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In-Vitro Disintegration Studies of different Parameters of Meloxicam

Ashutosh Kumar* and Anoop Singh

Department of Pharmacy, Bhabha University, Bhopal (M.P.) - India

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Abstract

Compressed parameters were tested for the physical parameters such as hardness, thickness, stability, weight weight evaluated for drug content, in-vitro release profile. Average. The weight difference of the tablet was predicted by direct compression that all the tablets showed the same weight with lower standard deviation values within acceptable variation as shown in the table. The *in-vitro* disintegration study was done using the USP type II tablet disruption tester using basket type at 50 rpm for all types, using 900 ml of 0.1N HCL and 6.8 phosphate buffer dissolution medium. Samples withdrawn using the UV spectrophotometer were analyzed. In direct compression, the F1 shows good response due to the presence of superdisoning. It can be concluded that the sample given by the Meloxicam was authentic and the result of this study, in accordance with the official monographs and standards given in the literature. Various data ready to prepare spectroscopy and standard curve was reproducible and can be used for further formulation study in formulation studies.

Keywords: Formulation, Disintegration, Meloxicam

Introduction

In recent decades, various types of pharmaceutical research have been done to develop new dose forms. Considering the quality of life, most of these efforts have been focused on ease of medication. In addition to the various dosage forms developed to improve the ease of administration, the fastest dissolved tablet (RDT) is the most widely preferred business product. Oral cavity is an attractive site for the administration of medicines because administration has ease. Various dosage forms such as pills, capsules; The liquid preparation is administered by the oral route. During the last decade, rapidly disintegrating tablets (FDT) technologies that make pills in the mouth without chewing and excessive water intake attracts a lot of attention.

Meloxicam is in a class of non-steroidal anti-inflammatory drugs (NSAIDS) drugs. Meloxicam works by reducing the hormone which causes swelling and pain in the body. Meloxicem is used to reduce the pain, swelling and hardness caused by rheumatoid arthritis and osteoarthritis.

In the present work studies on in-vitro disintegration were determined and reported.

Materials and Methods

Materials

Meloxicam API and excipients like Isapgula husk, Cross linked tragacanth, Cassia Tora, starch paste, Magnesium stearate, Talc, Lactose were supplied by PG Tech Research Institute, Indore

Physical Parameters of Drug

Organoleptic Properties: Organoleptic properties are used to identify drug via sense including taste, smell, sight & touch.

***Corresponding Author**

Solubility: Solubiity of Meloxicam was determined qualitatively by simple dissolution method in different solvents.

Melting point: The Melting point of a solid is the temperature at which it changes from solid state to liquid state. In this method the pre sealed capillary was filled by the small amount of drug. Then capillary and thermometer was placed in apparatus. Then see capillary for melting the drug. The temperature was noted when the drug starts to melt and till it is completely melted. It is determined by Melting point apparatus. Melting point of meloxicam is between 253 -255°C.

Particle size: Particle size is used for comparing dimensions of solid particles, gaseous or liquid particle. It is useful because it determines solubility. Particle size determination of meloxicam was done by optical microscopy using stage micrometer. A very little amount of drug was taken on slide 1 drop of liquid paraffin was added on slide, it was observed under microscope. Observe the particle size of 100 particles under microscope the average particle size of the drug was calculated.

pH: Prepare buffer solution (7.0 pH) by dissolved buffer tablet (7.0 pH) in water and calibrate the pH meter with
7.0 pH. 1 gm of meloxicam dissolved in 100 ml. Boil water and cool properly. After the cooling drug solution pH was determined by pH meter. The pH value of meloxicam is acidic 7.2 -7.5

Partition Coefficient: Partition coefficient determination of meloxicam was done by simple shaking flask method. The 50 mg of drug was dissolved in 10 ml of distilled water and 10 ml of carbon tetrachloride in separating funnel, shake well for 1 hr than stand for at least 24 hrs for phase separation. Partition coefficient of meloxicam is 4.

$$P_{o/w} = C_{oil} / C_{water}$$

Pre compression parameter: The parameters were determined as per standard procedure mentioned in Indian Pharmacopoeia

U.V. Spectrometer: The identification of drug done by UV spectrophotometer method. The small amount of drug dissolve in 0.1n hydrochloric acid scanned in UV. The highest peak is λmax for the meloxicam from the spectra 342 nm (λmax of meloxicam) was obtained. The spectral data from this scan was used for the preparation of calibration curve of meloxicam.

