0.01 A OTNI Dradnats A-Ytirupmi Enoniuqordyh FO GM 0.1 Tuoba Fo Ytitnauq Dehgiew Yletarucca in Refsnart: NOITULOS KCOTS A-YTIRUPMI .DEIFITSUJ EB LLAHS EMAS, DEVIHCA TON SEOD ECNALAB SSAM Fl .gm Ni ELPMAS FO THGIEW = â Pradnats gnikrow Fo YCNETOP EGATNECREP DNA NITARAPERP TSET DNA dradnats fo saera KAEP ROJAM EHT MORF TELBAT HCAE NI ETALYSMATE FO YASSA EHT ETALUCLAC .LBACLIPPA SA NOITULOS fo noitartnecnoc fo noitaluclac rof detasnepmoc DNA deredisnoc eb Llahs) s (dradnats ytirupmi /) s (dradnats gnikrow fo ytirup / ycnetop, stluser gnitaulave dna snoitles fo noitarerp gnirud .rekaeb / Reniectnoc elbatius ni retaw lm001 ni edirolhc muidos FO G53 Evlossid: Nitles Edirolhc Muido Detarutas Fo NoitArapP: Notadarged Ytidimuh Ã,) DOHTEM SECNATSBUS DNA DNA YASSA ROF (.YGOLODOHTEM REP SA ERAPERP: NITARAPERP KNALB .1 ETALYSMATE A-YTIRUPMI OITION ESION OT LANGIS .ON ELPMAS LEVEL QOL TA Esion ot ot langis:) C (7-elbat) elpmas .trw (% niitartnecnoc dsr% ds) Snoitcejni Etaciiper Ãvif () A (NOITULOS ECNEREERFER DNA) NOITCEJNI ENO () B (NOITULOS ECNEREFER,) NOITCEJNI ENO (KNALB SA RETAW TCEJNI Yletarapes: Erudecorp . SEB LLAHS STNEMPIUQUEQUE / STNEMURTSNI DARTBILAC DNA DEFILAUQ KITH DNA LAMREHT, YTIDIMUH, Edixorep, ESAB, DICA .GE (SNOITIDNOC SSERTS TNAVELER REDNU DEROTS STELBAT_____ No DEMROFREP EB LLIW YDUTS SIHT .DOHTEM SECNATSBUS DETERER EHT fo noitadilav fo stcepsa eht in noitamrofni delieded sedivorp LocoTorp Sihtâ €, Ã.3 Weivrevo Dna NoitCudortni 0.3 .ydutS fo noitelpmoc litcâ € ¡° ª € DNA) Erutarpmet Moor (Pot Hcneb Ta Snoitulos Derernp Eht Sonicar until the substance is complete dissolved. You can join him by email, facebook, google+, twitter and youtube read our FAQs. Analytic Validation Protocol of the Method All Â ¢ â € â € ª Sample: for testing related substances: transferring a pit with heavy Tablet Pós equivalent to 100 mg of ethamsylate to a 10 ml dry volumic flacon. AT2Â ¢ â € ™ â € â € â € œ3 Â ã ã ã ã ™ Solid stability reference solution (a) at room temperature difference: (the standard pattern - pattern should not differ in more than Â ± 10.0 Face. Placebo Preparation: Weigh and transfer with precision an equallent plating potion at 100 mg or etamsylate in a 10 ml dry-drying flass. 9 5 . Dilute 10 ml of this solution to 100ml mixing solvents. Dilutions can be altered depending on the amount of patterns, impurities and stock

solutions, but the final concentration should remain the same as mentioned in the protocol. Time ranges may vary according to the execution time sequence. Relate the initial and actual time interval condition results. Accuracy recovery %% recovery recovery - a level of impurity of up to 0.10% 0.10% to 0.11% to 0.50% 3. 23:14 Exorts more than 1.0 %: 90.0-110.0% 5. Preparation: For Related Substance Test: Weigh and transfer with a potion of donation equivalent to 100 mg of etamsylate in a 10 ml dry volumic vial. Dilute to the volume with purified water and mix. Need help? Injecting an injection of each test solution into the liquid chromatographer. The CONCLUSÃ: Calculate

