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FORMULATION AND PROCESS VALIDATION OF MELOXICAM TABLETS

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Keywords:

Meloxicam, Validation, Process validation, Wet method, Dissolution, HPLC, Assay and kinetic study

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ABSTRACT: Aim: The aim of present work is to analytical estimation and process validation of conventional tablet dosage form of Meloxicam. **Materials and Methods:** Tablets were prepared by wet granulation method. Then coating is done as film coating. **Results and Discussion:** Melting point, pH of drug was measured in triplicate and mean was notedi.e.253°C, 3.9. The maximum absorption was found to be 350 nm by UV. Various tests like Angle of repose, Bulk density, tapped density, Carr's Index and Hausner's ratio are performed at blend stage. Dissolution test and assay is performed of all the three batches. A kinetics study is performed for all the three batches and the result was found satisfactory. **Conclusion:** Results of the performed tests are to be assessed & summarized to confirm that the procedures followed consistently meet its pre-determined specifications and quality attributes. No maximum variation is found in results. So, our product is validated.

INTRODUCTION: Validation is a systematic approach to identifying, measuring, evaluating, documenting and re-evaluating a series of critical step, in the manufacturing process that requires control to ensure a reproducible final product [1, 2, 3]. It has become a necessary step to ensure better quality of medicinal product, throughout manufacturing, storage, handling and distribution. Quality cannot be inspected or tested into finished product. Thereby each step must be controlled to maximize probability that finished products meet all specifications [4, 5]. Process Validation is 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 Standards [6,7].

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Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) used to relieve various types of pain, including pain caused by musculoskeletal conditions, osteoarthritis, and rheumatoid arthritis. With a longer half-life than most other NSAIDS, it is a favorable option for those who require once-daily dosing.

MATERIALS AND METHODS:

Materials: The following chemicals were used: Meloxicam (Combitic Global Caplet Pvt. Ltd., India), Microcrystalline cellulose (Lobachemie Pvt. Ltd.), Starch (Lobachemie Pvt. Ltd.), Magnesium Stearate (Arora), Talc (Arora), Di-Calcium Phosphate (Lobachemie Pvt. Ltd.), Lactose (Medilaw Pharma), Sodium Benzoate (Libraw Pharma), Sodium Starch Glycolate (Knowwell Pharma), Colour Insta Moist Shield-II white and Colour Iron Oxide Yellow Lake (Vikram Therma).

Methods:

Determination of Melting Point: Small quantity of drug was placed into a sealed capillary tube. The tube was placed in the melting point apparatus. The

temperature in the apparatus gradually increased and the temperature at which entire drug gets melted was noted. The melting point of the drug was determined by Perkin Elmer DSC 4000. The small amount of the drug sample was placed on the aluminum Pan and instrument was operated at a heating rate of 10ºC-20ºC/ minute for 10º to 350 ºC. The thermogram was obtained and melting point was noted down [9].

Solubility Studies: The solubility study of Meloxicam was performed in distilled water and ethanol, dimethyl formamide, separately by keeping the drug containing test tube on vortex mixture.

Preparation of Standard Curve in Methanol: Accurately weighed 100mg of Meloxicam and was dissolved in 10 ml of 1 M Sodium Hydroxide and 40 ml of methanol, cool and add sufficient methanol to produce 100 ml. Standard stock solution containing 1000 µg/ml. Form this standard stock solution, a series of dilution (100, 200, 300, 400 µg/ml) were prepared using methanol. The absorbance of these solutions was measured spectrophotometrically against blank of Meloxicam at 350 nm for Meloxicam. Absorbance of drug at different concentrations was calculated and graph was plotted.

Infrared Spectroscopic Analysis: The FTIR spectrums of moisture free samples of Drug, all excipients and physical mixture were recorded on IR spectrophotometer. The scanning range varies from 4000 – 400 cm^{-1} and resolution was 1 cm^{-1}.

Preparation of Tablets: Different formulations of an conventional tablets of Meloxicam (F1-F3) were prepared by wet granulation method (Table 1) by using different excipients Like Microcrystalline cellulose, Starch, Di-Calcium Phosphate, Lactose, Gelatin, Sodium Benzoate, magnesium Stearte and Meloxicam.

TABLE 1: FORMULATIONS CONTAINING MELOXICAM (IN MGS)

Ingredients (mg)	F1	F2	F3
Meloxicam	15	15	15
Starch	120	120	120
Di-Calcium Phosphate	50	50	50
Lactose	75	75	75
MCCP	15	15	15
Gelatin	2.7	2.7	2.7
Sodium Benzoate	0.3	0.3	0.3
Starch (For Paste)	10	12	14
Magnesium Stearate	2	2	2
Sodium Starch Glycolate	6	4	2
DR Coat HSP	10	10	10
Colour Iron Oxide	1	1	1

Procedure for Wet Granulation: Appropriate quantities of Meloxicam and excipients like Starch, Di-Calcium Phosphate, Lactose and Micro-crystalline Cellulose powder were measured accurately and all the measured powders were sifted through Sieve no #40. The above sifted materials were mixed rapidly for 5 min and again passed through sieve no 40. Water having ((2%)) w/v amount of Starch, gelatin and Sodium Benzoate was used as the granulating solution and the solution was added to the mixture in step 2 and was kneaded or 2-5 min, then the kneaded mass was passed through sieve no # 16 to obtain the granules. The granules obtained in step 3 were dried in a tray drier at 50°C for 2 hrs. The dried granules were lubricated uniformly with weighed quantities of Talcum, Magnesium Stearate and Sodium Starch Glycolate. The above granules were compressed into tablets by CADMACH multi station tablet compression machine by using 19.1 X8.75 mm punch. Before starting coating, average weight of core tablets was recorded. After coating process, the appearance and weight gain during coating was tested.