Preparation of standard curve:
100mg of meloxicam was weighed correctly and transferred to the 100 ml volumetric flask for stock solution. Then the volume up to 100 milliliters was made using 0.1 N HCL. The solution of 10ml for the standard solution was drawn from the solution of the stock and then 100ml made in the second 100 ml volumetric flask and it is considered to be the standard solution of 100ml in another 100ml volumetric flask and this is considered as standard solution of 100µg/ml concentration. Aliquots were prepared from above solution by taking 2,4,6,8,10 ml was drawn and diluted to 10ml to get 2,4,6,8,10 ppm concentrations. The solutions were analyzed at 342 nm using UV visible spectrophotometer.

Infrared Spectrometer: Infrared spectrometery analysis of Meloxicam was done by Nujol mull method by mixing powdered KBr with drug & Excipients. Peak was recorded.

Drug-Excipient Compatibility Study: The compatibility of the drug with formulation excipients was studied in three different conditions by keeping the lubricating mixture, such as petridge, with black patches and all pouches. All samples were studied for physical and chemical changes.

Formulation Manufacturing Process:

Sifting:
Meloxicam was sifted through 20 meshes. Other excipients were sifted through 40 mesh individually.

Dry mix:
The sifted material Meloxicam, Isapghule husk, Cross linked tragacanth, starch paste, lactose, Talc were taken in a large size poly bag and mixed properly by action. Finally magnesium stearate was added and mixed for about 5 minutes, so that the surface was coated with lubricant evenly.

Compression:
The powder blend was compressed into tablets using round shaped punches to get tablets of 75 mg weight on a 16 station rotary tablet machine.

Table 1: Formulation Table

Ingredients (mg)	F1	F2	F3	F4	F5
Meloxicam	7.5	7.5	7.5	7.5	7.5
Isapghule husk	15	-	-	3.75	-
Cross linked tragacanth	-	15	-	-	3.75
Cassia Tora	-	-	15	-	3.75
Starch paste	1.25	1.25	1.25	-	-
Lactose	48.75	48.75	48.75	48.75	48.75
Talc	1.25	1.25	1.25	1.25	1.25
Magnesium Stearate	1.25	1.25	1.25	1.25	1.25
Distilled Water	Qs	Qs	Qs	Qs	Qs
Total (mg)	**75**	**75**	**75**	**75**	**75**

Evaluation Parameters

Evaluation of physical parameters:

The only limitation of commercially manufactured pills is that they are available only in certain dosage strengths and combinations. To provide the flexibility of mixed formulations, pharmacists can prepare molded and compressed tablets for their patients. The molded tablet is compounded using a tablet triturate mold. Compressed pills can be made using a tablet press or single-punch table ting machine.

Tablet Thickness and Size:

For the uniformity of the tablet size, the thickness and diameter of the bullets were important. Thickness and diameter were measured using the vanary caliper.

Tablet Hardness:

The tablet should be hard enough to face mechanical stress during the packaging, shipment and handling by the consumer. Standard tablet franchisee test applied to built tablets. However, there are many hand-operated tablets hardness testers that can be useful. Examples of tools are Strong Cobb, Pfizer and Stokes Hardness Tester.

Friability:

Fability is a measure of tablet power. Roche friabilator was used to test the friability using the following procedure. Twenty bullets were weighed properly and placed in a tumbling device that swirls at 25 rpm and drops bullets through a distance of six inches with each revolution. After 4 minutes, pills were weighed and the percentage loss in the weight of the tablet was determined.