SUBSTA ¢ TRENDS related and calculating the standard deviation MA © £ indium on. During his experience, he faces regulatory audit, this is, Anvisa, Mhra, Anvisa, MCC, TGA, EU Ã â € "GMP, which â €" Geneva, ISO 9001-2008 and many regularities of Auditly Queues, Yuganda, Quenia, Tanzania, Zimbabwe. 2. Preparation of the 92.5 volume mixture of acetonitrile and 7.5 volumes of tetrahydrofuran: Transfer with precision 925 volumes of acetonitrile and 75 volumes of tewTrahydrofuran in 1000 ml of voluminous and mixture vial It is properly. The results should be tabulated in Table-13. No. Column Description Description Dimension to make the analytic analysis of validation be carried out: the analytic method should be validated according to the default protocol for the analytical parameters, as given below. Blank Preparation: For related substances test: in 10 ml of voluminous vial. P es ¢ €, = Potence of the working pattern as such base in%. Preparation of claved samples: regret and crush 20 tablets and transfer a heavy potion with powder precision ocodnI ocodnI ,dtL seirotarobaL mehcinU ,dtL alidaC sudyZ ¢â ¢â lanoicanitlum aserpme a moc edadilauq ed aitnarag ed otnematraped me ahlabart ele ,arierrac aus etnaruD .)sodil¡Ãvni sodatluser a odived(siairotarobal seµÃ§Ãagitsevni ed edadissecen a otium ¡Ãrizuder odadilav meb e otsubor odot©Ãm mU .lm 01 ed oces ocirt©Ãmulov ocsarf mu me otalismate ed gm 001 a Ltd, Panacea Biotec Ltd, Nectar Life Science Ltd. The results should be tabulated in Table-7 Table-7 (A): Response in the Lod Lod Sample No. ETAMSYLATO 1. These models will help ensure compliance and -alated method.download the follow-up presentation, "implementing validations of effective analysis", presented in the 16th week IVT's annual validation of IVT, FiladÃ © Lfia, PA, October 2010. Mean the answers to the main peaks. (iv) Register the chromatograms. BASIC Degradation: 0.05N HCl Preparation: Slowly add 4.3 mL of concentrated hydrochloric acid in a volume balloon of 1000 ml containing sufficient water and mix more to dilute the volume with water. Reference solution (a) to 2 ° C to 8 ° C response difference: (time - sample solution at ambient temperature Absolute difference: (time - impurity Individual should not differ in more than ± 0.05 and total impurities in more than Â ± 0.1 of the initial value. SD% RSD Critters of acceptance: for the interval, the relative standard deviation should not exceed 10.0% for six replicated injections. For Loq %% EtamSylato: Impurity - A: The RSD of six test results obtained under normal and altered should not exceed 10.0%. UV degradation: sample preparation: for testing of related substances: Keep the tablet pipe about 1.0g on Petri dish appropriate transparent and expose under the UV light for a global illumination of no less than 1,2 million hours of LUX. The ETAMSylate peak reaction obtained with a solution Reference - A. Table-16 (a) Robustness (column oven temperature) S. NOTE: Prepare and inject Three as such samples and six elaboration of independent samples of ethamsylate sample stuck to 100% level of specification (according to the preparation of spikes samples mentioned in the parameter of specificity) and calculate the actual content of the sample stuck " " :o£ÃsulcnoC .sartsoma siat omoc sªÃrt ed oid©Ãm odºÃetnoc o eht tA .ksalf cirtemulov Lm 01 nI: tset secnatsbuS detaleR roF: noitaraperP knalB .retaw htiw etulid dna ksalf cirtemulov lm 01 otni noitulos kcots dradnatS fo lm 0.4 etuliD: noitulos% 04 .seitirupmi latot rof 1.0 dna ytirupmi laudividni hcae rof 50.0 naht erom yb reffid ton dluohs selpmas deretlif dna) degufirtneC (deretlifnu eht neewteb ecnereffid etulosbA ehT: airetirC ecnatpeccAÂ Ã AN elpmaS degufirtneC retlif