Angle of Repose (θ): Angle of repose is an indication of fractional forces existing between granules particles. The maximum angle possible between the surface of the pile of granules and the horizontal plane gives the angle of repose.

$$\tan(\theta) = h/r$$

Where (**θ**) = angle of repose, h = height of heap of granules, r = radius of heap.

Method: Weighed quantity of granules were poured through the funnel from the fixed height on the graph paper. Then circumference of the heap was marked by pencil. The radius of circle formed was measured and angle of repose then calculated on the parameter found the radius of circle and height of the heap.

Bulk Density: Bulk density of powder is the ratio of the mass of an untapped powder sample and its volume indicating the contribution of the intra-particulate void volume. The bulk density is expressed in g/ml. Bulk density is determined by weighing powder intoa dry graduated 250 ml cylinder. The powder was carefully levelled without compacting, volume was recorded, and bulk density g/ml was calculated using the following formula.

Bulk density = Mass of the Blend powder / **Volume occupied by the powder blend**

Tapped Density: Tapped density is obtained by mechanically tapping a graduated measuring cylinder or vessel containing a powder sample. After observing the initial powder volume to weight, the measuring cylinder or vessel is mechanically tapped, and volume readings are taken until little less than 1% further volume change is observed.

Mechanical tapping is achieved by raising the cylinder or vessel and allowing it to drop under its own weight at specified distance. Secure the cylinder in the holder of the apparatus with weighed powder sample. Measure 100-200 taps and observe the corresponding volumes to the nearest graduated unit.

Tapped density = Mass of the powder Blend taken / Tapped Volume of the powder blend

Carr's Index: The Carr's Index and Hausner's ratio are measures of the porosity of a powder to be compressed. They measure the relative importance of interparticle interactions. For poor flow materials, there are frequently greater interparticulate interactions and a greater difference between the bulk and tapped densities. These differences are reflected in the compressibility Index and Hausner's Ratio. Carr's Index was calculated using the following formula.

$$\text{Carr's Index} = 100 \times (TD-BD) / TD$$

Hausner's Ratio: The Hausner's Ratio is a number that is correlated to the flow ability of a powder orgranular material [7]. Hausner's ratio is calculate using following formula:

$$\text{Hausner's ratio} = TD / BD$$

Evaluation of Tablets: The formulation tablets were evaluated for the following physical parameters.

Thickness: Thickness depends on the die filling, physical properties of material to be compared. There is possible of small variation in the thickness of individual tablet in a batch. But it should not appear to the unaided eye. The thickness and diameter can be measured by vernier caliper.

Weight Variation Test: Twenty tablets were selected randomly and weighed individually. Calculate average weight compare the individual tablet weight to the average. Not more than two of the individual weight derivate from the average weight by more than percentage shown in tablet and nonderivate by more than twice the percentage.

Hardness: Tablets must possess sufficient strength or hardness and can be measured by Monsanto hardness tester. Ten tablets were randomly picked from each formulation and were evaluated for hardness and can be expressed in kg/cm^2.

Friability: Friability can be performed in Roche friabilator, Pre weighed ten tablets were introduced in the friabilator. Then the machine was operated for 100 revolutions. Tablets were dropped from a distance of six inches each revolution. Tablets were then dusted and reweighed. Loss of less than 1% in weight is considered to be within the specification and acceptable.

$$F(\%) = W_{initial} - W_{final} / W_{initial} \times 100$$

Disintegration Time: This test determines whether tablet disintegrate with in prescribed time when placed in liquid medium.

Introduce one tablet into each six tubes of the basket add a disc to each tube and suspend the

assembly in the beaker containing water maintained at 37±2° C, operate the apparatus for 30 minutes left the basket out of it water and observed.

The tablet passes the test if all of them are disintegrated, i.e. in all the tubes no part of the tablet is left. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets; not less than 16 of the 18 tablets tested disintegrate completely.

Drug content: Assay: (BY HPLC):
Mobile Phase Preparation:
Mobile Phase A: 0.1 % w/v of potassium dihydrogen orthophosphate adjusted to pH 6.0 with 2 M Sodium Hydroxide.

Mobile Phase B: Methanol

Gradient method should be followed in **Table 2.**

TABLE 2: MOBILE PHASE GRADIENT

Time (Min)	Mobile Phase A (% v/v)	Mobile Phase B (% v/v)	Comment
0-2.5	60	40	Isocratic
2.5-12	60→30	40→70	Linear Gradient
12-25	30	70	Isocratic
25-26	30→60	70→40	Linear gradient
26-30	60	40	Re-equilibration

Chromatographic Condition:

Use a stainless-steel column (15 cm X 4.0 mm) packed with end-capped octadecylsilyl silica gel for chromatography (5 µm) (Inertsil ODS 2 is suitable)

1. Use gradient elution and the mobile phase described below.

2. Use a flow rate of 1.0 ml per minute.

3. Use an ambient column temperature.

4. Use detection wavelength 350 nm.

5. Inject 10µl of each solution.

Standard Preparation: Weigh accurately 30 mg of Meloxicam in 10 ml of 1 M Sodium Hydroxide and 40 ml of methanol, cool and add sufficient methanol to produce 100 ml.

