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Process Validation of Cefixime Powder for Suspension Dosage Form, 50 mL

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Abstract

The objective of this research investigation was to study the prospective process validation of Cefixime powder for oral suspension. Quality cannot be assured solely through in-process and finished product inspections and testing; rather, it must be integrated into the manufacturing process. To ensure that the finished product meets all quality specifications, these processes must be carefully controlled. Building quality into the product requires meticulous attention to several factors, including the selection of materials, product and process design, control of variables, in-process controls, and finished product testing. Critical process parameters were identified using process capability analysis and evaluated by challenging their lower and upper release specifications. Three initial process validation batches were conducted under consistent conditions, including batch size, methods, equipment, and validation criteria. Critical parameters were evaluated at multiple stages of the manufacturing process, including dispensing, sieving, dry mixing, filling, and sealing, in accordance with the validation protocol. A drying time of 120 minutes at 60°C was found to be appropriate for achieving a moisture content of crushed sugar within the specified limit of NMT 0.2%. The optimal mixing uniformity was achieved at 70 minutes at 8 RPM, as indicated by a relative standard deviation (RSD) ranging from 1.29% to 2.33%, well within the acceptance criterion of NMT 5.0%. The results obtained from all three validation batches at each stage of manufacturing confirmed compliance with the acceptable range of 90% to 110%. Furthermore, the active content in the reconstituted liquid suspension remained within the acceptable range of 90% to 110% on both Day 1 and Day 7, ensuring stability over the intended period. These findings confirm that the process validation data from three consecutive batches provides a high degree of assurance that the manufacturing process for Cefixime powder for oral suspension consistently produces a product that meets predetermined specifications and quality standards.

Keywords: Prospective Process Validation; Control Variables; In-Process Control

Abbreviations

RSD: Relative Standard Deviation; PQ: Performance Qualification; CPP: Critical Process Parameter; BMR: Batch Manufacturing Record; BPR: Batch Packaging Record; DoE: Design of Experiments.

Introduction

The fundamental principle of quality assurance is that a drug should be manufactured to meet its intended purpose. Achieving this requires a thorough understanding of the processes and their performance [1]. Quality cannot be ensured solely through in-process and finished product inspections and testing; instead, it must be integrated into the manufacturing processes. To ensure that the finished product meets all quality specifications, these processes must be carefully controlled. Building quality into the product necessitates close attention to several factors, including the selection of high-quality materials and components, product and process design, process control, in-process monitoring, and finished product testing [2].

Through meticulous design and validation of systems and process controls, a high level of confidence can be established that every lot or batch produced will consistently meet its intended specifications. According to ICH guidelines, process validation is defined as: "The means of ensuring and providing documented evidence that processes, operating within their specified design parameters, are capable of consistently and reliably producing a finished product of the required quality [3]."

Purpose

Process validation aims to demonstrate that the proposed manufacturing process is appropriate and consistently produces a product of the desired quality, ensuring the process is both suitable and effectively controlled.

Importance of Process Validation

The main advantages to be obtained from validation are assurance of quality and process optimization, both resulting in a reduction of total costs [4].

This validated process demonstrates significant practical benefits in the pharmaceutical industry, particularly in terms of cost savings and scalability, thereby underscoring its industrial relevance in the pharmaceutical industry, the validation of a manufacturing process is not just a regulatory requirement—it has substantial practical implications that enhance both operational efficiency and product reliability. A validated process ensures that each batch of a pharmaceutical product is consistently produced to meet predefined quality standards. This consistency is critical for patient safety, product efficacy, and regulatory compliance [5].

Key practical benefits include:

- **Cost Efficiency**: Validated processes reduce batch failures, deviations, and recalls, leading to optimized use of materials, labor, and equipment. This minimizes waste, downtime, and compliance-related costs.
- **Scalability**: A validated process enables reliable scale-up from pilot to commercial production, supporting timely market entry and flexible response to demand without compromising quality.

Overall, validated processes enhance productivity, reduce costs, and ensure consistent delivery of high-quality medicines, underscoring their industrial and societal significance [6].