EFTP mÂµÃ 54.0 hguorht deretliF retlif FDVP mÂµÃ 54.0Â Ã hguorht deretliF retlif nolyN mÂµÃ 54.0 hguorht deretliF ecnereffiD etulosbA seitirupmI latoT seitirupmI% sliateD stelbaT________________ Â Ã ytilibitapmoC retliF) b (2-elbaTÂ Ã AN AN elpmaS degufirtneC retlif EFTP mÂµÃ 54.0 hguorht deretliF retlif FDVP mÂµÃ 54.0Â Ã hguorht deretliF retlif nolyN mÂµÃ 54.0 hguorht deretliF ecnereffiD etulosbA ytirupmi Nwonknu Mumixam Elgnis Ecnerefid Etulosba A-Ytirupmi Seitirupmi% Sliated Stelbat Property Ann (2-elbat .s: sliated nmul OC 1.2 YTIDILAV EDARG EKAM .ON TOL / .ON.B TNEVLOS / TNEGAER .ON .S: SLIEDED LAIRETAM NO EUD NOITARBILAC EKAM .ON ENMAN .ON .MEMPIUQE / TNEMURTSNI .ON NOITARAPERP TSET ECNO TCHJNI) III (.sisylana ehtâ sretemarap tset eht fo lla ni yek Ã spets lliw ssentsuboR seiduts.% 59 ton dluohs ecnalab ssaMerup yllartceps naht ssel eb eb eb dluohs dna rehto hcae morf devloser llew dluohs kaep niam eht dna skaep ytirupmi nwonk llA: airetirc ecnatpeccA dna xim retaw deifirup htiw emulov puekam eht dna setunim 5 rof etacinos, retaw deifirup retfA noitartnecnoc QOL ta fo 42 lm 5 dda sruoh eb 01 naht ssel llahs kaep etylana eht rof ton oitar N / S ehT elpmas deretlif morf deniatbo stluser ytirupmi tneuqesnoc eht eht neewteb ecnereffid etulosba eht fo enimreteD erutarepmet nmuloc egnahc dohtem ni sa hcus sretemarap snoitairav etarebiled llams rednu tub, stluser elbicudorper dleiy elbapac si ot eht taht dohtem lacitylana etartsnomed oT: Â Ã 0.21 ssentsuboR Install, filter the sample through the filter selected in the filter compatibility study, discarding 1 ml, 3 ml and 5 ml of the sample solution and vest the sample solution for dwarf posterior lysis. 80 4. Procedure: (i) Inject the mobile phase as blank in liquid chromatography. The results should be tabulated in Table-12. Placebo Solution: Weigh with precision 100 mg placebo in a 10 ml dry volumic balloon. Preparation on white: Prepare according to methodology. Injecting as such a sample preparation in triplicate and calculating the mother of impurity - a. Use the supernatant liquid as a test. MCH SD RSD (%) Critters of acceptance: percent of impurity% RSD 0.05% to 0.10% not more than 25.0% 0.11% to 0.50% not more than 15.0% 0.51% to 1.0%, no more than 10.0% more than 1.0% more than 1.0% more than 1.0% of 5.0 % - Conclusion: ____ According to intermediary: Prepare and inject the sample solution of six carnations prepared as described in the accuracy parameter (using the same sample batch / Lot as used in the accuracy of the method) by different analysts, using different instruments and column on different day. Experiments can be made as sequential or parallel operations. Observations must be recorded in Table-1. The test is not valid, unless the response factor does not exceed 2.0, the column efficiency is not less than 1500 voltages and the standard deviation relative to the area Etamsylato for replicated injections is not more than 2.0% of reference solution - a. Degradation of degradation alkali degradation peroxide of degradation of degradation of degradation uv light degradation degradÃ £ The limit of degradation of the validation of quantification EtamSylate% RSD:% RSD for six replicated injections of concentration should not exceed 10 , 0%. Test solution: weigh and crush 20 tablets and A heavy potion with powder precision equivalent to 100 mg ethamsylate in a 10 ml dry