International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1772-1788www.ijprajournal.com ISSN: 2456-4494

Process validation of pantoprazole

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Date of Submission: 01-08-2023 Date of Acceptance: 13-08-2023

Abstract: The purpose of this research is to explore the concurrent validation process of the pantoprazole tablet in pharmaceutical manufacturing. Concurrent validation is a necessary procedure that ensures the consistency and quality of pharmaceutical products by continuously monitoring and evaluating critical manufacturing parameters. The pantoprazole tablet is a commonly used proton pump inhibitor used for managing GERDs and acid-related issues. The concurrent validation process for this tablet involves establishing a relationship between important process attributes, in-process testing, and final product quality. Various crucial factors, such as the formulation composition, blend uniformity, tablet weight, hardness, disintegration and dissolution rates, are analysed during the concurrent validation process. Ensuring the identification and control of potential risks and deviations during pantoprazole tablet manufacturing is essential to maintain its effectiveness, safety, and compliance with regulations. In summary, this research provides a comprehensive overview of the concurrent validation process specific to pantoprazole tablets, emphasizing its importance in preserving product quality and patient well-being.

Keywords: Pantoprazole, validation, tablet, contraindication, reflux disease.

I. INTRRODUCTION:

1.1. TABLET: a tablet refers to a solid oral dosage form of medication. It is made by compressing a powdered drug substance with various excipients (fillers, binders, Disintegrates, lubricants, etc.) to form a solid, typically flat, disc-shaped tablet. Tablets are one of the most commonly used and widely available forms of medication, and they are designed to be swallowed whole. They can be produced in various shapes, sizes, and colours, depending on the specific drug and manufacturer. Tablets may also be formulated as extended-release or delayed-release, where the medication is released slowly or at a specific site in the gastrointestinal tract, respectively.

1.2. VALIDATION:Validation is the process of establishing documented evidence to demonstrate that a system, process, or equipment consistently produces the desired results according to predetermined specifications and requirements. It involves conducting a series of planned activities, such as testing, monitoring, and documentation, to ensure that a system or process meets all necessary quality, safety, and performance standards. Validation is an important step in various industries, including pharmaceuticals, to ensure the reliability, accuracy, and consistency of products and processes.Validation is a requirement mandated by regulatory agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). It typically involves following a series of well-defined procedures to confirm that a pharmaceutical process or equipment is qualified to perform its intended function.

1.2.1 TYPE OF VALIDATION:
a. Analytical Method Validation
b. Cleaning Validation
c. Equipment Validation
d. Process Validation

PROCESS VALIDATION:
Process validation is a systematic and documented approach to confirming that a particular process consistently produces results that meet predetermined quality specifications. It involves establishing evidence that a process is capable of consistently delivering products that meet the desired quality, safety, and efficacy requirements.
Stage of process validation

The validation process may include various activities such as:
1. Installation Qualification (IQ): Verifying that equipment or systems are installed correctly and in accordance with predetermined specifications and manufacturer recommendations.

2. Operational Qualification (OQ): Ensuring that equipment or systems are functioning within predetermined operational limits and performance criteria.
3. Performance Qualification (PQ): Demonstrating that equipment or systems consistently and reliably produce the desired results in accordance with predetermined specifications.
4. Process Validation: Confirming that a pharmaceutical process consistently and reliably produces pharmaceutical products as intended, meeting predetermined specifications.
Validation also involves establishing appropriate documentation, such as validation protocols, standard operating procedures (SOPs), and validation reports, to provide evidence that the process or equipment meets all necessary requirements. The purpose of validation in is to ensure the quality, safety, and efficacy of pharmaceutical products. It helps to identify and mitigate potential risks, ensures consistency in production, and ultimately contributes to patient safety.

TYPE OF PROCESS VALIDATION:
There are three main types of process validation:

A. Prospective validation: This type of validation occurs before the process is put into routine production. It involves systematically collecting and evaluating data to demonstrate that the process, equipment, and systems will consistently produce the desired quality of products. Prospective validation includes developing and executing validation protocols, analysing the data, and documenting the results.

B. Concurrent validation: This type of validation takes place during routine production. It involves collecting and analysing data on an ongoing basis to ensure that the process remains in a state of control and consistently produces products that meet quality specifications. Concurrent validation involves monitoring process parameters, performing regular quality checks, and addressing any deviations or issues that arise during production.

C. Retrospective validation: This type of validation involves evaluating historical data to establish documented evidence that a process consistently produces acceptable results. Retrospective validation may be conducted when there is a long history of successful production with extensive records available. It involves reviewing past production records, analysing data, and demonstrating that the process has consistently met the predetermined quality specifications.
In addition to these three types of process validation, there is also revalidation, which is performed periodically or when there are significant changes made to the process, equipment, or systems. Revalidation ensures that the process continues to meet quality requirements over time or after any modifications or changes that could impact the process performance.