Process Validation Protocol

Before starting any process validation activities, the following tasks must be completed to finalize the qualification process. Process validation will commence only after the qualification work is finished. And for the completion of qualification works, the following steps have to be done:

- **Design Qualification**
- **Installation Qualification**
- **Operational Qualification**
- **Performance Qualification**

Performance Qualification (PQ)

Performance Qualification serves as the documented confirmation that a process or system performs as intended across all anticipated operating ranges. To confirm the reliability of a process or system, three consecutive successful process validation batches must be produced, during which all critical process parameters are evaluated against their predefined specifications [7].

Process validation establishes documented evidence that a specific process, such as the production of pharmaceutical dosage forms, consistently produces a product meeting predefined specifications and quality attributes. This process is guided by a documented plan known as a validation protocol [8].

The validation protocol outlines the steps for conducting process validation, including testing parameters, product attributes, production equipment, and design points for acceptable test results. The protocol must be signed, dated, and include a document reference, protocol number, and revision number. At a minimum, the protocol should include the followings [9]:

Principle

This Protocol covers the process validation activities for the manufacture of Cefixime Powder for Suspension, 50 ml. Cefixime Powder for Suspension, 50 mL contains Cefixime (as Trihydrate) 100 mg/5 mL. Cefixime is an antibiotic useful to treat a number of bacterial infections. This includes otitis media, strep throat, pneumonia, urinary tract infections, gonorrhea and Lyme disease [10].

General Information

Product name	Cefixime Powder for Suspension, 50 ml
Active ingredient	Cefixime Trihydrate USP
Strength	100 mg/ 5 mL
Average filling weight	±2.0% of Average Calculated Wt.= 29.23 gm
Batch Quantity	1500 phials
Batch size	43.85 Kg
Packaging Mode	70 mL amber glass bottle
Pack Size	1×1's phial
Analytical test method.	Identification (HPLC)
	Assay (HPLC)

Objective

The objective of this Process Validation is three consecutive commercial batches of Cefixime Powder for Suspension, 50 mL to be considered for process validation which will establish the pre-determined specifications and other critical process parameter (CPP) that under the state of control as far as production process variability is concerned.

Scope

This protocol is applicable for manufacturing processes to be employed to prepare Cefixime Powder for Suspension, 50 ml.

Qualification and Training of Personnel

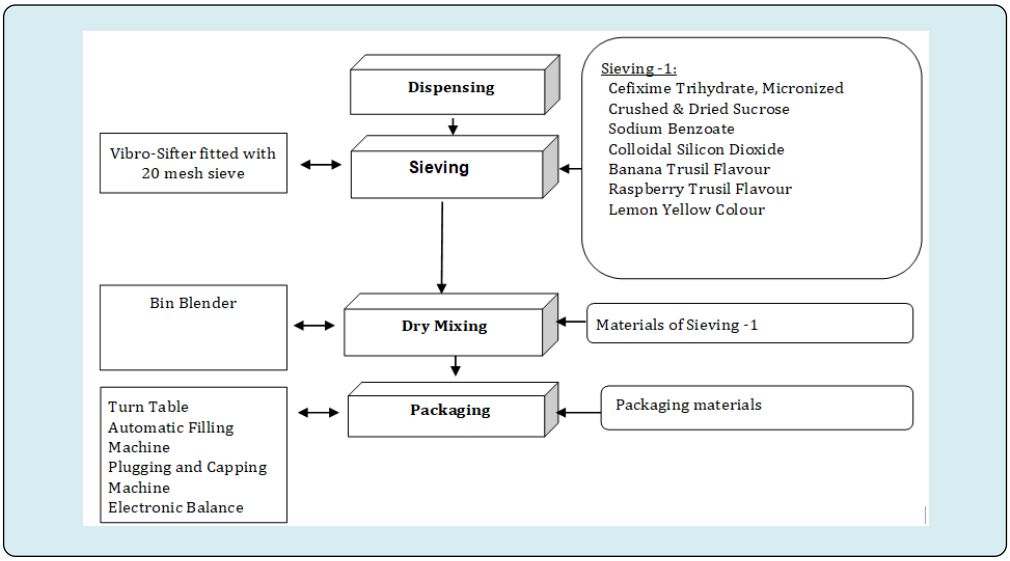
All who are involved in operating equipment and participating in the validation work should have been appropriately qualified & trained in the associated SOP / GMP Modules and process validation protocol [11].