Sample Preparation: Weight and powder 20 tablets. Moisten a quantity of the powdered tablets containing 30 mg of meloxicam with 10 ml of 1 M Sodium Hydroxide, add 40 ml of methanol and mix with the aid of ultrasound for 5 minutes.

Add a further 40 ml of methanol, mix for 3 hours using a magnetic stirrer and then with the aid of ultrasound for 5 minutes. Cool, add sufficient methanol to produce 100 ml and filter.

***In-vitro* Dissolution Studies:**
Procedure of Dissolution of Tablets:
Test Conditions.

1. Use apparatus 2, rotating the paddle at 50 revolutions per minutes.

2. Use 900 ml of a buffer prepared by dissolving 13.61g of potassium dihydrogen orthophosphate in 800 ml of water, adjusting the pH to 7.5 with 0.5 M Sodium Hydroxide, and adding sufficient water to produce 1000 ml, at a temperature of 37^0 C, as the medium.

Procedure:

1. After 45 minutes, withdrawn a sample of the medium and filter. Measure the absorbance of the filtrate**,** diluted with the dissolution medium if necessary, at 362 nm using dissolution medium in the reference cell.

2. Measure the absorbance of a solution prepared by dissolving 30 mg of meloxicam in 5 ml of methanol, adding 1 ml 0.1 M sodium hydroxide and sufficient dissolution medium to produce 100 ml. Dilute a volume of the resulting solution with sufficient dissolution medium to produce a solution containing 0.00075 % w/v of meloxicam.

Sample Preparation: The dissolution parameters were set and one tablet is placed in each basket and care was taken to exclude air bubbles from the surface of the tablets and immediately the apparatus was started, 25 ml of the sample was withdrawn and filter through Whatmann filter paper, 10ml of solution was replaced in to

dissolution medium, the same procedure was repeated at other time intervals. Take 10 ml from above solution and transfer into 25ml volumetric flask and volume makeup with dissolution media [10].

Drug Release Kinetics: The release kinetics was studied by various kinetic models such as zero-order plot, first-order plot, Higuchi plot, and Korsmeyer–Peppas plot.

To study the release kinetics of the nanoparticle gel data obtained from *in-vitro* drug release studies was plotted in various kinetic models: Zero-order as cumulative amount of drug releases versus time, first order as long cumulative % of drug remaining versus time, Higuchi model as cumulative % of drug released versus square root of time, and Korsmeyer–Peppas model as log cumulative % drug release versus long time. The best fit model was confirmed by the value of correlation coefficient near to one [12].

RESULTS AND DISCUSSION:

Melting Point Determination: The melting point of the drug was determined using DSC and was found to be 253^{O}C. The DSC thermograms of meloxicam shown in **Fig. 1.**

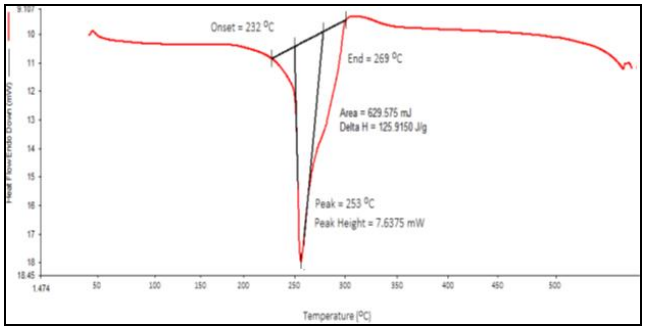


FIG. 1: DSC THERMOGRAMS OF MELOXICAM

Solubility Studies: Meloxicam samples are examined, and it was practically found to be insoluble in purified water and very slightly soluble in ethanol (96 per cent), soluble in dimethyl form amide.

FTIR Analysis: FT-IR spectroscopic analysis was carried out to characterize drug. The FT-IR spectraobtained was compared with that given in pharmacopoeia for Meloxicam. Diagnostic peaks and finger-print regions were found to be identical. These characteristics peaks are useful in identification of drug. FT-IR of Meloxicam and mixture containing Meloxicam, and all excipients was done for drug compatibility studies. The results obtained showed that there occur no interactions between the components when taken together.