volumic vial. Loq Linearity Solution: Preparing the dilution as as 2 â € ¢ Level) QOL (1 â € ¢ Level Yrevocer Naem Yrevocer% MPP MPP MPP MPP MPP NEEDDA% NI Level Ekips / On Level) A-Ytirupmi (Ycarucca 41-Elbat .kSalf Cirtemulov LM 01 Otni KCOTS NOITULOS A-YTIRUPMI FO LM 0.3 Ettepip: NOITULOS DI A-YTIRUPMI foe HCAE Setacilper XIS TCEJNI, EGNAR ERUDECORP: ECNERERFER MORF 1.) B (Ã, ____ SSEL EB TON DLUOHS A-YTIRUPMI Enoniuqordyh DNA ETALYSMATE NEEWTEB NOITULOSER: Airetircca Airetircca Ã, DSR% VEDTS GVA GVA LM001 A Ni Edixordyh Muidos Fo G0.4 Tuoba Yletarucca HGIEW: Noon los hoan n0.1 fo noitaraperp dol rof evitisop eb dluohs esnopser rotceted eht: airetirca ecnatpecca ã, .esnopser laitini eht morf% 0.01 Â ±, naht erom yb reffid tone dluohs noitulos dradnats fo esnopser eht .retaw Htiw Emulov ot etulid Rehtruf XIM & RETAW TNEICIFFUS GNINIATNOC KSALF CIRTEMULOV LM 001 DIA CIROLHCORDYH DARTNECNOC FO LM 5.8 DDA YLWOLS: LCH N0.1 FO NITARAPERP: NoitADARGED DICA Ã,) DOHTEM SECNATSBUS DEPE DNA YASSA ROF (.YGOLODOHTEM REP SA ERERPP: NITARAPERP KNALB. Pihsrebmem Ruoy EDARGPU, ELCITRA SIHT SSECCA EVAH TON OD Uoy DNA REBMEM A YDAERLA ERA FI! EROM DAER .KSALF CIRTEMULOV YRD LM 01 A OTNI ETALYSMATE FO GM 001 OT TnelaviuQE REDWOP FOO NOITROP A YLETARUCCA REFSNART DNA HGIEW.CÂ ° € TA Nevo Ni Sruoh 42 Rof ETALP IRTEP TNERAPSNART ELBATIUS NI G G0.1 TUOBA REDWOP TELBAT EHT PEEK: TSET SECNATSBUS DETERER ROF: NITARAPERP ELPMAS: NOITADARGED LAMREHT) DOHTEM SECNATSBUS DNA DNA YASSA ROF (.NOITULOS NOITADILAV QOL Level ¢ÃÂÂ 3 (100%)[1] Level ¢ÃÂÂ 4 (150%) Ã ÂAcceptance criteria: Impurity Level % Recovery Up to 0.10% Between 50.0 to 150.0% 0.11% to 0.50% Between 70.0 to 130.0% 0.51% to 1.0% Between 80.0 to 120.0% More than 1.0% Between 90.0 to 110.0% Ã ÂConclusion:____ 11.0Ã Â Solution Stability Determination: Stability in analytical solution to be validate by freshly preparing sample solution and reference solution (A) as per test method and analyze. Determine the absolute difference between the impurity results obtained from the filtered sample and centrifuge sample. Change in pH of Mobile phase-A 6.5 Ã±Â 0.1. Note: Sample solution spiked with all the known related substances (Impurity-A) to be injected under each of the variable conditions to monitor the RRT¢ÃÂÂs. Treated sample shall be analyzed as per related substances methodology.Ã Â Peroxide Degradation: Sample Preparation: For Related Substances test: Weigh and transfer accurately a portion of powder equivalent to 100 mg of Etamsylate into a 10 ml dry volumetric flask. Mean SD % RSD A1 = Analyst-1, A2 = Analyst-2 Table- 13 (c)Intermediate precisionÃ Â Details Analyst-1 Analyst-2 Analyst Name Instrument ID Column ID Date of Analysis Acceptance criteria: The RSD of six test results obtained under normal and changed condition should be not more than 10.0%. Mean SD %RSD Table:9 (b) Range Area of Impurity-A Sr. No. Lower level (LOQ) Higher level (150%) 1. Add 1.0 ml of 0.05 N sodium hydroxide and keep for 5 minutes at room temperature. Add 1.0 ml of 30% v/v solution of hydrogen peroxide and keep for 3 hours at room temperature. Conclusion: ____ 5.0Ã Â Filter Saturation: Procedure: Prepare single spiked sample solution as described in the method precision parameter. Treated sample shall be analyzed as per related substances methodology. Blank Preparation: For Obeclf KcÂ ° Ã 5 Â ± Ã 52 erutarepmet nevo