Formulation

The Cefixime Powder for Suspension, 50 mL will be manufactured with standard batch size of 1500 phials (43.85 kg) as per the below mentioned formula.

Name of Material	Specification	Standard Qty/ Batch (kg)
Cefixime Trihydrate, Micronized (as 89.286% of Cefixime) (overage 5.0%)	USP	1.764
Sucrose Eqv. to crushed & dried sucrose	BP	42.18 ≅ 41.405
Sodium Benzoate	BP	0.2253
Colloidal Silicon Dioxide	NF	0.3077
Banana Trusil Flavour	Ph. Grade	0.056
Raspberry Trusil Flavour	Ph. Grade	0.075
Lemon Yellow Colour	Ph. Grade	0.0113

Process Flow Diagram (Batch Size: 43.85 kg; 1500 phials)



List of Equipment & their Qualification Status

SL No.	Name of the Equipment	Manufacturer /Origin	Capacity	Qualification Status	Remarks
	Dispensing Booth	HJ Cleantech, China	N/R	√	Ok
	Pulverizer	Longchang, China	150 Kg/hr	√	Ok
	Hot-Air Circle Oven	Yutong, China	150 kg	√	Ok
	IBC 100 L	CANAAN, China	100 L	√	Ok
	Sifter	CANAAN, China	150kg/hr	√	Ok
	Blender	CANAAN, China	100 kg	√	Ok
	Powder Filling Machine	Brothers, India	100 Bottles/min	√	Ok
	Sartorious Electronic Balance	Sartorious, Germany	320 gm	√	Ok
	Sartorious Platform Balance	Sartorious, Germany	150 Kg	√	Ok
	Sartorious Platform Balance	Sartorious, Germany	100 Kg	√	Ok
	Platform Balance	Sartorious, Germany	06 Kg	√	Ok

Environmental Condition

Environmental condition during manufacturing activities should be previously qualified.

ISO Class	Room Identification	Temperature (°C)	% RH
8	Dispensing Room	22°C ±3°C	(40-45) %
8	Sieving Room	22°C ±3°C	(40-45) %
8	Blending Room	22°C ±3°C	(40-45) %
8	Powder filling & sealing Room	22°C ±3°C	(40-45) %

Details of The Manufacturing Process

The Process consists of dispensing, sieving and mixing. Then the premixed materials are finally filled & sealed in amber glass bottle. The following BMR (Batch Manufacturing Record) & BPR (Batch Packaging Record) should be used for the execution of the manufacturing and packaging process [12].

Steps	Document Type	Document No.
Manufacturing		
Dispensing, Sieving & mixing	Batch Manufacturing Record	BMR-PFS-004
Packaging		
Filling & Sealing (Primary Packaging)	Batch Packaging Record (Primary)	BPR (1)-PFS-004
Secondary packaging	Batch Packaging Record (Secondary)	BPR (2)-PFS-004

Summary of Critical Process Parameters for Cefixime Powder for Suspension, 50 ml
(Dispensing to Packaging)
Batch Size: 43.85 kg & Batch Quantity: 1500 Phials.

Steps of Manufacturing Process	Critical Parameter to be Checked	Results		
		Batch No. AA	Batch No. BB	Batch No. CC