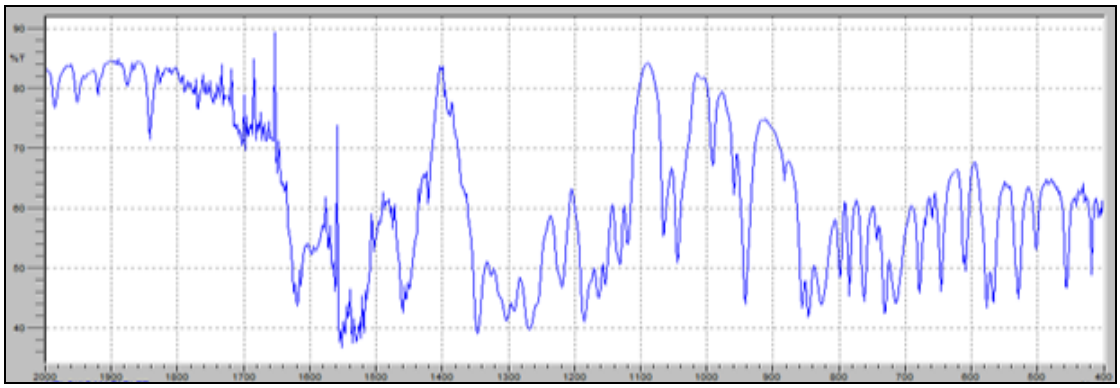


FIG. 2: FTIR OF MELOXICAM

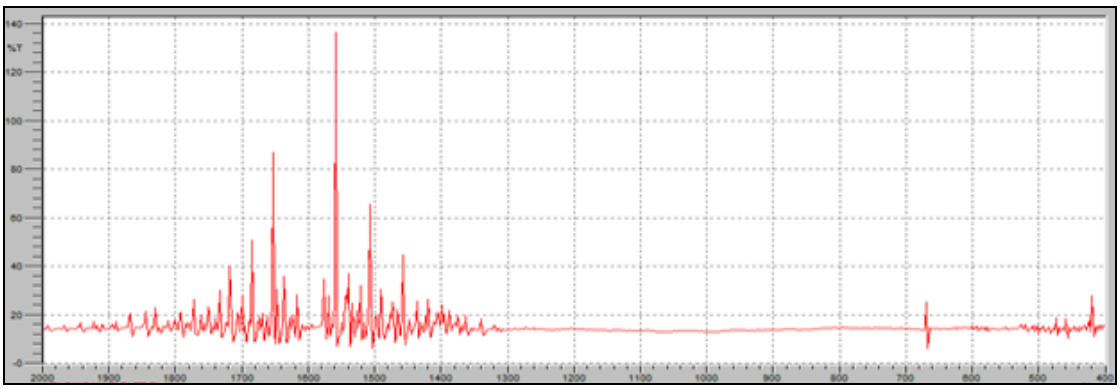


FIG. 3: FTIR OF EXCIPIENTS

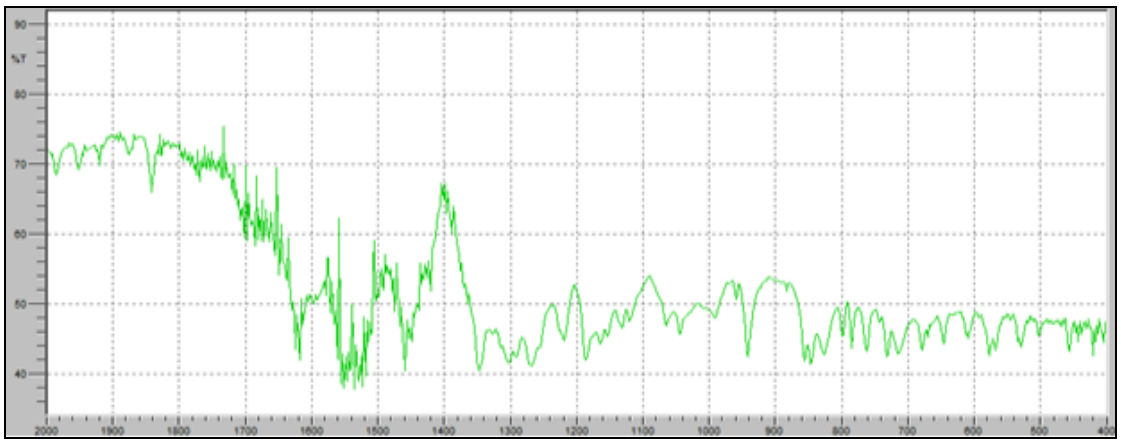


FIG. 4: FTIR OF PHYSICAL MIXTURE

Analysis by UV-Visible Spectrophotometry:

Stock Solution of Meloxicam: Stock solution of 100 µg/ml was prepared by dissolving 10 mg of Meloxicam in100 ml of distilled water. Dilution in the range of 10 of 100 µg/ml were scanned for determining λ max from 200-400 through UV spectrophotometer and λ max was found to be at 350 nm for Meloxicam. Calibration curve of Meloxicam was determined by plotting absorbance (nm) versus concentration (µg/ml) at 350 nm **Fig. 5**. The results obtained are shown in **Table 3.** From these solutions of conc. 100 µg/ml, 200µg/ml, 300µg/ml, 400µg/mland 500µg/ml were prepared.

TABLE 3: ABSORBANCE DIFFERENT DILUTIONS OF DRUG AT 350 NM IN METHANOL

S. no.	Conc. (µg/ml)	Abs.
1	100	0.200
2	200	0.372
3	300	0.537
4	400	0.723
5	500	0.876

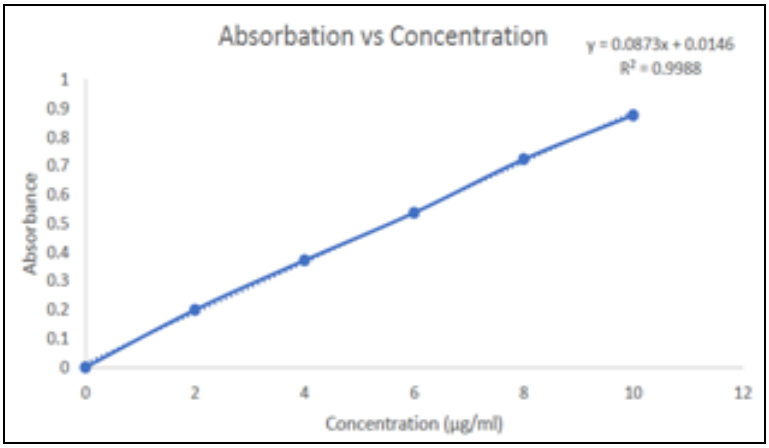


FIG. 5: STANDARD CALIBRATION CURVE OF MELOXICAM

Linearity of Meloxicam by HPLC Method:

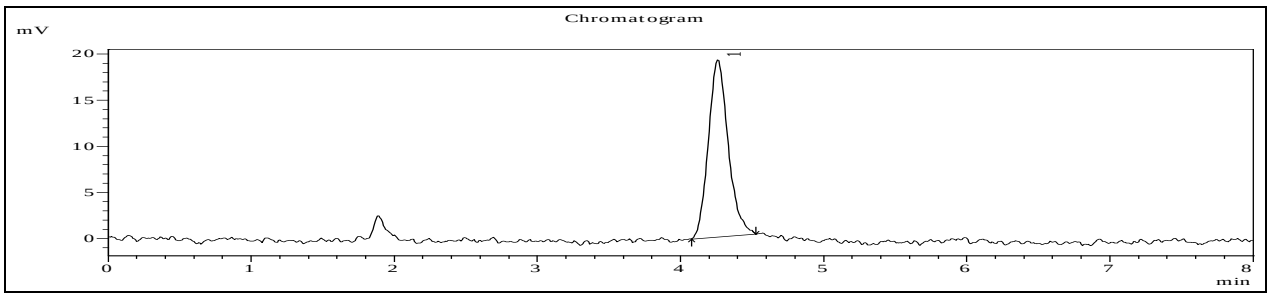
Preparation of Standard Graph:

Stock Solution of Meloxicam: Accurately weighed 100 mg of Meloxicam was dissolved in 100 ml of mobile phase. 1ml pipette out from above solution and taken in 10 ml volumetric flask and volume make up with mobile phase. Standard stock solution containing 100 µg/ml.

Standard Graph of Meloxicam: Form this standard stock solution, a series of dilution (100, 200, 300, 400, 500 µg/ml) were prepared using mobile phase. Result of linearity shown in **Table 4** and linearity curve shown in **Fig. 11**. And all the HPLC Chromatogram found in figure 6 to10

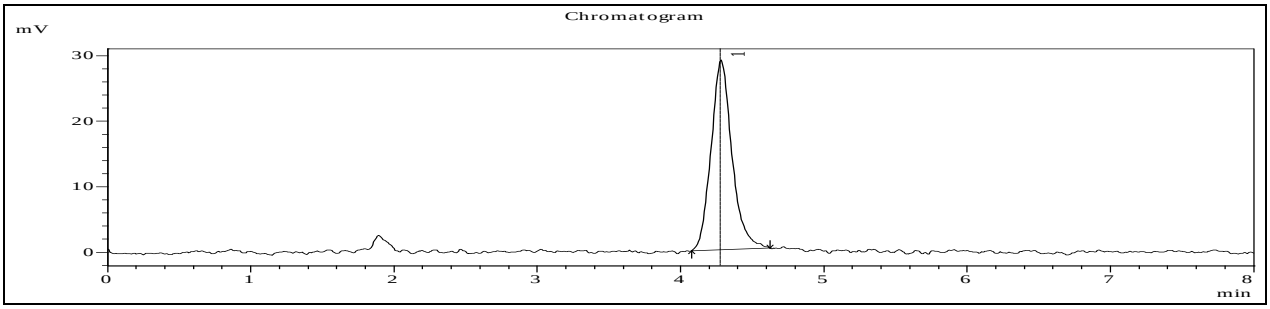
TABLE 4: AREA OF DIFFERENT DILUTIONS OF MELOXICAM

S. no.	Conc.(µg/ml)	Peak Area
1.	0	0
2.	100	185059
3.	200	293486
4.	300	391349
5.	400	492625
6.	500	591865



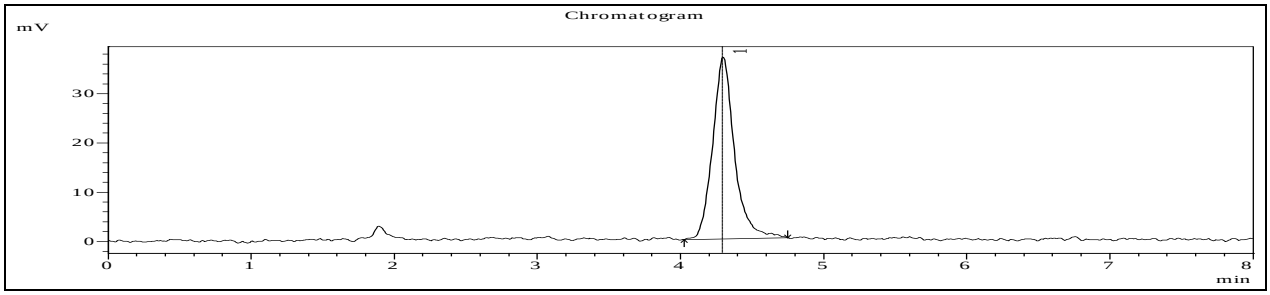
VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.258	185059	100.00	19217	100.00