2. DRUG PROFILE:
2.1. DRUG PROFILE OF PANTOPRAZOLE SODIUM
Pantoprazole is a medication from the class of proton pump inhibitors (PPIs) used to treat conditions related to excessive stomach acid production. Here is a brief drug profile of pantoprazole:

2.1.1PHYSIOCHEMICAL PROPERTIES OF THYROXINE SODIUM

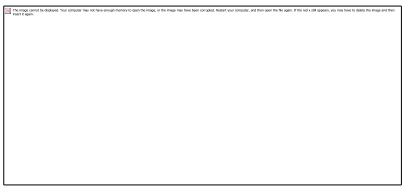

Figure: 1

ChemicaalStrucctureofPantaoprazoleTableet(S'ource:W'ikipedia)

- IUP"AC Na'me: - ('RS')-6-(Difluoromethoxy)-2-[(3,4-dim'ethoxypyr'idin-2-yl) methylsulfinyl]-1H-benz'o[d]imidaz'ole
- Molecu'larfor'mula:-$C_{16}H_{15}F_2N_3O_4S$
- Molecu'lar w'eight 383.3

2.1.2 MECHENISM OF ACTION:
Panto'prazole medicine is und'er the category of kno'wn as proton pump inhi'bitors (PPIs). Its mechanis'm of action involves decreasing the prod'uction of stomach acid by obs'tructing the enzyme responsible for the final phase in acid se'cretion in the st'omach.

- The parietal cells in the stomach lining contain proton pumps, which are proteins responsi'ble for releas'ing ga'stric acid into the stomach. These proton pumps are activated by a process that involves the secretion of hy'drogen ions (protons) into the stomach. Pantoprazole mechanism by binding irreversibly to the hydro'gen/potassium adenosine triphosp'hatase (H'+/K+ A'TPase) enzy'me, also called as the ga'stric proton pump.

This enzyme is located on the surface of the parietal cells and is responsible for pum'ping h'ydrogen ions into the stomach, leadin'g to the produ'ction of gastric acid.

- By binding to the gastric proton pu'mp, pantoprazole inhi'bits its activity, pr'eventing the release of hyd'rogen ions into the stomach. This inhibition blocks the final step in the production of gastric acid, effective'ly reducin'g stomach acid levels.
- Pantoprazole is known as a delayed-release medici'ne, which means it is design to pass through the stom'ach before being released in the small i'ntestine. Once released, it is then ab'sorbed into the bloo'dstream and reaches the parietal cells in the stomach lining, where it can bind to the gastric proton pum'p and exert its inhibitory effects.
- By red'ucing stomach acid pro'duction, pantoprazole helps to relie've symptoms associated with condition's like GE'RD, stomach ulcers, and Zoll'inger Ellis'on syndrome. It also promotes the healing of the esophagus and the digestive tract by allowing the injured tissues to repair themselves in a less acidic environment.

MATE'RIALANDMET'HODS

a. Proc'essValidati'onE'valuationParamet'ersatGr'anulationStage

Unitoperat'ion	Controlvari'able	Critica'lparameterstobechecked
Sifting	ScreenSize,SievesSize	Particlesizedistributionofthefinalproduct.
DryMixing	ChopperSpeed,ImpellerSpeed,DrymixingTime	Blendconsistency
BinderPreparation&addition	Time	UniformGranulation
Kneading	Impeller speed, Time,chopperspeed,	Speed and mixing time
Drying	Inlet/outlettemperatureandtim'e	dryingtime,moisturecontent
Lubrication	Mixingtime, Load,speed,	Blenduniformity

Table2:ProcessValida'tionEv'aluationParametersatGranula'tionStage

b. 'ProcessVal'idationtheE'valuationParametersatComp'ressionStage

U'nitoperatio'n	Contr'ol'varia'ble	Criticalp'arameterstobecheck
Compression	Compressionmachinespeed,Compressionforce	Disintegrationtime,Dissolutionrate,contentuniformity, Uniformityofweight,Thickness,Hardness,Friability,,assay

Table3:ProcessValida'tionEvaluat'ionParametersattheCompressionStageProcessValidationEvaluationParametersatPrimaryPackingStage

Unitoperation	Controlvariable	Criticalparameterstobe checked
StripPacking	SealingTemperature,Machine speed	Leaktest,Legibleprinting

Table4:ProcessValidationEvaluationParametersatthePrimaryPackingStage

RESPONSIBILITY

- ForconductingthevalidationofPantoprazol etablettheresponsibilityareasfollows-
- Quality assurance officer and the production In-charge are responsible for the manufacturing process and will perform a validation record and record the information that obtained.
- Quality assurance officer and the production In-charge will plan the study and

supervise the performance.