Dispensing	Check and ensure the dispensing booth are clean and line check is given as per current standard operating procedure.		Room Condition: Temperature: (22±2)°C	21°C	21°C	21°C
			Relative Humidity: (40-45)%	(42 to 43) %	(42 to 43) %	(42 to 43) %
	Check and ensure that balance is not due to calibration. Check for zero errors in the balance.		Check and ensure that the balance is calibrated. Check for zero error in the balance.	Checked & ensured	Checked & ensured	Checked & ensured
	Check and ensure the expiry date & potency of Cefixime Trihydrate.		Check and ensure the expiry date & potency of Cefixime Trihydrate.	Checked & ensured	Checked & ensured	Checked & ensured
	Check and ensure that all the scoops for dispensing are cleaned.		Check and ensure that all the scoops for dispensing are cleaned.	Checked & ensured	Checked & ensured	Checked & ensured
	Check and ensure the calculation of required quantity of Cefixime Trihydrate stated in the BMR.		Check and ensure the calculation of required quantity Cefixime Trihydrate stated in the BMR.	Checked & ensured	Checked & ensured	Checked & ensured
Checking of Dispensed Materials	Check and ensure that the all materials are issued as per BMR.		Check and ensure that the all materials are issued as per BMR.	Checked & ensured	Checked & ensured	Checked & ensured
Sieving through Vibro-shifter	Check and record the Temperature and Relative Humidity in processing area.		Room Condition: Temperature: (22±2)°C	22°C	22°C	22°C
	Temperature: (22±2)^{0}C and Relative Humidity: (40-45) %		Relative Humidity: (40-45)%	43%	42%	43%
	Check the integrity of the sieves before and after sifting through out the processing activity.		Check the integrity of the sieves before and after sifting through out the processing activity.	Checked & Found Ok	Checked & Found Ok	Checked & Found Ok
	Check and ensure visually all the equipment and equipment parts are cleaned.		Check and ensure visually all the equipment and equipment parts are cleaned	Checked & ensured	Checked & ensured	Checked & ensured
	Place the following materials into a SS container & sieve through vibration shifter fitted with 20 meshes and transfer the materials to bin.		Sieve Size: Mesh # 20 mm	20 mm	20 mm	20 mm
	Cefixime Trihydrate (Micronized)	1.764 Kg *				
	Sucrose (Crushed & dried)	41.405 Kg				
	Sodium Benzoate	0.2253 Kg				
	Colloidal Silicon Dioxide (Aerosil-200)	0.3077 Kg				
	Banana Trusil Flavour	0.056 Kg				
	Raspberry Trusil Flavour	0.075 Kg				
	Lemon Yellow Colour	0.0113 Kg				
	* Quantity variable					
Dry Mixing (Blending)	Blend the ingredients as per process validation protocol	Room Condition	Temperature: (22±2)°C	21°C	21°C	21°C
			Relative Humidity: (40-45) %	43%	42%	43%
		Blending Time: 70 Minutes		70 Minutes	70 Minutes	70 Minutes
		Blender speed: 08 RPM		08 RPM	08 RPM	08 RPM
		Size of the Bin: 100 L		100 L	100 L	100 L

Packaging (Primary & Secondary)	Check and record the Temperature and Relative Humidity. Temperature (22±2)°C and Relative Humidity (40- 45) %	Room Condition	Temperature: (22±2)°C	21°C	21°C	21°C
			Relative Humidity: (40-45) %	42%	43%	43%
	Check and verify that price, manufacturing date and expiry date overprinted on label and carton is as per current price list.	Check and verify that price, manufacturing date and expiry date overprinted on label and carton is as per current price list.		Checked and verified	Checked and verified	Checked and verified
	Check and ensure that all packaging materials (Primary & Secondary) are arranged for CEFIXIME PFS, 50 mL as per BPR.	Check and ensure that all packaging materials (Primary & Secondary) are arranged for CEFIXIME PFS, 50 mL as per BPR		Checked and ensured	Checked and ensured	Checked and ensured

Remarks: All the above-mentioned results are found within the specification.

Analytical Schedule

Unit operation	Analytical Schedule													
	Appearance	LOD at 105oC	Tapped Density	Bulk Density	Car's Index	Average filling weight	Water content (K.F Titrator)	Uniformity of weight	Blending Uniformity	pH (after reconstitution)	Deliverable volume	Suspensibility	Identification	Assay
After Crushing & Drying of Sucrose	√	√	-	-	-	-	-	-		-	-	-	-	-
Blending	√	-	√	√	√	-	-	-	√	-	-	-	-	-
During Filling & Sealing	√	-	-	-	-	√	-	√	-	-	-	-	-	-
Finished Product	√	-	-	-	-	√	√	√	-	√	√	√	√	√
Note: √ Denotes the test is required														