FIG. 6: 100 MCG DILUTION OF MELOXICAM



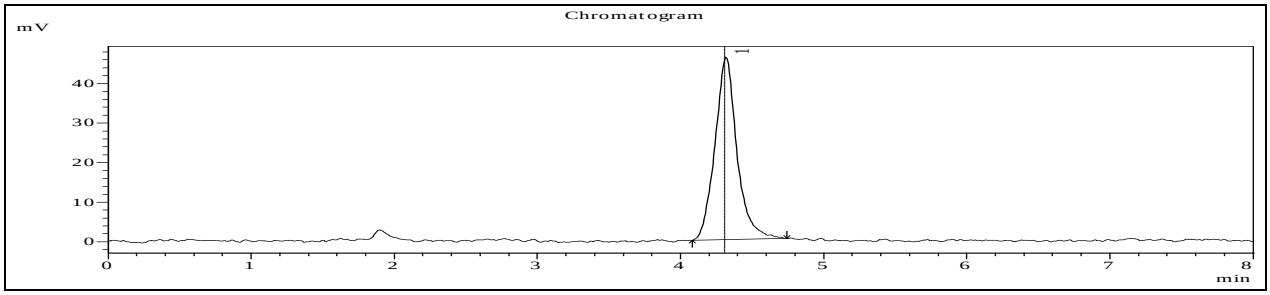
VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.283	293486	100.00	28977	100.00

FIG. 7: 200 MCG DILUTION OF MELOXICAM



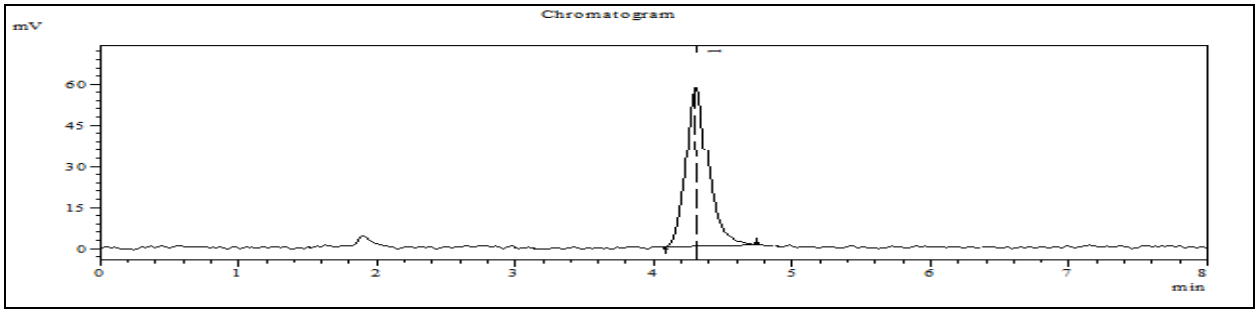
VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.300	391349	100.00	36861	100.00

FIG. 8: 300 MCG DILUTION OF MELOXICAM



VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.325	492625	100.00	46179	100.00

FIG. 9: 400 MCG DILUTION OF MELOXICAM



				VWD: Signal A, 350 nm Result
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.324	591865	100.00	56268	100.00

FIG. 10: 500 MCG DILUTION OF MELOXICAM

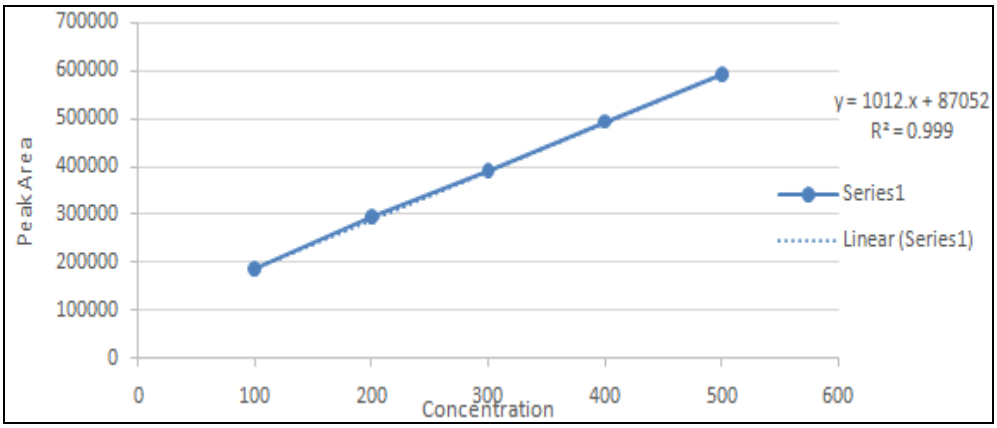


FIG. 11: LINEARITY CURVE OF MELOXICAM

Evaluation of Meloxicam Blended Granules: The blended granules of different formulation were evaluated for angle of repose, bulk density, tapped density, carr's index and Hausner's ratio. The results of these evaluations were as follows:

TABLE 5: PRE COMPRESSION PARAMETERS OF GRANULES

Form. Code	Angle of Repose (θ) (± SD)	Bulk Density (g/cc) (± SD)	Tapped Density (g/cc) (± SD)	Carr's Index (%) (± SD)	Hausner's Ratio(± SD)
F1	25.4±0.28	0.732±0.12	0.831±0.06	14.48±0.05	1.12±0.09
F2	25.7±0.34	0.779±0.08	0.892±0.14	15.21±0.06	1.14±0.07
F3	26.2±0.49	0.784±0.06	0.911±0.11	15.25±0.07	1.18±0.09

Angle of Repose: Angle of repose for the granules of F1-F3 was found to be (25.1 – 26.3), which indicates good flow property.