- Quality assurance officer and the production In-charge write the protocol and verify the conclusion of the records
- QA officer In-charge, QC and production will review and approve the protocol before the validation study and review and also approve the data in validation study

VALIDA'TION TE'AM:

ThevalidationteamconsistsofthefollowingmembersasgiveninTableNo5

Designation	**Department**
Q'A manager	Q'A department
Q"C manager	Q'C depa"rtment
Q"C officer	Q'C depar'tment
Prod'uction officer	Production d'epartment
Prod'uction manager	Produ'ction dep'artment

Table no 5: Validation Team

MASTERFORMULA,SPECIFICATION

Test procedure details

- MasterFormula

Sr.No.	ItemName	Std.	RMSpecificationNumber	RMSTPNumber
1	PantoprazoleSodium Eq.toPantoprazole	I.P.	SPNRM-110	STPRM-59
2	Mannitol	I.P.	SPNRM-111	STPRM-62
3	LactoseMonohydrate	I.P.	SPNRM-152	STPRM-121
4	Povidone	I.P.	SPNRM-151	STPRM-125
5	Iso-PropylAlcohol	I.P.	SPNRM-75	STPRM-42
6	PurifiedTalc	I.P.	SPNRM-102	STPRM-47
7	SodiumStarchGlycolate	I.P.	SPNRM-101	STPRM-46
8	DRCoatSeal	I.H.	SPNRM-188	STPRM-64
9	Iso-PropylAlcohol	I.P.	SPNRM-75	STPRM-42
10	Methylenedichloride	I.P.	SPNRM-76	STPRM-43
11	DRCoatECS(Plain)	I.H.	SPNRM-114	STPRM-65
12	ColorYellowoxideofIron	I.P.	SPNRM-177	STPRM-155
13	Iso-PropylAlcohol	I.P.	SPNRM-75	STPRM-42
14	CalciumStearate	I.P.	SPNRM-116	STPRM-67
15	DibutylphthalateLRGrade	I.H.	SPNRM-115	STPRM-66
16	CrosPovidone	I.P.	SPNRM-105	STPRM-53
17	SodiumCarbonateAnhydrous	I.P.	SPNRM-189	STPRM-163

Table6:MasterFormula

ManufacturingFormula:

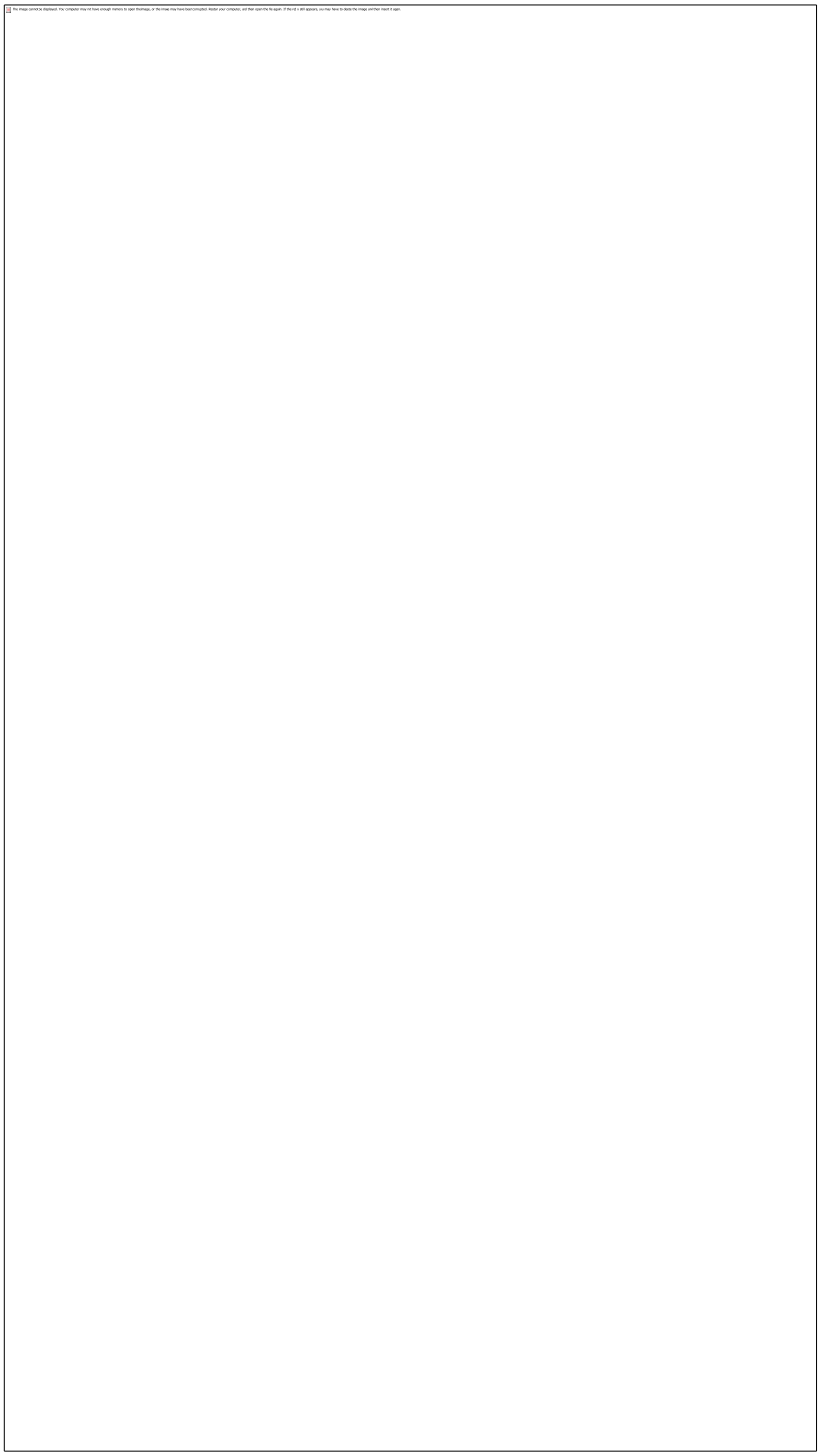

Table7:ManufacturingFormula

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

Ingredientsandtheirfunctions:

- **DryMixing**

Fordrymixing,allnecessaryingredientsandtheirfunctionsarelistedbelowinTableNo8

Sl	IngredientName	Category	Function
1.0	PantoprazoleSodium Eq.toPantoprazole	Active	ProtonPumpInhibitor
2.0	Mannitol	Inactive	Excipient
3.0	LactoseMonohydrate	Inactive	Excipient
4.0	Povidone	Inactive	Binder
5.0	Iso-PropylAlcohol	Inactive	Solvent

Table8:DryMixing

- **Lubrication**

Forlubrication,allnecessaryingredientsandtheirfunctionsarelistedbelowinTableNo9

Sl	IngredientName	Category	Function
6.0	SodiumStarchGlycolateI.P.	Inactive	Lubricant
7.0	SodiumCarbonateAnhydrous	Inactive	Lubricant
8.0	Calcium StearateI.P.	Inactive	Lubricant
9.0	PurifiedTalcI.P.	Inactive	Vehicle
10.0	CrosPovidoneI.P.	Inactive	Binder

Table9:Lubricatingagents

- **Seal/Entericcoating**

Forentericcoatingallnecessaryingredientsandtheirfunctionsarelistedbelow-

SLNo	IngredientName	Category	Function
11.0	DRCoatSeal	Inactive	Filmformer
12.0	DRCoatECS(Plain)	Inactive	Filmformer
13.0	Iso-PropylAlcoholI.P.	Inactive	Solvent
14.0	MethylenedichlorideI.H.	Inactive	Solvent
15.0	ColorYellowoxideofIron	Inactive	Colorant
16.0	DibutylPhthalateLRGrade	Inactive	Solvent

Table10:Seal/Entericcoating

CalculationofAPI

Quantitytobetaken(X)=[Claim×100×100]÷A×(100−L)

WhereAisassayonananhydrousbasisin%andLiswatercontentin%S

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

EQUIPMENT'SREQUIRED

S.No	NameoftheEquipment	IdentificationNo.	Size/Capacity
1	Digitalelectronicbalance	SLS/NB/015	300.00kg
2	Digitalelectronicbalance	SLS/NB/014	300.00gm
3	Digitalelectronicbalance	SLS/NB/021	600.00gm
4	Digitalelectronicbalance	SLS/NB/023	100.00kg
5	MechanicalSifter	SLS/PR/002	30"
6	OctagonalBlender	SLS/PR/005	400.00ltr
7	CompressionMachine(27stn.)	SLS/PR/013	65,000-70,000tablets/hr.
8	DustcollectorMachine(27stn.)	SLS/PR/014	65,000-70,000tablets/hr.
9	De-DustingMachine(27stn.)	SLS/PR/015	65,000-70,000tablets/hr.
10	MetalDetector	SLS/PR/083	————
11	ColloidMill	SLS/PR/007	————
12	Auto-CoaterMachine	SLS/PR/021	48"
13	TabletShortingTable	SLS/PR/010	————
14	Alu-AluPacking Machine	SLS/PR/022	30,000-35,000tabs/hr.
15	ConveyerbeltforAlu-AluPackingMachine	SLS/PR/023	30,000-35,000tabs/hr.
16	InkjetPrinter	SLS/PR/079	2,500-3,000 Cartons/hr.

