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**PROCESS VALIDATION OF DICLOFENAC SODIUM, PARACETAMOL AND CHLORZOXAZONE TABLETS**

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**Abstract**

Validation is a tool of quality assurance which provides confirmation of the quality in equipment systems, manufacturing processes, software and testing methods. Validation of the individual steps of the processes is called the process validation. In this study the process validation was carried out for the combined tablet dosage form which contains Diclofenac sodium 50mg, Paracetamol 325 mg and Chlorzoxazone 250 mg. In tablet dosage form, critical parameters like dry mixing, drying, lubrication and compression were taken up for validation studies. In -process quality monitoring of all critical processing steps was done for three production batches. Assay after lubrication was within the specified limit, indicating blend uniformity. Physical parameters such as weight variation, hardness test and friability and assay were checked and results found within the acceptance criteria. During packing operation, blisters were checked and found satisfactory. Thus process validation of Diclofenac sodium 50mg, Paracetamol 325 mg and Chlorzoxazone 250 mg in combined solid dosage form was successfully completed and found within the specifications.

**Keywords:** Process validation, Diclofenac sodium, Paracetamol, Chlorzoxazone, Tablet dosage form.

## Introduction

As per USFDA, Validation1-7 is defined as establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre- determined specifications and quality characteristics. Validation is also be defined as documented act of proving that any procedure, process, equipment, material, activity or system actually leads to the expected results as per WHO guidelines. Process validation is a requirement of the current good manufacturing practices regulation

for the finished pharmaceuticals. The different types of process validation are described below: ***Prospective validation*:** Normally it is undertaken whenever the process for a new formula (or within facility) must be validated before routine pharmaceutical production commences.

***Retrospective validation:*** Achieving validation by documenting all the historical information (e.g., release data) for existing products and using that data to support the position that the process is under control.

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***Concurrent validation****:* Documenting the evidence that a process does what it purports to do base on information generated during actual implementation of the process.

***Revalidation:*** Indicates that the process must be validated once again, may not necessarily mean the original program must be repeated however.

In this study the process validation was carried out for the combined tablet dosage form which contains Diclofenac sodium 50mg, Paracetamol 325 mg and Chlorzoxazone 250 mg. The critical parameters like dry mixing, drying, lubrication and compression were taken up for validation studies.

In -process quality monitoring of all critical processing steps was done for three production batches. Physical parameters such as weight variation, hardness test, friability, dissolution and assay were checked and results found within the acceptance criteria. During packing operation, blisters were checked and found satisfactory.

## Materials and methods

Materials used in the manufacturing of tablets are shown in Table 1 and the equipments and instruments used in the production are mentioned in Table 2 &3 respectively.

### Table No. 01: List of raw materials and their functions

**S.No Ingredients Function**

1. Paracetomol API (Antipyretic, Analgesic & Anti inflammatory )
2. Starch Binder
3. Chlorzoxazone API (Muscle relaxant)
4. Starch (P) Binder/Diluent
5. Citric acid Buffer
6. Methyl paraben sodium Anti microbial Preservative
7. Propyl paraben sodium Anti microbial Preservative
8. Sunset yellow (S) Colourant
9. Purified Water Vehicle
10. Diclofenac sodium API (Analgesic & Anti inflammatory )
11. Cellulose acetate phthalate Polymer
12. Talc Glidant
13. Magnesium sterate Lubricant
14. Sodium lauryl sulphate Surfactant

### Table No. 02: List of equipment and their uses

|  |  |  |
| --- | --- | --- |
| **S.No** | **Name of Equipment** | **Uses** |
| 1. | Rabid mixer granulator | Dry Mixing |
| 2. | Sifter with SS sieves 16#,40#,60# | Sifting |
| 3. | Balance | Weighing |
| 4. | Fluid bed drier | Drying |
| 5. | Octagonal blender | Blending |
| 6. | Multimill with 1.5mm Screen | Sifting |
| 7. | Jacketed stainless steel kettle for starch paste preparation | Binding |
| 8. | Rotary Tablet Press | Compression |

**Evaluation of tablets**

### Table No. 03: List of instruments and their uses

**S.No Instrument Name Uses**

1. Analytical balance Weighing
2. Disintegration Test apparatus Disintegration time
3. Vernier caliper Thickness
4. Tablet friability test apparatus Friability
5. Monsanto Hardness Tester Hardness

The critical parameters considered during the process validation of Diclofenac sodium 50mg, Paracetamol 325 mg and Chlorzoxazone 250 mg in tablets were Dry mixing, Drying, Lubrication

Compression, Blister packing, Weight variation, Hardness Test, Thickness, Friability, Disintegration Time and Assay.