Carr's Index: The carr's index for the granules of F1-F3 was found to be (14.52 -15.34 %), which shows good flowing properties.

Hausner's Ratio: Hausner's ratio was found to be (1.13 – 1.15) it indicates good flow properties of the granules.

Post Compression Parameters:

TABLE 6: POST COMPRESSION PARAMETER OF THREE BATCHES

S. no.	Form. Code	Thickness (mm)*	Hardness (Kg/cm^2)	Friablity (%)*	Weight Variation(mg)**
1	F1	5.64	9	0.41	307.5
2	F2	6.70	10	0.27	307.9
3	F3	5.68	9	0.24	306.5

Disintegration Test of Three Batches at Post Compression Stages:

TABLE 7: DT OF THREE BATCHES

S. no.	Form. Code	Disintegration Time
1	F1	6
2	F2	6
3	F3	7

Disintegration Test of Three Batches after Coating:

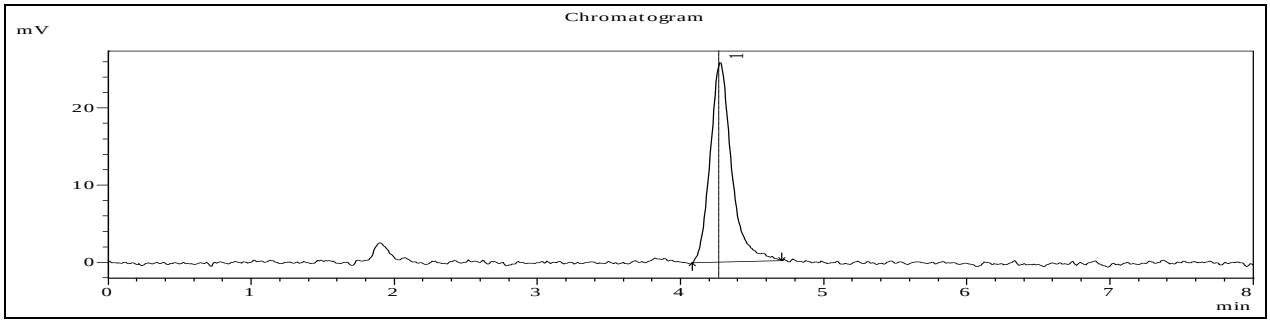
TABLE 8: DT OF THREE BATCHES

S. no.	Form. Code	Disintegration Time
1	F1	15
2	F2	16
3	F3	14

Assay: Potency of all three batches was found to be in below table.

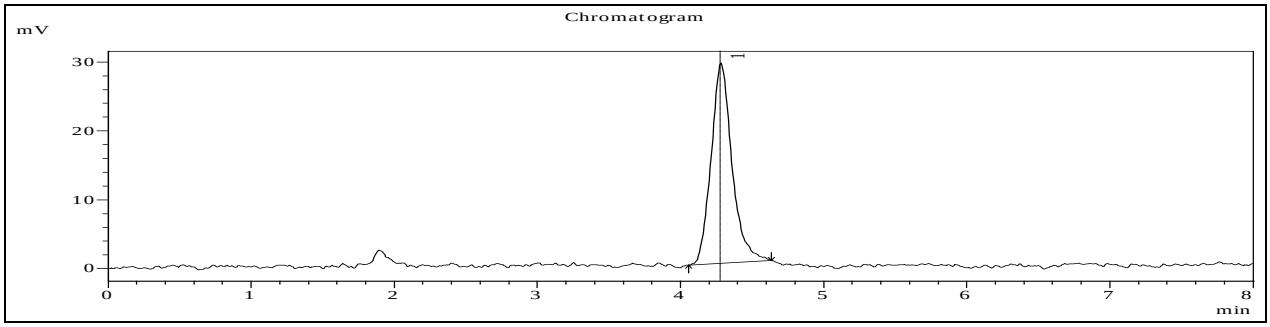
TABLE 9: ASSAY OF ALL THREE BATCHES

S. no.	Form. Code	Assay
1	F1	99.9
2	F2	99.8
3	F3	99.8



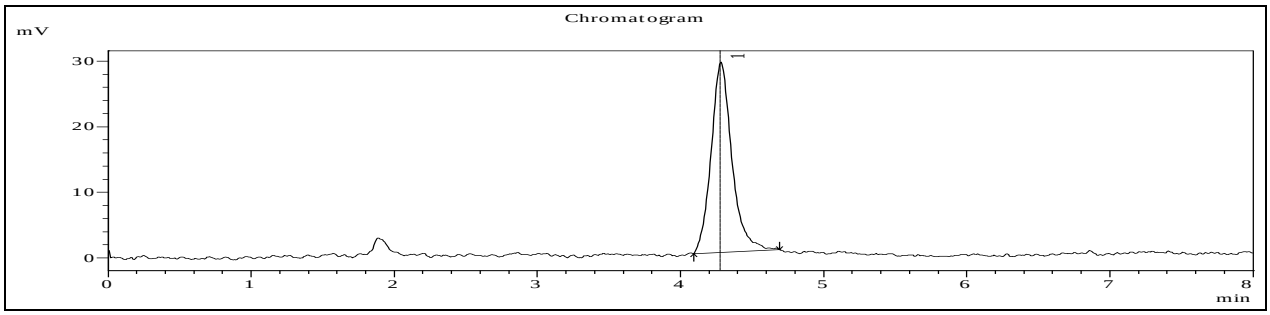
VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.275	268433	100.00	25831	100.00