Calibration & Qualification Status of Lab. Equipment

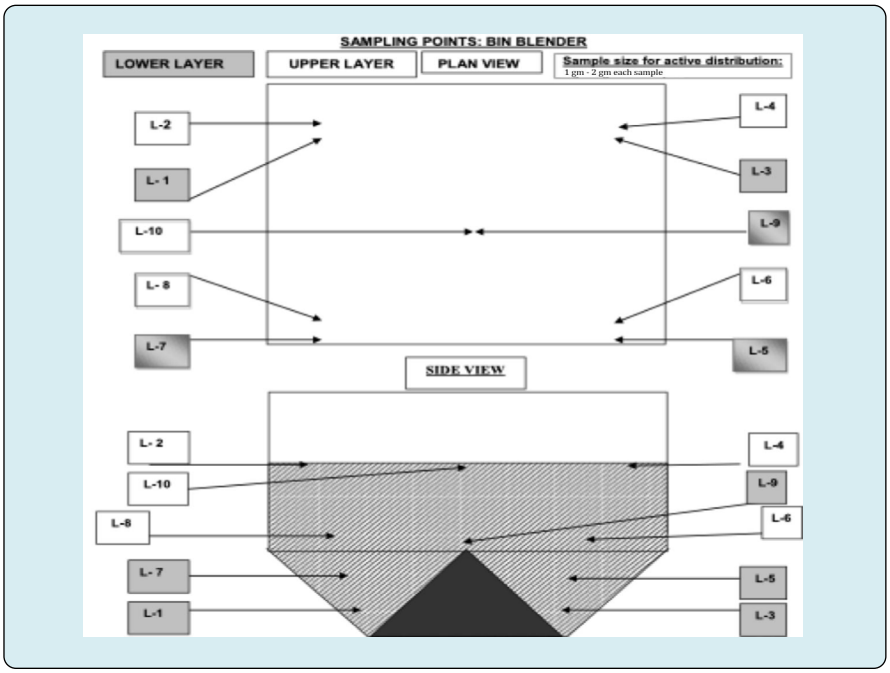
SL No.	Name of the Equipment	Manufacturer /Origin	Qualification Status	Calibration Status
1	HPLC	Waters Corp., USA	√	√
2	Electronic Analytical Balance	Mettler Toledo	√	√
3	Electronic Analytical Precision Balance	Mettler Toledo, Switzerland	√	√
4	K.F. Titrator	Metrohm, Switzerland	√	√
5	pH Meter	Mettler Toledo	√	√
NB: √ implies that all equipment were verified and certified that they have proper qualification & Calibration status.				

Sampling Details

Sampling details	
Process stages	Method of Sampling
After Crushing & Drying of Sucrose	Sampling: Sample will be taken from dryer to check LOD at 105°C of the crushed & dried Sucrose.
	Sample size: min. 1500.0 mg and max. 2500.0 mg

Blending	Sample for Blending/Mixing uniformity.	Write down the following information on a sample polybag
		a) Product Name
		b) Batch No.
		c) Sample location
		d) Date of sampling
		Sampling: 10 No. of Samples (10) will be taken from Bin Blender after 70 minutes of mixing with blender speed at 8 RPM to check the Cefixime content into the blended materials. Follow Appendix A for sample location/points.
		Sample size: min. 1000.0 mg and max. 2000.0 mg
	Sample for Bulk & Tapped density, Carr's Index:	Write down the following information on a sample polybag.
		a) Product Name
		b) Batch No.
		c) Sample location
		d) Date of sampling
		Sampling: Samples will be taken from container after blending. Follow Appendix A for-sample location/points
		Sample size: min. 20.0 gm and max. 25.0 gm
During Filling & Sealing	Sample for filled & sealed product testing:	Collect samples with following ID:
		a) Product Name
		b) Batch No.
		c) Sample location
		d) Date of sampling
		Sampling: Collect sample from filling & sealing area to perform the analysis as per specification.
		Sample size: Approx. 14 phials
Finished product	Collect samples for stability study as per stability study protocol.	

(13) Appendix-A



Summary of Test Result for Cefixime Powder for Suspension, 50 ml

(After crushing and drying of sucrose at 60^0C & 120mins.)
Batch size: 43.85 kg & batch quantity: 1,500 phials

Test Parameters	Specifications	Results		
		Batch No. AA	Batch No. BB	Batch No. CC
Appearance	White, odorless free flowing powder	Complies	Complies	Complies
Moisture Content	Not more than 0.2 %	0.15%	0.17%	0.14%

Remarks: All the results are found within the specification.