% loss = [(Initial wt. of tablets – Final wt. of tablets)/ Initial wt. of tablets] ×100

Tablet disintegration:

Commercially available disintegration and dissolution mechanism is available. Most pharmacists will not have this equipment. However, a simple disintegration mechanism can be made. Start by supporting up to 2 inches of 10 mesh screen below 1000 ml beaker. Fill the beaker with 1000 ml water, add a stirring bandage, and place the beaker on a magnetic stirring plate. Stir in medium speed. Leave pills on the net screen and record the time needed to break the bullets. The timing of a proper dissolution should be between 15 to 30 minutes, although time will depend on the product, stirring speed, etc.

Uniformity of Weight

Twenty bullets were selected at random and the average weight was calculated. Weight variation

was calculated and returned. P. Compared with standards.

Dissolution Studies

To assess their capacity in the desired controlled drug delivery, studies of drug-release doses of control release in in vitro drug release studies were studied in simulated gastric and intestinal fluids. 100% rpm, 37 was 0.5 degrees Celsius and drug release study using the USP dissolution test mechanism I at pH

1.2 buffer (900 ml) (i.e. 0.1 n Hcl) for 2 hours, because the average gastric vaccination time is approximately 2 hours. The dissolution medium was replaced with pH 6.8 phosphate buffer (900 ml) and the experiment continued for 10 hours. At different time intervals, samples of 5 ml were withdrawn and 5 ml of medication was replaced by free dissolution medium. Samples extracted by UV spectrophotometer were analyzed using multi-component mode of analysis.

Results and Discussion

Organoleptic properties:

Organoleptic properties of meloxicam are given below- **Colour**: Pale yellow powder; **Odour**: Odourless; **Taste** : Slightly bitter in taste.

Physical examination of the powdered drug shows the characteristic odour, colour it may be predicted as meloxicam.

Solubility properties:

Qualitative Solubility – The value of qualitative solubility of meloxicam are shown below

Table 2: Qualitative solubility of meloxicam

Solvents	Solubility properties of the drug
DMSO	+++-
Dimethyl formamide	+++-
Chloroform	+++-
Hydrochloric acid (1 N)	++++
Hydrochloric acid (0.1 N)	++++
Acetone	+---
Ethanol	+---
Distilled water	+---

++++ Very Soluble
+++- Soluble
++-- Sparingly soluble
+--- very slightly soluble

Qualitative solubility studies of drug shown in table 7 depicted that the drug lipophilic in nature and it is more soluble in organic solvents as compare to hydrophilic solvents so it can be concluded that drug is lipophilic innature.

Melting point:

Melting point of drug was found to be 253 °C which is nearby to standard value of melting point of meloxicam. So it shows that the drug is pure.

Particle size:

The result of the microscopic evaluation for the measurement of particle size of the drug particles are given below in table 8.

Table 3: Particle size of meloxicam

S. No.	Size Range	Mid Point	No. of Particles	M.P. X N	M.P.x N x L.C.
1.	0-1	0.5	06	03	5.82
2.	1-2	1.5	09	13.5	12.15
3.	2-3	2.5	11	27.5	53.35
4.	3-4	3.5	27	94.5	183.33
5.	4-5	4.5	23	103.5	200.79
6.	5-6	5.5	24	132	256.06
			$\sum n = 100$		$\sum d = 714.5$

Least Count (L.C.) = 1.94

Particle size of meloxicam = $\sum d / \sum n$

= 714.5 / 100

= 7.14 micrometer

Particle size was found to be 7.145 µm. Particle size distribution pattern depicted in fig. 7.4 shows that drug particles are distributed in a range of 1-6 µm and maximum number of particles are present in size range of 4-6 µm. this distribution pattern also indicates that the drug is amorphous in nature

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Particle size distribution of meloxicam-