FIG. 12: CHROMATOGRAM OF STD. MELOXICAM



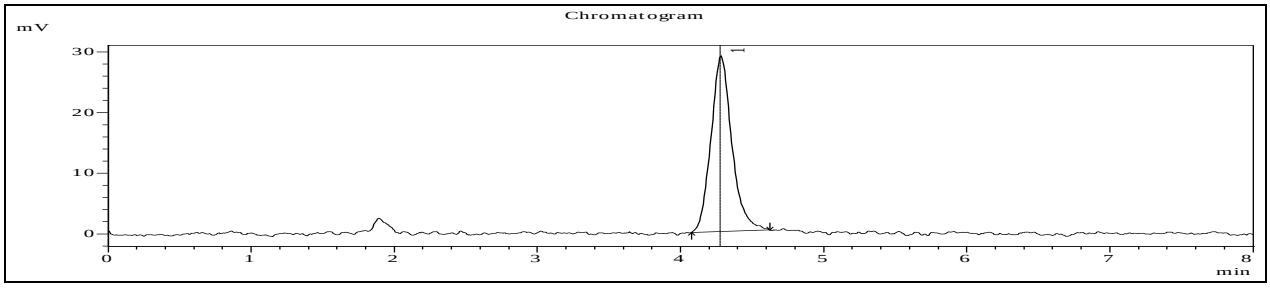
			VWD: Signal A, 350 nm Result	
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.283	293960	100.00	29046	100.00

FIG. 13: CHROMATOGRAM OF F1 FORMULATION



VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.283	293655	100.00	29036	100.00

FIG. 14: CHROMATOGRAM OF F2 FORMULATION



VWD: Signal A, 350 nm Result				
Retention Time	**Area**	**Area %**	**Height**	**Height %**
4.283	293486	100.00	28977	100.00

FIG. 15: CHROMATOGRAM OF F3 FORMULATION

In-vitro Dissolution Studies:

TABLE 10: *IN-VITRO* DRUG RELEASE OF FORMULATIONS AT DIFFERENT TIME INTERVALS

S. no.	Time intervals	F1	F2	F3
1	0	0	0	0
2	5	10.2	11.7	10.5
3	10	25.7	27.1	26.8
4	15	47.8	46.2	48.0
5	20	69.4	71.3	70.4
6	25	85.1	86.6	87.3
7	30	97.2	96.9	97.4

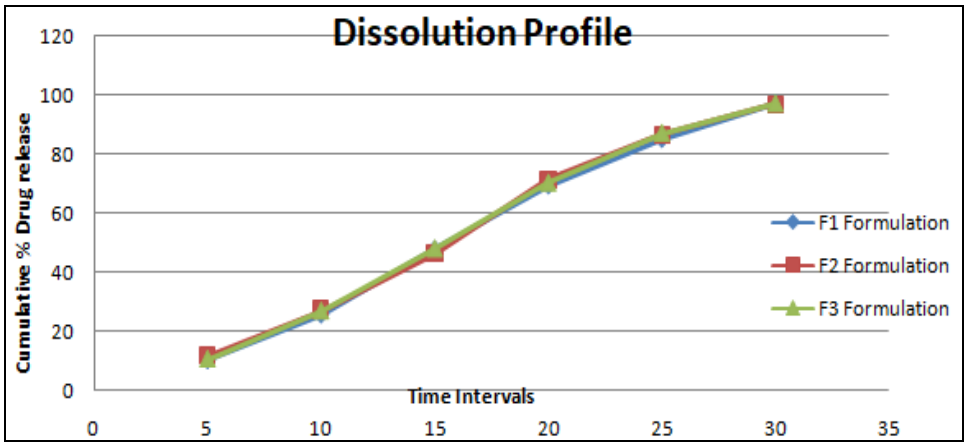


FIG. 16: DRUG RELEASE PATTERN OF F1 TO F3

Drug Release Kinetics: It was observed that the Peppas model was found to be best suited with R^2value of 0.997 for formulation F1. It was observed that the Peppas model was found to be best suited with R^2 value of 0.995 for formulation F2. It was observed that the Peppas model was found to be best suited with R^2 value of 0.996 for formulation F3. A kinetics study is performed for all the three batches and the result was found satisfactory.

CONCLUSION: The present work on the analytical estimation and process validation of conventional tablet dosage form of Meloxicam film coated tablet. So, we prepared and evaluated the Meloxicam film coated tablet for three consecutive batches. No maximum variation is found in results. So, our product is validated. Samples are to be collected from respective stages and appropriate tests are to be carried out depending on the validation protocol. Results of the performed tests

are to be assessed & summarized to confirm that the procedures followed consistently meet its pre-determined specifications and quality attributes.

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