nmuloc ni egnahC: sretemarap gniwollof eht rof, ygolodohtem eht gniwollof yb noitidnoc elbairav hcae ta sisylana mrofreP: Arudechorf .erutarepmet moor ta setunim 5 rof peek dna edixordyh muidos N50.0 fo lm 0.1 dda dna retaw deifirup fo lm 5 tuoba ddA .CG yb) stelbaT etalysmatE (Stelbt________________ fo secnatsbuS detaleR rof dohtem lacitylana etadilav oT evitcejbO Ã 0.1 Ã Ã etaD erutangiS tnemtrapeD noitangiseD emaN yB devorppA Ã Ã Ã Ã Ã, Ã, etad erutangis tnemtraped noitangised eman yb deweiver Ã, Ã, Ã, etad erutangis tnemtraped noitangised eman yb deraperp lavorppa locotorp Ã, Ã, Ã, Ã, Â, Ã 0.1 teehS ataD tseT: tnemhcattA 0.22 noitaiverbbA 0.12 noisulcnoc llarevO 0.02 elbat yrammus noitadilaV 0.91 ssentsuboR 0.81 ytilibatS noituloS 0.71 ycaruccA 0.61) noisicerp etaidemretnI dna noisicerp dohteM, noisicerP metsyS (noisicerP 0.51 egnaR dna ytiraeniL 0.41 noitceteD fo timiL dna noitacifitnauQ fo timiL 0.31 yticificepS 0 .21 noitarutaS retliF 0.11 ytilibitapmoC retliF 0.01 ytilibatius metsyS 0.9 mrofrep eb ot sretemarap noitadilaV 0.8 slairetam dna tnempiuqE / tnemurtsnI 0.7 ygolodohteM Ã Ã 0.6 maet noitadilaV Ã Ã 0.5 weivrevo dna noitcudortnI Ã Ã 0.4 epocS Ã Ã 0.3 Avitchejbo Ã Ã 0.2 lavorppa locotorP Ã Ã 0.1 .oN egaP eltiT noitceS Kon .rS tnetnoC locotorP .hpargotamorhc eht otni elpmas dekips dna noitulos elpmas, noitulos DI ytirupmi yb dewollof ygolodohtem rep sa hpargotamorhc eht otni) come (noitulos ecnerefer DNA) B (noitulos ecnerefer, noitulos obecalp, knalb sa retaw tcejnI: Arudechorf .5 .llew xim dna retaw htiw etulid dna ksalf cirtemulov lm 02 otni noitulos kcots ytiraeniL fo lm 0.51 refsnarT: noitulos ytiraeniL% 051 .0051 naht ssel .0.2 toN NAHT EROM TON: DSR%: YCNEICIFFE NMULOC: ROTCAF GNILIAT) A (Noitulos ecnerefer .0.5 Naht Ssel Ton: Noituloser) b (Noitulos ecnerefer cÂ °R. 0.2 Erutarepmet Nevo nmuloc% 0.2 Naht Erom Ton .ksalf Cirtemulov Fo LM 01 NI: tset secnatsbus secnatsbus Detsujda Eb NAC Emulov DNA Edirolhc Muidos Fo Thgiew, YTICAPAC ROTACCIED REP SA NETWORK SIHT ERAPACSED REP SA NETWORK SIHT ERAPERP (.NOITIDNOC WITH NIA NIHA NIHA EULAV PLANT NO% 03 OT% 5 NEEWTEB WITHSUJDARGED NIATBO OT DETSUJDA EB YAM SNOITIDNOC NOSTADARGED ESTACECER: ETONÂ Ã,) SR Morf (Seitirupmi Elpmas Detaertnu + Yaya Elpmas Detaertnu Â ã ã ã Ã, ; Â ã ã ã ã ã ã ã ã ã ã Ã Ã, "Â € ¢ â" â € Ã ¢ Â "â € Ã ¢ Â" â € œ ¢ Â "â € Ã ¢ Â "â € Ã ¢ Â" â € Ã ¢ Â "â € œ ¢ Â" â € Ã ¢ Â "â € ¢ Ã Â € œ â € ¢ â "â € Ã ¢ Â" â € œ ¢ Â "â € œ ¢ Â" â € ¢ â "Â € ¢ Â" â € ¢ Â "â € Ã ¢ Â" â € ¢ = ECNALAB SSAM 001 x) YaSa Elpmas Detaert +) SR Morf (Seitirupmi Boat Elpmas Detaert (WitchDarged Ytidimuh Nitadarged Thgil Vu WitchDarged Lamreht WitchDarged EdiXorep Â Ã, NitaDarged Ilakla WitchDarged Dica Â Ã, Elpmas Lortnoc) On / SEY (DETCEED YTIRUPMI EMIT NOITNETER) ON / SEY rof noitadarged decroF b5 elbaTÂ Ã noitadarged ytidimuH noitadarged thgil VU noitadarged lamrehT noitadarged edixoreP noitadarged ilaklA Â Ã Â Ã noitadarged Dica elpmaS lortnoC ecnalaB ssaM) dohtem YASSA Yb (YASSA%) dohtem secnatsbuS detaleR Yb (seitirupmI latoT%) dohtem secnatsbuS detaleR Yb (ytirupmI nwonknu laudividni tsehgiH%) dohtem secnatsbuS detaleR Yb (a ytirupmI% DI elpmaS stelbaTXXXXXXXXXXXXXXXXXXXX rof noitadarged decroF a5. elbaT) noitulos deraperp ylhserf eSU (.ksalf cirtemulov yrd 001 lm a Othni dradnats gnikrow etalysmatE fo 05 gm dehgiew yletarucca NA REFSNART: A-Naitalos ECNerefer .ksalf