Table11:EquipmentList

PROCESSFLOWCHART

Followingarethestepsthatmustbefollowedtodothevalidationofthepantoprazoletablet

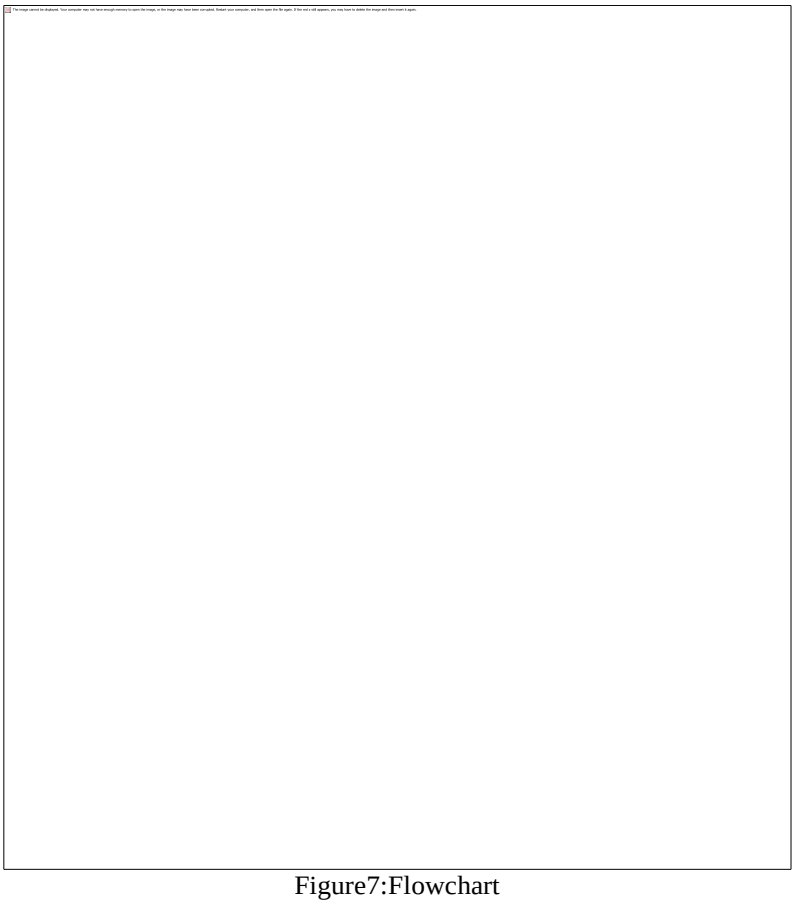

Figure7:Flowchart

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

GENERALINSTRUCTION

Thegeneralinstructionsareasfollows-

a. All processes shall be carried out at Temperature, not more than 30°C andRelativehumiditynotmorethan55%.

b. Temperature and RH shall be recorded at the start of each stage and thereafteratanIntervalof4hours.

c. Check each material for the correctness of weight and A.R. No.and recordthedetailsinBMR.

d. Dispensing labels of Raw materials shall be attached to the Batch ManufacturingRecord.

e. All the personnel should be in good health and should practice good sanitizationhabits.

f. Any deviation from the procedure should be documented and approved byQA-Manager.

g. In-processQualityAssurancepersonshallcounter-checkthegrossweight,netweighttareweightofactive pharmaceuticalingredientsaswellasexcipients.

h. FollowthecurrentversionsoftheStandardOperatingProcedures(SOPs)forVerificationpriortocarryingoutoperations,cleanlinessofarea,equipmentandcontainers.

i. Verificationandcalibrationofweighingbalances.

j. VerificationandrecordofLineclearances.

- **DispensingVerification**

a. Checktheweighingbalanceforzeroerrors.

b. Carry out the dispensing of Active Pharmaceutical Ingredients and ExcipientsofthebatchinDispensingBooth.(Note:In-processQuality Assuranceperson shall counter-check the gross weight, net weight tare weight of activepharmaceuticalingredientsaswellasexcipients)

c. CarryoutthedispensingoperationasperthestandardOperatingProcedure

d.

- **VerificationofDispensedMaterial**

a. CheckeachmaterialweightandA.R.No.and recordthedetailsinBatchManufacturingRecord.

a. Process Instructions

a. All processes shall be carried out at Temperature NMT 30°C and RelativehumidityNMT55%.

b. Temperature shall be recorded at the start of each stage and thereafter at anintervalof4hours.

c. Dispensing labels of Raw materials shall be attached to the Batch ManufacturingRecord.

d. All the personnel should be in good health and should practice good sanitizationhabits.

e. Any deviation from the procedure should be documented and approved byQA Manager.

f. In-processQualityAssurancepersonshallcounter-checkthegrossweight,netweighttareweightofactive pharmaceuticalIngredientsaswellasexcipients.

g. FollowthecurrentversionsoftheStandardOperatingProcedures(SOPs)for

h. Verificationpriortocarryingoutoperations, cleanlinessofthearea,equipmentandcontainers.

i. Verificationandcalibrationofweighingbalances.

j. VerificationandrecordofLineclearances.

- **SafetyInstructions**

a. Safetyprecautionstobetakenwhenhandlingthepowderfor Manufacturing.

b. Protect the respiratory organs from active substances using the mask as perrequirement.

c. Storethepowders.s.containerclosedthelidproperly.

d. FollowPersonalhygienicrequirements.

MANUFACTURINGPROCESS

a. Shifting

i. Sift the Raw materials through 80 and 40 sieves and collect them in a doublepolybag.

ii. SiftthePantoprazoleSodiumI.P.,MannitolI.P.,CrossPovidoneI.P.andSodium Starch Glycolate I.P. through a 40-sieve and collect in a double polybag.

iii. SifttheCalciumStearateI.P.,PurifiedTalcI.P.,throughan80-sieveandcollecttheminadoublepolybag.