Summary of Test Result for Cefixime Powder for Suspension, 50ml

(Blending)
Batch size: 43.85 kg & Batch Quantity: 1,500 phials

Test Parameters	Specifications	Results		
		Batch No. AA	Batch No. BB	Batch No. CC
Description/Appearance	Off white to pale yellow powder.	Complies	Complies	Complies
Active Distribution on	All individual results are within ± 10 % (Absolute) of mean value % RSD: NMT 5.0%	70 minutes & 8RPM	70 minutes & 8RPM	70 minutes & 8RPM
Back: Left – Lower		3.56%	3.49%	3.50%
Back: Left – Upper		3.44%	3.51%	3.59%
Back: Right – Lower		3.50%	3.67%	3.47%
Back: Right – Upper		3.51%	3.63%	3.50%
Front: Right – Lower		3.47%	3.46%	3.49%
Front: Right – Upper		3.60%	3.56%	3.64%
Front: Left – Lower		3.53%	3.58%	3.54%
Front: Left – Upper		3.49%	3.47%	3.50%
Middle – Lower		3.49%	3.45%	3.61%
Middle – Upper		3.51%	3.65%	3.61%
Average Value		3.51%	3.55%	3.54%
Maximum deviated		3.60%	3.67%	3.64%
% RSD		1.29%	2.33%	1.70%

Remarks: From the above-mentioned analytical results, it is found that all are complies with the predetermined specification.

In this section, critical parameters such as **drying time** and **blending speed** are optimized through a series of well-structured studies, often underpinned by risk assessment and design of experiments (DoE).

- **Drying Time**: Drying time is optimized through evaluating of different drying durations and temperatures to identify conditions that achieve target moisture levels without degrading the product or affecting flow properties.
- **Blending Speed**: Proper blending ensures uniform distribution of the API and excipients, critical for dose uniformity. Blending speed is optimized by varying speed and time to achieve homogeneity without causing particle size reduction or segregation. Samples are taken at different intervals and tested for content uniformity to establish the optimal blending parameters [13].

These critical parameters are confirmed during **process performance qualification (PPQ)** runs, ensuring they consistently produce product meeting predefined quality attributes. The data obtained supports a robust, reproducible manufacturing process, aligned with regulatory expectations and operational efficiency [14-20].

(16-A) Summary of Test Result for Cefixime PFS, 50 ml (Finished Product)

Batch Size: 43.85 kg & Batch Quantity: 1,500 Phials
Starting of Filling & Sealing

Test Parameters	Specifications	Results		
		Batch No. AA	Batch No. BB	Batch No. CC
Description/Appearance	An almost white free flowing powder with a characteristic pleasant odor which forms yellow suspension on reconstitution.	Complies	Complies	Complies
Identification of Cefixime Trihydrate	Must be positive	Positive	Positive	Positive
Average filling weight	± 2.0 % of calculated weight	29.21 gm	29.06 gm	29.17 gm
Uniformity of filling weight	± 3.0 % of average filling weight	-1.43 % to + 1.40 %	-1.96 % to + 1.58 %	-1.54 % to + 0.69 %
Water Content (by K.F.)	Not more than 2.0 %	0.50%	0.55%	0.58%
pH (after reconstitution)	2.5 to 4.5	3.87	3.85	3.86
Suspendibility	Should form a yellow uniform suspension in 3 minutes when reconstituted with 30 mL water.	Complies	Complies	Complies
Deliverable volume	Average volume: NLT 50 mL	50.0 mL	50.1 mL	50.2 mL
	Individual volume: NLT 47.5 mL	49.0 mL	49.0 mL	49.0 mL
Active Content/5 mL Cefixime (as Trihydrate)	Release Limit: 90.0 mg to 110.0 mg	105.0 mg	104.1 mg	105.3 mg

Remarks: From the above-mentioned analytical results, it is found that all are complies with the predetermined specification [20-23].