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#### Dry Mixing

The dry-mixing step involves mixing of active ingredients with the other additives using Rabid Mixer Granulator (RMG). The content of Paracetamol, Chlorzoxazone in the dry mix were tested and also to validate dry mixing time were the

critical variables that determine content uniformity. Mixing speed was 5, 10, 15 minutes and the sample were collected at 5 stages Top, Middle left, Middle, Middle right and bottom. In dry mixing stage, 3 batches like I, II, and III were considered for validation.

**Fixed Parameters**

Time interval studies : 5, 10, 15 minutes

Measured response uniformity : Description, blend uniformity.

Acceptance criteria : Not less than 90% &

not more than 110% of the Label claim

#### Drying

The drying step involves drying of wet mass. The level of moisture in the granules is important factor. If level of moisture is more in granules then blend will have poor flow & distribution characteristics. If level of moisture in blend is less it will produce tablet with capping, high friability

and chipping problems. During drying the granules which will influence the quality parameters like Assay of paracetamol and chlorzoxazone. Drying of granules in FBD controls the levels of moisture. In drying stage, 3 batches like I, II, and III were considered for validation.

### Fixed Parameters

Analysis : 5, 10, 15 minutes Acceptance criteria : Not less than 90% &

not more than 110% of the Label claim

#### Lubrication

Lubrication is to be carried out as per batch manufacturing record. The samples were collected at various stages at top, middle, and bottom with the mixing speed at 5, 10, and 15 min. Samples were collected at the lubrication stage and carried out the testing of content uniformity Assay, Description, Tapped density, Bulk density etc. In lubrication stage, three batches such as Batch I, II and III were considered for validation.

#### Compression

This step involves consistent flow of an adequately lubricated, into dies where the granules are being compressed into tablets. Compression is to be carried out as per batch manufacturing record. The samples were collected at the various stages i.e. at start up, high and low RPM speed. Testing were carried out for content uniformity, Appearance, Group weight, Individual weight, Thickness, Hardness, Friability, Disintegration time, Assay, Dissolution. In compression stage, three batches such as Batch I, II and III were considered for validation.

#### Blister Packing

Packing is to be done as per batch packing record. In packing stage, three batches such as Batch I, II and III were considered for validation.

#### Weight variation

Twenty tablets were randomly selected form each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated.

#### Thickness

Five tablets were randomly selected from each batch and there thickness and diameter was measured by using digital vernier caliper.

#### Hardness

The crushing strength kg/cm² of prepared tablets was determined for 5 tablets of each batch by using Monosanto tablet hardness tester. The average hardness and standard deviation were determined.

#### Friability

Five tablets were weighed and placed in the Electro lab friabilator and apparatus was rotated at 25 rpm for 4 minutes. After revolutions the tablets were

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dedusted and weighed again. The percentage friability was measured using the formula,

%F= {1-(Wt/W)}×100

Where,

%F= friability in percentage W= Initial weight of tablet

Wt= Weight of tablets after revolution

#### Assay 8

High performance liquid chromatography (HPLC) method used for simultaneous determination of diclofenac sodium, paracetamol and chlorzoxazone and in tablets.