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

b. BinderPreparation

i. Take15.0kgIsoPropylAlcoholandPovidone0.30kgandPreparePast.

c. Granulation

i. Load the sifted material Pantoprazole Sodium I.P. Mannitol I.P., and LactoseMonohydrateI.P.inRMGanddrymixthematerialfor30minutes.
ii. BindershouldbeaddedintotheRMGslowlytoformthewetgranules.
iii. On completion of granules collect the wet mass in the clean FBD bowl with atrolley.

d. Milling

i. The wetted granules are passed through a multi-mill and collected in an S.S. container.AllthegranulesspreadintheFBDbowl.

e. Drying

i. LoadthewetgranulesinFBDandStratdrying.
ii. Dry the material at an inlet temperature of 500C ± 50C and an Outlet temperatureof450C±50Cforabout50minutesto1hourtillthemoisturecontentofgranulesreachesNMT2.0%to3.0%w/w.
iii. FinalGranuleShouldBeShiftedthrough30Sieve

f. BlendingandLubrication

Transfer all the material into the octagonal blender and add Purified Talk I.P., CrosPovidone I.P. Sodium Carbonate Anhydrous I.P. and Sodium Starch Glycolate I.P.Mix for 15 minutes.Final lubrication addition of Calcium stearate IP. Mix for 5minutesthentakesamplesforanalysisasperthesamplingplan.

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

COMPRESSSION

EstablishedtheCompressionMachineontheparameterwhich are given below andcompressedthetablet.

Sn.No.	TabletParameter	SetValue
1	Appearance	Whitein color,rounded,bi Convex, unscored &un-coatedtablets.
2	Averageweightoftablet	145mg±7.5%
3	Weightof20tablet	2.900gm
4	Uniformityofweight	Averageweightoftablet± 7.5%
5	Thickness	3.4mm(± 0.2mm).
6	Hardness	NLT5.0kg/cm2
7	Friability	NLT 1.0%w/w
8	DisintegrationTime	NLT 15minutes
9	Dissolution: In0.1MHCl InBuffer	For120Minutes NotLessThan75.0%
10	Assay:	NotLess than 90.0% and NotMoreThan110.0%ofthe labeled amount of Pantoprazole

Table12:CompressionParameter

TABLETINSPECTIONDOCKET

Specification forsemi-finished

S.No.	TabletParameter	Setvalue
1	Appearance+ + of tablet	Whitecolored,rounded,biconvex,un-Scored&uncoatedtablets.
2	Averageweightoftablet	145mg±7.5%
3	Weightof20tablet	2.900gm
4	Uniformityofweight	Averageweightoftablet±7.5%
5	Thickness	3.4mm(±0.2mm).
6	Hardness	NLT5.0kg/cm2
7	Friability	NLT 1.0%w/w
8	DisintegrationTime(DT)	NLT 15minutes

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

9	Dissolution: In0.1MHCl InBuffer	For120Minutes NLT 75.0%
10	Assay:	NLT 90.0% and Not More Than110.0%ofthelabeledamountofPantoprazole

Table13:Tabletinspectiondocketforsemi-finished

COATING

Procedureofsealcoatingsolutionpreparation

i. After complete dissolution then add Methylene chloride IP. Above solutionwithcontinuousstirring.
ii. Passtheabovematerialthrough200sieveso fcleannyloncloth.
iii. Thecompletesolutionfiltersandcloseinthe coatingsolutiontank

Procedureforentericcoatingsolutionpreparation

i. DisperseDR-CoatECS(Plain)I.H.andColorYellowOxideofIronIP.With I.P.A.Withcontinuousstirring.
ii. AddDibutylPhthalateLRgradeinthea bovesolutionwithcontinuousstir-ring.
iii. Passtheabovematerialthrough200sieveso fcleannyloncloth.
iv. Thecompletesolutionfiltersandcloseint hecoatingsolutiontank.

ProcedureofCoating

i. Make surethatPaniscleanedandthecleanedlabelisaffixed.
ii. LoadthetabletinCoatingPanandsetthesp raygun.
iii. SettheTemp.ofair.
iv. SettheRPMoftheCoatingPan
v. Settheatomizingpressure.
vi. Loadthecoatingsolutioninaspraygunan dstartthecoating.
vii. Afterfinishing pointofcoatingsolutiondrythetabletsatinlettemperature 50°C-60°Cinacoatingpanwithcontinuoushotair.
viii. After complete drying of tablets unload the tablets in cleaned labeled S.S.drum and HDPE drum lined with poly bags and send them to the coatedquarantinearea.
ix. SettheAutocoaterMachineonthefollowingparameterandcoatthetablet(seeTableNo14)

Inprocessparameters	Standard&Limit
Tabletloadinkg	Kg
Avg.wt.ofcoretabs.	145mg±7.5%
RPMofpan	7-8RPM
Inlettemperature	65°C±5°C
Exhausttemperature	55°C±5°C
Bedtemperature	45°C±5°C
Airpressure	NMT4.0kg/cm2
Avg.wt.ofcoatedtablets	150mg±7.5%
Weightgain	2.0%to3.0%
GunDistance	NMT8inch

Table14:Autocoatermachineparameter

i. TableinspectiondocketforCoatedTablets

i. EnsurethelineclearancefromQ.A.inthetabletinspectionareatobeginoperation.
ii. De-dustthetablettotakeoutfinepowderandgranulesasreprocessingrecovery.
iii. Inspectthetabletsfortheirdefectslikebrokentablets,blackparticles, chipping,blistering, cracking,peelingoffetc.
iv. CollectthegoodtabletincleanedandlabelledHDPEdrumsdoublelinedwithpolybags.