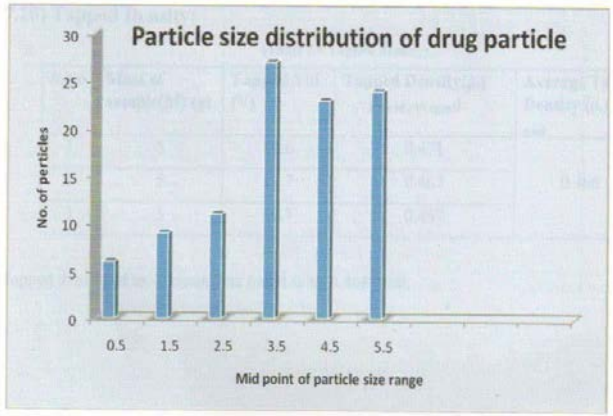


Fig 1: Particle size distribution of Meloxicam

pH: The pH value of meloxicam was found to be 7.5

Partition Coefficient: Partition coefficient was found to be 3.6-4. This shows that the drug is lipophilic.

Preformulation Studies The results were found within the limit.

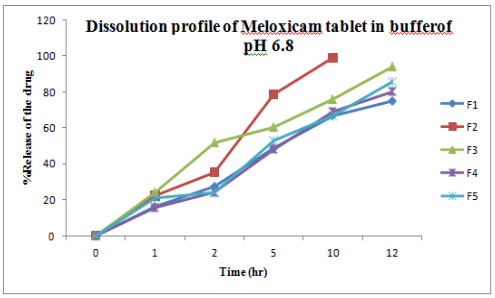
Evaluation of Tablet

Table 4: Physical evaluation of the tablet

Formulation code	Uniformity of weight (mg)	Hardness (Kg/cm^2)	% Friability	Thickness (mm)
F1	74.2 ± 0.8	2.2 ± 0.25	0.42 ± 0.20	4.2 ± 0.14
F2	73.9 ± 0.5	1.9 ± 0.12	0.35 ± 0.06	4.1 ± 0.12
F3	73.7 ± 0.4	2.1 ± 0.15	0.38 ± 0.08	3.9 ± 0.16
F4	75.9 ± 0.7	2.3 ± 0.20	0.42 ± 0.10	4.3 ± 0.10
F5	74.6 ± 0.8	2.2 ± 0.08	0.37 ± 0.11	4.0 ± 0.11

Table 5: *In vitro* drug release of different formulations

Time (hr)	F1	F2	F3	F4	F5
0	0	0	0	0	0
1	16.14	22.213	24.012	15.65	20.92
2	27.32	35.14	51.56	24.23	23.98
5	48.65	78.43	60.21	47.78	52.76
10	66.47	98.78	75.79	68.9	66.55
12	74.77	-	93.66	79.91	85.43



The Characteristics of different formulation were done to determine different parameters. The rated parameters are bulk density, taped density, compression index and angle of the repo, the index of carry is shown.

Bulk density of powder for test batch and customized construction of direct compression was found 0.351 g / cc; The taped density was found at 0.468gm / cc, which indicates that the powder was not heavy. The angle of repaired drug powder 34.91 was found, which indicates good flow of powder. Compensability Index found 25.26%. Quantity of zero was found 3.5 Hosner's ratio was found 1.3, indicating that the powder was washed.

Compressed parameters were tested for the physical parameters such as hardness, thickness, stability, weight weight evaluated for drug content, in-vitro release profile. Average. The weight difference of the tablet was predicted by direct compression that all the tablets displayed low standard deviation of uniform weight within acceptable variation according to the IPA as shown in the table.

For all formulating USP type II tablet dissolution tester for in-vitro disintegration study, the type of employment was performed at 50 rpm using 0.1 N HCl 900 ml and 6.8 phosphate buffer dissolution medium at 50 rpm.

Samples withdrawn using the UV spectrophotometer were analyzed. In direct compression, the F1 shows good response due to the presence of superdisoning.

Conclusion

It can be concluded that the sample given by the Meloxicam was authentic and the result of this study, in accordance with the official monographs and standards given in the literature. Various data ready to prepare spectroscopy and standard curve was reproducible and can be used for further formulation study in formulation studies.

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