#### Chromatographic Condition

The mobile phase was prepared by mixing solvents, Methanol and Buffer (70:30) v/v ratio. The Buffer consists of equal volume of 0.01 (M) ortho Phosphoric Acid and 0.01 (M) Monobasic Sodium Phosphate, pH adjusted to (2.5±0.2) with orthophosphoric acid. The prepared mobile phase was filtered through a Millipore 0.45 µm membrane filter and ultrasonically degassed prior to use. Methanol and Water in the ratio of 70:30 (v/v) was used as diluent throughout the experiment. The detection wavelength was set at 254 nm. The elution was done at a flow rate of 1.0 ml/min under ambient condition.

#### Standard Solution

A standard stock solution of Paracetamol (1000 mcg/ml), Diclofenac sodium (120 mcg/ml) and Chlorzoxazone (1000 mcg/ml) were prepared in diluent. Subsequent dilutions were made in diluent to prepare the concentrations 40,42,44,46,48 and 50 mcg/ml for Paracetamol; 10,12,14,16,18 and 20 mcg/ml for Diclofenac sodium and 45,48,51,54,57 and 60 mcg/ml for Chlorzoxazone. The calibration curve was done by plotting peak area against sample concentration for each ingredient.

#### Procedure

Twenty tablets were finely powdered and weighed accurately in the electronic balance (model Metler Toledo AG285). The powder equivalent to 325 mg of paracetamol, 250 mg of chlorozoxazone and 50 mg of diclofenac sodium was weighed accurately and dissolved in 250 ml methanol (HPLC Grade). The solution was filtered through 0.45 µm Millex- HV syringe driven membrane filter unit. Further appropriate dilutions have been made to get

concentration of 50µg/ml of paracetamol, 60 µg/ml of chlorzoxazone, 20-µg/ ml of diclofenac sodium. Twenty µl of this solution was injected in triplicate under the specified conditions. The peak areas obtained were related to slopes and intercepts from the calibration data to calculate concentration of the drugs

**Results and discussion**

**Dry mixing:** The content of Paracetamol (Para), Chlorzoxazone (Chlor) in the dry mix were tested and also to validate dry mixing time, were the critical variables that determine content uniformity. Mixing speed was 5, 10, 15 minutes and the sample were collected at 5 stages Top, Middle left, Middle, Middle right and bottom. In dry mixing stage, 3 batches like I, II, and III were considered for validation. Dry mixing result of all the batches was well within the acceptance criteria and shown in Table 4.

**Drying:** In drying stage, 3 batches like I, II, and III were considered for validation. Drying of all the batches was with in the acceptance criteria and shown in Table 5.

**Lubrication:** The samples were collected at various stages at top, middle, and bottom with the mixing speed at 5, 10, and 15 min. Samples were collected at the lubrication stage and carried out the testing of content uniformity Assay, Description, Tapped density, Bulk density etc. In lubrication stage, three batches such as Batch I, II and III were considered for validation. Lubrication of all the batches was within the acceptance criteria and shown in Table 6.

**Compression:** The samples were collected at the various stages i.e. at start up, high and low RPM speed. Testing were carried out for content uniformity, Appearance, Group weight, Individual weight, Thickness, Hardness, Friability, Disintegration time, Assay, Dissolution. In compression stage, three batches such as Batch I, II and III were considered for validation. Compression of all the batches of tablets was with in the acceptance criteria and results were shown in Table 7.

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### Table No. 04: Result of dry mixing – mixing uniformity