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

v. Collectthedefectivetabletseparately.
vi. Aftercompletionofinspectionrecordtheweightofagoodtablet.

PACKAGINGFORMULARECORD

- **Specificationforfinishedproducts**

S.No.	PARAMETERS	SPECIFICATION
1.	DescriptionofDosageform	Yellowcolored,rounded,biconvex,unscored&entericcoatedtablets.
2.	DescriptionofPackage	10tabletspackedinBlisterPack.
23.	2Dimension	Diameter–7.6mm(±0.2mm).
		Thickness–3.4mm(±0.2mm).
4.	Identification	Shouldbepositiveforpantoprazolesodium
5.	AverageWeightofTablet	150mg±7.5%
6.	UniformityofWeight	Averageweightoftablet±7.5%
7.	DisintegrationTime In0.1MHCl InBuffer	Tabletsshouldnotswallowed,crackedwithin2Hrs. NotMoreThan60Minutes
8.	Dissolution: In0.1MHCl InBuffer	For120Minutes NotLessThan75.0%
9.	RelatedSubstances	ShouldbecomplieswithI.P.
10.	Assay EachentericcoatedtabletcontainsPantoprazoleSodiumIP Eq.toPantoprazole40mg	NotLessThan90.0%andNotMoreThan110.0%ofthelabeledamountofPantoprazole.
11.	StorageCondition	Below25ºC
12.	ShelfLife	2.0years.

Table:PackagingSpecificationforthefinishedproduct

- **Quantityofpackingmaterialused**

S.No	PackingMaterials	Specification	Unit	Quantityperbatch
1	PrintedAluminumFoil(167mm)	I.H.	Kg	10.000
2	AluminumFoil(170mm)	I.H.	Kg	40.000
3	Carton	I.H.	Nos	2500
4	5-plycorrugatedbox	I.H.	Nos	25

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

5	BoppTape60mm	I.H.	Nos	01

Table:Packingmaterialused

- **Precautionswhilepackaging**

Followingarethenecessaryprecautionsthatmustbecare of-

i. EnsurethatEquipmentshouldbefreefromtr acesofanypreviousbatchidentity/residue.Washwater reportsshouldbeavailableasapplicable.
ii. Ensurethatallpersonnelshouldwearproper uniforms,asapplicable.
iii. Ensurethatallcomponentsofthepreviousb atch/productshouldberemovedfromtherespectivepac kingareapriortopackaging.
iv. Ensurethatallmaterialsofthebatchtobepac kedshouldbecorrectedandmatchedwiththebatchpack ingrecordpriortopackaging.
v. EnsurethatEnvironmentalconditionsarem aintainedduringpackinginprimarypackagingandseco ndarypacking.
vi. EnsurethatinprimarypackingTemperature NMT300CandRelativehumidityNMT55%.

Packaging:

- **Alualupackaging**

The coding details for setting up the Alu Alu packing machine as per the Batch ProductionRecord(BPR)shouldbeprovidedbythepro ductionchemistresponsiblefor the production process. These details typically include specific instructions andparameters to ensure accurate and compliant packaging. It is important to consulttheproductionchemistforthefollowinginform ation:-

1. BatchNo:
2. Mfg.Date:
3. ExpDate:
4. MRPRs:

- **MonoCartonoverprinting**

i. Settheinkjet-codingmachineasperBPRthatdetailshouldbeprovide dbytheconcernedproductionchemist.Thiswillcontai nthefollowing

1. BatchNo:
2. Mfg.Date:
3. ExpiryDate:

N.B-
Incaseofthephysician'ssampleMRPRs.Willnotbethe reonthemonocarton.
Overprintthefirsttwomonocartonsandtaketheapproval signaturesofoneProductionChemistandoneQ.A.Chemi st.
AttachoneapprovedSpecimencartoninBPRandaseco ndcartonintheprintingsectionfortherecord.

- **CorrugatedBoxPrinting**

Corrugated box label detail should be provided by the concerned production chemistandaffixthebatchdetails.Thiswillcontainthef ollowing

1. ProductName:
2. BatchNo.:
3. Mfg.Date:
4. Exp.Date:
5. Quantity:

N.B-
Inthecaseofthephysicians'samplebatchprintP/Sonth eshipperwithredink.

- **Packagingoffinishedgoods**

Pack the Pantoprazole Sodium Tablets I.P. as per the current Approved packingspecifications.

- **TransferofPackedGoods**

Aftergettingthefinishedreport,transfertheproducttot heFinishedProductstorewith a Finished Goods Transfer Note. The original copy of the transfer note shouldbeattachedtotheBatchRecord.