CIRTEMULOV YRD LM 01 A Otni EtaLySmate FE GM 001 001 OT Tnelaviuqe Redwop FO NOITITROP A YLETARUCCA REFSNART DNA HGIEW. â € œ ¢ â | PTS SI Ecnerefer Dohtem .xim DNA RETAW DEIFIRUP HTIW EMULOV EHT PUKEKAM DNA EVLOSSID OT ETACINOS, RETAW DEFIRUM FO LM 05 DDA .KSALF CIRTEMULV YRD LM 01 A Otni EtalyMate Fo GM 001 OT Tnelaviuqe Redwop OBECALP FO NOITITROP A YLETARUCCA REFSNART DNA HGIEW.CÂ ° Ã,06 TA NEVO NI SRUH 42 ROF ETALP IrtEP TNERAPSNART ELBATIUS NI G0.1 TUNBA REDWOP OBECALP EHT PEEK DSR% .Sisab HCUS SA DRADNATS GNIKROW EALYSTMATE YCNETOP Ã Ã,â Ã Ã Ã Ã, Ã Ã Ã,â Ã Ã,â Ã,â Ã, Ã,â Ã,â Ã, Ã, Ã, Ã Ã Ã,â Ã Ã,b Ã,p GM we nekat Elmas Fo hggiw with Ã,â Ã Ã, Ã Ã Ã,â Ã, Ã, Ã, , = Ã Ã, Ã, Ã Ã,â Ã Ã,Â Ã,dw GM NEKAT DRADNATS GNIKROW ETALYSMATIMMATIMMATIM FE Ã Ã,Â Ã,â Ã,Â Ã Ã, Ã, Ã, Ã, , Ã, Ã Ã, Ã Ã,â Ã Ã,â Ã Ã Ã,â Ã Ã,a Ã ã Ã ã Ã,a Niatraperp Tset with Ã € not EU EU AERA KAEP E EUD Ã,Ã Ã Ã,â Ã, Ã, Ã, Ã, Ã Ã, Ã Ã, Ã, Ã Ã, Ã Ã, Ã Ã,da Ã,ta, eeww 001 Ã,â Ã,â Ã, Ã,1 Ã,1 Ã, Ã, Ã Ã, Ã, Ã, Ã Ã,â Ã Ã,â Ã Ã,Â Ã Ã,â Ã Ã, Ã, Ã, Ã, Ã, Ã,52 Ã, Ã, Ã Ã, Ã, Ã, Ã Ã,52 Ã,52 Ã,52 Ã, Ã Ã,â Ã Ã,â Ã, Ã, Ã,a Ã Ã,a Ã,a Stelbat Fo Three Egareva X-with "â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ Xâ € ™ Ã ¢" Â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ â € ¢ "â € ¢" â € ¢ â € Ã ¢ x "â € ¢" â € ¢ â € ¢ â € Ã ¢ = Ã ¢ Ã ¢ Ã ¢ Ã Ã Ã ¢ Ã Ã Ãlet Ã, Ã, Ã, Ã,02 Ã,02 Ã,02 Ã,, Ã, Ã, Ã Ã Ã,01 Ã,01 Ã,01 Ã,0 Ã Ã Ã, Ã,5 Ã,5 Ã,5 Ã,5 Ã, Ã, Ã, Ã, Ã, Ã, Ã Ã,â â Ã Ã,â Ã Ã, Ã Ã, Ã Ã,â Ã,â Ã Ã, NookUCLAC .Seitiruppi Latuat DNA Ytirupmi Nwonknu Mumixam Elgnis, A-Ytiruppi Etalulac: Nookuraclack Ecnatpeccaâ €, Loughini Loughini Morf ESnopcer Fo ECneffid% AERA KAEP) SROOH (NOITCEJNI FO EMIT) Câ € ° Ã,8 OT Câ € () A (NOITULOS ECNEREFER FO YTILIBATS) B (51 with,: Elbatâ Ã, Loughini Loughini Morf Esnopcer Fo ECneffid% AERA KAEP) SROOH (NOITCEJNI FO EMIT) ERUARPMET MOOR TA () A (NOITULOS ECNEREFER FO YTILIBATS) AND (51 Ã,,,.51-Elbat Ã,.51-Elbat We DedroCer Eb Llans Stluser .11-Elbat NI DetacUBAT EB Llans Stluser EHT .SHEHP ELIBOM HTIW KSALF CIRTEMULOV LM02 OT ELPMAS Denetlif Evoba Fo LM 0.1 etulid Rehrtruf: 0.6 Yossa Rof.) 0.6 (YGolodohTem Nevig Sisylana Sisylana Desoporp Elmas Lortnoc SA) Elmas Lortnoc (NOITULOS TSET DNA A-NOITULOS ECNEREFER, B-NOITULOS ECNEREFER, B-ESAHP ELIBOM, A-ESAHP ELIBOM EREAPERP: NOITULOS FO NOTATARPERP .2 QOL .RETLAFF EFTP. MâµÃµ 4.0, FDVP MâµÃµ4.0, NOLL Mâ.0 HGUORH T RetLift, Egats Noitartwyl EHT Ta .1 Setirupmi Latirupi Ytiuxam Nwonknu Mumixam Elgnis A-Ytirupmi .on Elmas with Ã,nisicerp dohtem11 -elbat .hpargatamc EHT NOITULOS HCAE TCEJNI DNA TIMIL NOTATCIFICIFICIFIEPS EVIF% 05 DNA% & Qol Noitulos Niatbo OT Snoitulos Ytiraenil erandil ERUDECORP six replicate injections of LOQ concentration should not be more than 10.0% and signal to noise ratio at LOQ concentration shall not be less than 10.Ã Â Conclusion: ____ Ã Â8.0Ã Â (A) Linearity: Linearity: To demonstrate that the analytical method is capable to obtain test results, which are directly proportional to the concentration of analyte. 