(16-B) Middle of Filling & Sealing

Test Parameters	Specifications	Results		
		Batch No. AA	Batch No. BB	Batch No. CC
Description	An almost white free flowing powder with a characteristic pleasant odor which forms yellow suspension on reconstitution.	Complies	Complies	Complies
Identification of Cefixime Trihydrate	Must be positive	Positive	Positive	Positive
Average filling weight	± 2.0 % of calculated weight	29.13 gm	28.83 gm	29.23 gm
Uniformity of filling weight	± 3.0 % of average filling weight	-1.72 % to + 1.37 %	-1.18 % to + 2.32 %	-2.46 % to + 2.60 %
Water Content (by K.F.)	Not more than 2.0 %	0.58%	0.63%	0.44%
pH (after reconstitution)	2.5 to 4.5	3.82	3.84	3.83
Suspendibility	Should form a yellow uniform suspension in 3 minutes when reconstituted with 30 mL water.	Complies	Complies	Complies
Deliverable volume	Average volume: NLT 50 mL	50.2 mL	50.0 mL	50.0 mL
	Individual volume: NLT 47.5 mL	48.0 mL	48.0 mL	48.0 mL

Active Content/5 mL Cefixime (as Trihydrate)	Release Limit: 90.0 mg to 110.0 mg	105.1 mg	103.6 mg	104.2 mg

Remarks: From the above-mentioned analytical results, it is found that all are complies with the predetermined specification.

(16-C) Last of Filling & Sealing

Test Parameters	Specifications	Results		
		Batch No. AA	Batch No. BB	Batch No. CC
Description	An almost white free flowing powder with a characteristic pleasant odor which forms yellow suspension on reconstitution.	Complies	Complies	Complies
Identification of Cefixime Trihydrate	Must be positive	Positive	Positive	Positive
Average filling weight	± 2.0 % of calculated weight	28.85 gm	29.53 gm	29.08 gm
Uniformity of filling weight	± 3.0 % of average filling weight	-1.59 % to + 1.40 %	-1.62 % to + 1.35 %	-1.90 % to + 1.32 %
Water Content (by K.F.)	Not more than 2.0 %	0.52%	0.49%	0.54%
pH (after reconstitution)	2.5 to 4.5	3.88	3.81	3.85
Suspendibility	Should form a yellow uniform suspension in 3 minutes when reconstituted with 30 mL water.	Complies	Complies	Complies
Deliverable volume	Average volume: NLT 50 mL	50.1 mL	50.2 mL	50.0 mL
	Individual volume: NLT 47.5 mL	49.0 mL	48.5 mL	48.5 mL
Active Content/5 mL Cefixime (as Trihydrate)	Release Limit: 90.0 mg to 110.0 mg	103.5 mg	104.6 mg	105.0 mg

Remarks: From the above-mentioned analytical results, it is found that all are complies with the predetermined specification [23-27].

(17) Test Result for Cefixime PFS, 50 ml (Final & Finished Product)

Active content in the reconstituted liquid suspension on both Day 1 and Day 7

Test Parameters	Specifications	Results					
		Batch No. AA		Batch No. BB		Batch No. CC	
		1st Day	7th Day	1st Day	7th Day	1st Day	7th Day
Identification of Cefixime Trihydrate	Must be positive	Positive	Positive	Positive	Positive	Positive	Positive
pH (after reconstitution)	2.5 to 4.5	3.88	3.28	3.71	3.65	3.85	3.7
Active Content/5 mL Cefixime (as Trihydrate)	Release Limit: 90.0 mg to 110.0 mg	103.5 mg	102.8 mg	102.68 mg	102.90 mg	104.0 mg	103.85 mg

Remarks: From the above-mentioned analytical results, it is found that all are complies with the predetermined specification.

Conclusion

The results obtained from all three batches at each stage indicate that the process validation of Cefixime Powder for oral suspension consistently produces batches with acceptable outcomes, without any significant deviations from documented evidence. This validation provides a high degree of assurance that the manufacturing process for Cefixime Powder for oral suspension reliably produces a product that meets its predetermined specifications and quality attributes. So, on the basis of these results, it can be declared that the process is validated and this process can be

routinely used to produce products.

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