RESULTS

A. Report for the concurrent process validation of pantoprazole tablet
Batches (under Validation):

Product's Name	Batch No	Batch Size
Pantoprazole sodium 40 tabs.	a	1.50 Lac.

Table No. - batches under validation

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

B. **Equipment and Instrument-:** Following Equipment's and instruments shall be used in manufacturing of Pantoprazole Tablets 40 mg as per the given below table

Sr. No.	Name of the Equipment or instrument	Qualified [Yes or No]
a	Sifter	Yes
b	Octagonal Blender	Yes
c	Rapid Mixer Granulator	Yes
d	Strip or blister sealing Machine	Yes
e	Stirrer	Yes
f	Fluid Bed Dryer	Yes
g	Paste kettle	Yes
H	Compression Machine	Yes
I	Multi mill	Yes

Table No.- List of Equipment or Instrument that required

C. Equipment Cleaning: The cleaning status of equipment or instruments shall be described as Per the table which given below:

Table Number 19– Equipment Cleaning Status

Sr. No.	Area / Equipment	Cleaned
A	shifter	ok
2	Paste kettle	ok
3	Octagonal blender	ok
4	stirrer	ok
5	Multi mill	ok
6	Fluid Bed Dryer	ok
7	Rapid mixer granulator	ok
8	Compression Machine	ok
9	Strip or blister sealing Machine	ok

D. Status on Calibration: The status of calibration of different gauges, thermometer, sensors, balances Etc. shall be described as per the following table:

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

Sr. No.	Measuring Device	Calibration status
1.	Weighing Balance (Granulation)	Calibrated done
2.	Balance (IPQC)	Calibrated done
3.	Magnehelic gauges	Calibrated done
4.	Weigh Balance (Coating)	Calibrated done
5.	FBD inlet Temperature gauge	Calibrated done
6.	Thermo Hygrometer	Calibrated done
7.	Vernier Calibres	Calibrated done
8.	Blister or Strip Machine Temperature gauge	Calibrated done
9.	Friability Apparatus	Calibrated done
10.	Disintegration Test Apparatus	Calibrated done
11.	IR Moisture balance	Calibrated done
12.	Thermo Hygrometer (Coating)	Calibrated done
13.	Pressure gauges	Calibrated done
14.	Thermo Hygrometer (blister strip packing)	Calibrated done
15.	Leak Test Apparatus	Calibrated done

Table No. 19: Status of Calibration

E. Drying:

% LOD OF Dried Granules		
	Batch no:	Batch No.- X
	Location	
Sample A	Top Left	2.45
Sample B	Bottom Right	2.64
Sample C	Middle	2.76
Sample D	Top Right	2.96
Sample E	Middle	2.76
RSD (NMT 6 %)	------	2.71

F. Observation and Results of Uncoated/Core Tablets
Batch no. 1

Physical parameter & Test procedure No.	Acceptance measures	Batch 1	
Description	Conforms	Conform	Conform
Average weight	340.47 mg ±5.0%	343	343
Uniformity of weight :	Within ± 5% of the Average weight	342	342
		338	343
		331	339
		342	341

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

		342	344
		343	339
		343	343
		337	343
		342	345
		338	342
		342	341
		342	342
		338	343
		342	343
		338	341
		343	342
		339	339
		341	343
		342	341
		342	344
Minimum		337	339
Maximum		343	345
Weight variation ± %		3.17	1.37
Dimension	9.0mm ±0.3mm	9.08	9.01
		9.2	9.02
		9.04	9.01
		9.03	8.98
		9.04	9.02
Thickness :	3.7mm ±0.3mm	3.76	3.72
		3.72	3.79
		3.76	3.67
		3.6	3.7
		3.68	3.72
Hardness :	NLT 3.1 Kg / cm	8.63	8.92
		7	8.31
		8.15	8.83
		7.8	7.63
		7.92	7.6
Friability :	NMT 1.0 % w/w	0.33	0.19

Table No. 20: Results of Uncoated/Core Tablets at Different stages

International Journal of Pharmaceutical research and Applications
Volume 8, Issue 4, Jul.-Aug. 2023, pp: 1769-1771www.ijprajournal.com ISSN: 2456-4494

II. CONCLUSION

Conclusion: all the analytical data review during process validation of pantoprazole tablets has been found satisfactory

In conclusion, the pharmaceutical concurrent process validation of pantoprazole tablet is a precarious step in guaranteeing the quality, safety, and efficacy of this medication. Through the utilization of several analytical methods, like HPLC (high-performance liquid chromatography), dissolution testing, and stability testing, this validation process aims to verify that pantoprazole tablets meet the required quality standards. The results obtained from the validation process are essential in confirming the purity, identity, and strength of the active ingredient, pantoprazole, within the tablets. Additionally, dissolution testing ensures that the tablets dissolve completely and release the active ingredient within the specified timeframe, ensuring optimal therapeutic efficacy. Stability testing provides valuable information on the shelf-life of the medication, ensuring that it remains effective and unaffected by environmental factors throughout its intended usage period.

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