120 6. System suitability Filter Compatibility Filter Saturation Specificity (Interference Study and Forced Degradation) Limit of Quantification and Limit of Detection Linearity and Range Precision System Precision Method Precision Intermediate Precision Accuracy Solution Stability Robustness Note: Experimental plan and Data Evaluation System suitability to be done as per methodology and to be monitored throughout the experiment. Test Preparation:As per respective degradation condition mentioned under Specificity study. Add about 700 ml of water, shake to dissolve and make up the volume with water adjusting the pH 4.0 with glacial acetic acid. Conclusion: ____Ã Â Forced Degradation Study: Objective: Forced degradation studies are performed to demonstrate that the analytical method is stability indicating. 50% solution:Dilute 5.0 ml of Standard stock solution into 10 ml volumetric flask and dilute with water. 0.5Ã ÂÃ ÂÃ ÂÃ ÂÃ ÂÃ Â = Correction factor of Impurity-AÃ Â Reference Specification No.:QC/ Reference STP No.:QC/STP/ Acceptance Criteria: S. No. Material Name B.No./Lot No. Potency/Purity Validity Reagent and Solvent Details: S. Conclusion: ____ Separately inject blank, placebo solution,reference solutions and six independent sample preparation of Etamsylatesample prepared as per methodology. The test is not valid unless the tailing factor is not more than 2.0, column efficiency is not less than 1500 o£Ã§Ãacifitnauq ed etimil e o£Ã§Ãceted ed etimiL)b(6-alebaT)%(QOL detderP)%(DOL DETDEVERP)MPP(KOL detciderP)Æ¯Ã(XYETS %06 %06 %05 0.5 %04 0,4 %03 0,3 %02 0,2 %01 0.1 o£Ã§Ãartnecnoc ed aer¡Ã ad atsopseR)MPP(adigirroc o£Ã§ÃartnecnoC)%(o£Ã§ÃartnecnoC .on.rs)a-azerupmi(o£Ã§ÃacifitnauQ ed etimil e o£Ã§Ãceted ed etimil)a(6-alebat o£Ã§Ãacifitnauq ed etimil = ªÂÃ QOL o£Ã§Ãceted ed etimiL = ¬â Ã ari doL o£ÃssergeR ed ahniL ad arocnÃ ªÂÃ ¬â ¢Ã ¢Â Ã ±Ã S o£Ãsserger ed ahnil ad laudiser o£Ãrdap oivsed = Ã ¬â Ã ¬â Ã ¬â Ã ¬â Ã ¬â Ã ¬â ¢Ã ¬â ¢Ã ¬â ¢Ã" ¬â ¢Ã - "¬â Ã" "¬â ¢Ã" ¬â ¢Ã "¬â ¢Ã ¬â Ã" ¬â Ã "" " ¬â ¢Ã "¬â ¢Ã -" ¬â ¢Ã = doL - ¬â Ã ¯Ã -¡ÂÃ 3.3 :olucl¡ÃC .alumr³Ãf etniuges a odnazilitu A - azerupmi arap o£Ã§Ãacifitnauq ed etimil e o£Ã§Ãceted ed etimiL ed rolav o raluclac e)MPP(adigirroc o£Ã§Ãartnecnoc a e ocip ed aer¡Ã a odnasu ybetalysmate e A - azerupmi a arap laudiser o£Ãrdap oivsed o e atsocne od oivsed o enimreteD .aug¡Ã moc riulid e ocirt©Ãmulov ocsarf ed lm 01 me o£Ãrdap euqotse ed o£Ã§Ãulos ed lm 0.6 riulid :%06 ed o£Ã§ÃuloS .ocituªÃcamraf opmac me acir aicnªÃirepxe ed sona 41 ed siam moc aidnÃ ad ocituªÃcamraf lanoissiforp mu ©Ã ele ,acituªÃcamraf o£Ã§Ãatneiro ad rodadnuf e rotua o ©Ã ramuK vihS .rS O .2-alebaT an sadartsiger res meved seµÃ§Ãavresbo sA .edadimu ed aram¢Ãc me %57 edadimu me saroh 42 rop)apmat mes(atreba o£Ã§Ãidnoc me ocirt©Ãmulov ocsarf o ahnetnaM .rarutsim e adacifirup aug¡Ã moc emulov o meµÃpmoc e revlossid arap odacinos ,adacifirup aug¡Ã ed lm 05 enoicidA .erutsim e adacifirup aug¡Ã moc emulov o megaiuqam e avlossid ,adacifirup aug¡Ã ed lm 5 enoicidA .%0,2 a seroirepus o£Ãs o£Ãn sadacilper seµÃ§Ãejni arap etalysmatE ed aer¡Ã a arap ovitaler o£Ãrdap oivsed o e sacalp sA for unknown impurity) Sr.No. Concentration (%) Corrected Concentration (ppm) Area Response 1.0 10 % 2.0 20 % 3.0 30 % 4.0 40 % 5.0 50 % 6.0 60 % Slope STEYX (ÂÂ) Predicted LOD (ppm) Predicted LOQ (ppm) Predicted LOD (%) Predicted LOQ (%) Prepare LOD solution containing Impurity-A and Etamsylate as per predicted concentration and inject in duplicate to confirm the detection limit. If product/material did not show degradation with worst condition, then it shall be reported as Product/Material did not degrade under specified conditions. No. Impurity Acceptance criteria 1. 