**Content**

**Time Sample Taken Batch No I Batch No I Batch No I**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Para** | **Chlor** | **Para** | **Chlor** | **Para** | **Chlor** |
| Top | 115.87 | 114.26 | 111.35 | 132.43 | 125.65 | 124.35 |
| Middle Left | 110.91 | 122.20 | 126.34 | 124.67 | 124.56 | 136.76 |
| Middle | 112.85 | 135.46 | 78.90 | 67.89 | 132.78 | 123.87 |
| Middle Right | 80.85 | 76.20 | 89.76 | 89.70 | 86.56 | 76.86 |
| Bottom | 116.75 | 127.30 | 134.23 | 123.45 | 56.78 | 89.54 |
| 5 min **Maximum** | 116.75 | 135.46 | 134.23 | 132.43 | 132.78 | 136.76 |
| **Minimum** | 80.85 | 76.20 | 78.90 | 67.89 | 56.78 | 56.78 |
| **Mean** | 107.45 | 115.08 | 108.12 | 107.63 | 105.27 | 110.24 |
| **SD** | 0.15 | 0.23 | 0.24 | 0.28 | 0.32 | 0.26 |
| **%RSD** | 14.0 | 20.0 | 21.8 | 25.7 | 30.0 | 23.3 |
| Top | 137.88 | 126.26 | 112.23 | 123.43 | 125.65 | 134.23 |
| Middle Left | 126.65 | 142.40 | 134.54 | 135.67 | 154.56 | 136.89 |
| Middle | 77.85 | 75.56 | 79.90 | 67.90 | 142.78 | 153.97 |
| Middle Right | 135.85 | 145.30 | 65.76 | 89.65 | 86.65 | 76.56 |
| Bottom | 154.75 | 134.30 | 124.23 | 146.45 | 66.80 | 85.65 |
| 10 min **Maximum** | 154.75 | 75.56 | 134.54 | 146.45 | 154.56 | 153.97 |
| **Minimum** | 77.85 | 145.30 | 65.76 | 67.90 | 66.80 | 76.56 |
| **Mean** | 126.60 | 124.76 | 103.33 | 112.62 | 115.29 | 117.46 |
| **SD** | 0.29 | 0.28 | 0.29 | 0.33 | 0.37 | 0.34 |
| **%RSD** | 22.9 | 22.8 | 28.4 | 29.2 | 32.4 | 29.1 |
| Top | 99.88 | 98.26 | 96.45 | 99.80 | 97.65 | 99.78 |
| Middle Left | 99.91 | 99.20 | 95.67 | 96.34 | 97.89 | 99.66 |
| Middle | 99.85 | 98.46 | 98.90 | 97.80 | 97.90 | 99.87 |
| Middle Right | 98.85 | 96.20 | 99.80 | 96.78 | 96.75 | 98.76 |
| Bottom | 98.75 | 97.30 | 99.78 | 94.56 | 97.67 | 98.67 |
| **Maximum** | 99.91 | 99.20 | 99.80 | 99.80 | 97.90 | 99.87 |
| 15 min **Minimum** | 98.75 | 96.20 | 95.67 | 94.56 | 96.75 | 98.67 |
| **Mean** | 99.45 | 97.88 | 98.12 | 97.06 | 97.57 | 99.35 |
| **SD** | 0.005 | 0.01 | 0.01 | 0.01 | 0.004 | 0.005 |
| **%RSD** | 0.59 | 1.18 | 1.97 | 1.98 | 0.48 | 0.58 |

**Sample Taken**

### Table No. 05: Result of drying

**Content (%)**

**Batch No I Batch No I Batch No I**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Para** | **Chlor** | **Para** | **Chlor** | **Para** | **Chlor** |
| Top | 98.33 | 98.89 | 99.87 | 98.86 | 98.16 | 98.76 |
| Middle | 99.43 | 99.52 | 98.76 | 99.67 | 95.78 | 97.56 |
| Bottom | 99.12 | 99.21 | 96.80 | 97.65 | 96.76 | 98.67 |
| **Mean** | 98.96 | 99.21 | 98.48 | 98.73 | 96.90 | 98.33 |
| **Maximum** | 99.43 | 99.52 | 99.87 | 99.67 | 98.16 | 98.16 |
| **Minimum** | 98.33 | 98.89 | 96.80 | 97.65 | 95.78 | 97.56 |

### Table No. 06: Result of lubrication

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Test** | **Batch No I** | **Batch No II** | **Batch No III** |
|  | Description | Complies | Complies | Complies |
| 10 min Assay | Complies | Complies | Complies |
| 15 min Description | Complies | Complies | Complies |
| Assay | Complies | Complies | Complies |
| 20 min Description | Complies | Complies | Complies |
| Assay | Complies | Complies | Complies |

**Time Interval Content of Paracetamol,Chlorzoxazone, Diclofenac sodium**

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### Table No. 07: Result of compression

**Test Batch Number**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Batch No I** | **Batch No II** | **Batch No III** |
| Description | Complies | Complies | Complies |
| Average Weight(mg) | 918.4 | 918.9 | 918.5 |
| Uniformity of weight(mg) | Complies | Complies | Complies |
| Thickness (mm) | 5.98 | 5.84 | 5.75 |
| Friability (%w/w) | 0.08% | 0.07% | 0.09% |
| Hardness | 6.06 | 6.05 | 7.08 |
| Assay | Complies | Complies | Complies |
| Disintegration Time | 4’44’’ | 4’56’’ | 4’67’’ |

**Weight variation:** Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20

tablets was calculated. Weight variation of all the batches of tablets was within the acceptance criteria and the results were shown in Table 8.

### Table No. 08: Result of weight variation

|  |  |  |  |
| --- | --- | --- | --- |
| **S.No** | **Batch No I (mg)** | **Batch No II (mg)** | **Batch No III (mg)** |
| 1. | 916.3 | 914.3 | 917.3 |
| 2. | 918.9 | 908.9 | 928.9 |
| 3. | 901.6 | 901.6 | 911.6 |
| 4. | 922.6 | 912.4 | 922.9 |
| 5. | 919.1 | 919.7 | 920.1 |
| 6. | 906.3 | 916.3 | 906.3 |
| 7. | 911.6 | 910.6 | 921.6 |
| 8. | 922.0 | 892.0 | 924.0 |
| 9. | 925.5 | 925.5 | 925.9 |
| 10. | 914.9 | 916.0 | 914.0 |
| 11. | 905.2 | 905.9 | 915.2 |
| 12. | 939.2 | 929.2 | 920.2 |
| 13. | 926.3 | 926.8 | 926.9 |
| 14. | 931.5 | 921.5 | 921.5 |
| 15. | 912.5 | 922.5 | 911.5 |
| 16. | 898.2 | 895.2 | 898.8 |
| 17. | 935.7 | 915.7 | 915.9 |
| 18. | 919.9 | 909.9 | 929.9 |
| 19. | 921.2 | 921.5 | 901.2 |
| 20. | 918.5 | 919.5 | 919.9 |
| **Maximum** | 939.2 | 929.2 | 929.9 |
| **Minimum** | 898.2 | 892.0 | 898.8 |
| **Average** | 918.4 | 915.6 | 917.6 |

**Thickness:** Five tablets were randomly selected from each batch and their thickness was measured by using digital vernier caliper. The Thickness of

all the batches of tablets was within the acceptance criteria and the results were shown in Table 9.

### Table No. 09: Result of thickness

**Thickness (5.7mm-6.5mm)**

**S.No**

**Batch number**

**I II III**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | 5.8 | 6.5 | 5.8 |
| 2. | 5.9 | 6.4 | 5.7 |
| 3. | 6.1 | 5.7 | 5.8 |
| 4. | 6.3 | 5.9 | 6.1 |
| 5. | 5.8 | 6.1 | 6.0 |
| **Average** | 5.98 | 6.12 | 5.88 |
| **Maximum** | 6.3 | 6.5 | 6.1 |
| **Minimum** | 5.8 | 5.7 | 5.7 |

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**Hardness:** The crushing strength kg/cm² of prepared tablets was determined for 5 tablets of each batch by using Monosanto tablet hardness tester. The average hardness and standard deviation

were determined. The hardness of all the batches of tablets was within the acceptance criteria and the results were shown in Table 10.

### Table No. 10: Result of hardness

**Hardness**

**S.No**

**(4.0kg/cm²-10.0 kg/cm²) Batch number**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **I** | **II** | **III** |
| 1. | 4.5 | 4.6 | 7.6 |
| 2. | 5.8 | 5.0 | 5.0 |
| 3. | 6.0 | 6.1 | 4.5 |
| 4. | 7.5 | 5.5 | 5.5 |
| 5. | 6.5 | 6.0 | 6.5 |
| **Average** | 6.6 | 5.44 | 5.82 |
| **Maximum** | 7.5 | 6.1 | 7.6 |
| **Minimum** | 4.5 | 4.6 | 4.5 |

**Friability:** Five tablets were weighed and placed in the Electro lab friabilator and apparatus was rotated at 25 rpm for 4 minutes. After revolutions the tablets were dedusted and weighed again. The

friability of all the batches of tablets was within the acceptance criteria and the results were shown in Table 11.