150 Correlation Coefficient % Y-intercept Slope Ã ÂTable-8(b) LinearityÃ Â Impurity-A Sr. No. % Concentration Corrected concentration Area 1. The approximate retention time of Etamsylate peak is about 4.5 minutes and relative retention time of Impurity-A is about 1.5. Note: Disregard any peak in sample chromatogram if peak observed at the retention time of blank and placebo. Placebo Reference solution (B) Reference solution (A) Impurity-A ID solution Sample solution Spiked sample solution Specificity (Forced Degradation Study): Condition Mass Balance Peak purity (Pass/Fail) Control Sample All the known impurity peaks and main peak should be well resolved from each other and should be spectrally pure.Mass balance should not be less than 95%. 20% solution:Dilute 2.0 ml of Standard stock solution into 10 ml volumetric flask and dilute with water. Table-13(a): Intermediate Precision (Signal to noise ratio at LOQ level) Sample No. Signal to noise ratio Impurity-A Etamsylate A1 A2 A1 A2 1. Standard Preparation: Weigh accurately 63.0 mg Etamsylate working standard into a 25 ml dry volumetric flask, sonicate until it gets dissolved and dilute to volume with water. Add sufficient water and sonicate to dissolve and further dilute to volume with water. Filter through 0.45ÃµÂ filter and discard first few ml of the filtrate. Placebo preparation: Weight and transfer A pit of placebo equivalent to 100 mg of ethamsylate in a 10 ml dry volumic volume. bottle.

Cleaning Validation Protocol Template; ... The validation of an analytical method is the process by which it is established that the performance characteristics of the method, such as Precision, Accuracy, Specificity, Linearity, Limit of Detection (LOD), Limit of Quantitation (LOQ) and Robustness meet the requirements for the intended ... The validation engineer will prepare a suitable test protocol using appropriate template. 5.3.1 Installation. The protocol will describe the name, version number, location, control and ensure that appropriate security restrictions are implemented at the time of ... Mar 14, 2019 · Guidance for Industry: Analytical Procedures and Methods Validation for Drugs and Biologics. US Food and Drug Administration, Rockville, MD, 2015. Krause SO, et al. PDA Technical Report 57: Analytical Method Validation and Transfer for Biotechnology Products. PDA: Bethesda, MD, 2012. USP : Transfer of Analytical Procedures. Jul 30, 2018 · Test method for each tests shall be mentioned in the protocol. Location of sampling points shall be done as per specified in Validation protocol or as per SOP. Frequency for all above mentioned tests shall be mentioned in the individual validation protocol. Validation of water system shall divide in to three different phases as follows. Nov 05, 2016 · METHOD VALIDATION Method validation is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from method validation can be used to judge the quality, reliability and consistency of analytical results; it is an integral part of any good analytical practice. 14. Validation is the process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in testing and then production maintains the desired level of compliance at all stages. In the pharmaceutical industry, it is very important that in addition to final testing and compliance of products, it is also assured that the process will consistently …

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