### Table No. 11: Result of friability

**Friability (Not more than 1%)**

**S.No**

**Batch number**

**I II III**

|  |  |  |  |
| --- | --- | --- | --- |
| 1. | 0.08 | 0.07 | 0.08 |
| 2. | 0.06 | 0.08 | 0.06 |
| 3. | 0.07 | 0.09 | 0.07 |
| 4. | 0.08 | 0.07 | 0.08 |
| 5. | 0.09 | 0.08 | 0.06 |
| **Average** | 0.07 | 0.08 | 0.07 |
| **Maximum** | 0.09 | 0.09 | 0.08 |
| **Minimum** | 0.06 | 0.07 | 0.06 |

**Disintegration Time:** Five tablets were randomly selected from each batch and their disintegration time were determined by using Tablet Disintegration Test apparatus. The disintegration

time of all the batches of tablets was within the acceptance criteria and the results were shown in Table 12.

### Table No. 12: Result of disintegration time

**Disintegration Time (Not more than 15 min)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **S.No** |  |  | **Batch number** |  |
|  |  | **I** | **II** | **III** |
| 1. | 4’44" |  | 4’55” | 5’55” |
| 2. | 5’15” |  | 5’10” | 4’15” |
| 3. | 5’20” |  | 4’10” | 4’34” |
| 4. | 4’30” |  | 4’20” | 4’35” |
| 5. | 4’25” |  | 4’46” | 4’30” |
| **Average****Maximum Minimum** | 5’ 27”5’20”4’25” |  | 5’ 10”5’10”4’10” | 5’ 24”5’55”4’15” |

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**Assay:** The powder equivalent to 325 mg of Paracetamol, 250 mg of Chlorozoxazone and 50 mg of Diclofenac sodium was weighed accurately and dissolved in 250 ml methanol (HPLC Grade). The solution was filtered through 0.45 µm Millex- HV syringe driven membrane filter unit. Further appropriate dilutions have been made to get

concentration of 50µg/ml of Paracetamol, 60 µg/ml of Chlorzoxazone, 20-µg/ ml of Diclofenac sodium. Twenty µl of this solution was injected in triplicate under the specified conditions. The assay of all the batches was within the acceptance criteria and shown in Table 13.

### Table No. 13: Results of HPLC assay

**Diclofenac sodium Paracetamol Chlorzoxazone**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Amt. claimed****(mg/tablet)** | **Amt. found****(mg/tablet)** | **Amt. claimed****(mg/tablet)** | **Amt. found****(mg/tablet)** | **Amt. claimed****(mg/tablet)** | **Amt. found****(mg/tablet)** |
|  | 49.54 |  | 324.52 |  | 249.50 |
|  | 48.54 |  | 325.12 |  | 249.85 |
| 50 | 49.52 | 325 | 324.25 | 250 | 249.55 |
|  | 50.20 |  | 325.14 |  | 250.10 |
|  | 50.10 |  | 324.89 |  | 248.95 |
| **Mean** | **49.58** | **Mean** | **324.78** | **Mean** | **249.59** |
| **SD** | **0.59** | **SD** | **0.34** | **SD** | **0.38** |
| **RSD** | **1.33** | **RSD** | **0.12** | **RSD** | **0.17** |

**Conclusion**

Based on the results obtained, it was concluded that three validation batches of Tablets containing Diclofenac sodium 50mg, Paracetamol 325 mg and Chlorzoxazone 250 mg, comply with the approved In-process and finished specifications defined for the product. The overall review of results shows consistency and reproducibility within and between batches. These results demonstrate that the manufacturing process was under control throughout all stages, within and between batches. Hence it was concluded that the manufacturing process and the equipments adopted were robust enough and produce product meeting predetermined standards and quality attributes. Therefore the Process stands Validated.

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