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To Study A Formulation, Development And Optimization Of Lornoxicam 8mg Tablets

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Abstract : *Tablet dosage form constitutes a major portion of the drug delivery systems that are currently available. These are usually prepared with the aid of suitable pharmaceutical excipients. They may vary in appearance, size, shape, weight, hardness, thickness, disintegration and dissolution characteristics and in other aspects depending on their intended use and method of manufacturing. Tablets are manufactured primarily by either granulation or direct compression. The latter involves the compression of a dry blend of powders that comprises drugs and various excipients. The simplicity and cost effectiveness of the direct compression have positioned direct compression as an attractive alternative to traditional granulation technologies. Fast disintegrating (DT) dosage form provides an opportunity to manufacturers to extend product life cycle and to expand market. Fast disintegrating tablets have this opportunity over conventional tablets. Lornoxicam is non steroidal anti-inflammatory drug (**NSAID**) and used in treatment of post traumatic pains (PTP), muscular and skeletal pains, joint disorder and rheumatic arthritis (RA). Fast onset of action is required in these indications and to improve bioavailability as well. Lornoxicam fast disintegration tablets were prepared by direct compression method by using Low substitute hydroxypropylcellulose (HPC) as disintegrating agent and optimized sodium bicarbonate and calcium hydrogen phosphate, anhydrous. Independent variables were concentration of excipients used in the formulation while dependent variables were disintegration time and percent drug released. Optimized formulation, T-06, showed drug content (100.527%), disintegration time (40sec), percent drug released (102.179%). Present study demonstrated potential for rapid absorption, improved bioavailability, effective therapy and patient compliance.*

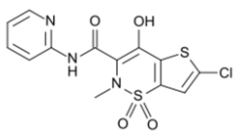
Keywords: ***DT*** *= Disintegration Test,* ***NSAID*** *= Nonsteroidal anti-inflammatory drug, PTP = Post traumatic pains, RA= Rheumatic arthritis, HPC = Hydroxypropylcellulose*

I. Introduction

Lornoxicamis a non-steroidal anti-inflammatory drug (NSAID) of the oxicam class with analgesic (pain relieving), anti-inflammatory and antipyretic (fever reducing) properties. It is available in oral and parenteral formulations. Lornoxicam is used for the treatment of various types of pain, especially resulting from inflammatory diseases of the joints, osteoarthritis, surgery, sciatica, and other inflammations. The drug is contraindicated in patients that must not take other NSAIDs, possible reasons including salicylate sensitivity, gastrointestinal bleeding and bleeding disorders, and severe impairment of heart, liver or kidney function. Lornoxicam is not recommended during pregnancy and breastfeeding and is contraindicated during the last third of pregnancy. Lornoxicam has side effects similar to other NSAIDs, most commonly mild ones like gastrointestinal disorders (nausea and diarrhea) and headache. Severe but seldom side effects include bleeding, bronchospasms and the extremely rare Stevens–Johnson syndrome.

Chemical formula: $C_{13}H_{10}ClN_3O_4S_2$
Molecular weight: 371.8192 g/mol

Chemical structure:



1.1. Mode Of Action :

Like other NSAIDS, lornoxicam's anti-inflammatory and analgesic activity is related to its inhibitory action on prostaglandin and thromboxane synthesis through the inhibition of both COX-1 and COX-2. This leads to the reduction of inflammation, pain, fever, and swelling, which are mediated by prostaglandins. However, the exact mechanism of lornoxicam, like that of the other NSAIDs, has not been fully determined Lornoxicam is absorbed rapidly and almost completely from the GI tract (90-100%).

Lornoxicam is 99% bound to plasma proteins (almost exclusively to serum albumin). Lornoxicam is metabolized completely by cyp 2C9 with the principal metabolite being 5'-hydroxy-lornoxicam and only negligible amounts of intact lornoxicam are excreted unchanged in the urine. Approximately 2/3 of the drug is eliminated via the liver and 1/3 via the kidneys in the active form.

1.2. Tablets Formulation And Development

A tablet is a pharmaceutical dosage form. It comprises a mixture of active substances and excipients, usually in powder form, pressed or compacted from a powder into a solid dose. The excipients can include diluents, binders or granulating agents, glidants (flow aids) and lubricants to ensure efficient tabletting; disintegrants to promote tablet break-up in the digestive tract; sweeteners or flavours to enhance taste; and pigments to make the tablets visually attractive. A polymer coating is often applied to make the tablet smoother and easier to swallow, to control the release rate of the active ingredient, to make it more resistant to the environment (extending its shelf life), or to enhance the tablet's appearance.

The compressed tablet is the most popular dosage form in use today. About two-thirds of all prescriptions are dispensed as solid dosage forms, and half of these are compressed tablets. A tablet can be formulated to deliver an accurate dosage to a specific site; it is usually taken orally, but can be administered sublingually, buccally, rectally or intravaginally. The tablet is just one of the many forms that an oral drug can take such as syrups, elixirs, suspensions, and emulsions. Medicinal tablets were originally made in the shape of a disk of whatever color their components determined, but are now made in many shapes and colors to help distinguish different medicines. Tablets are often stamped with symbols, letters, and numbers, which enable them to be identified. Sizes of tablets to be swallowed range from a few millimeters to about a centimeter.

1.3. Tabletting Formulations

In the tablet-pressing process, it is important that all ingredients be fairly dry, powdered or granular, somewhat uniform in particle size, and freely flowing. Mixed particle sized powders segregate during manufacturing operations due to different densities, which can result in tablets with poor drug or active pharmaceutical ingredient (API) content uniformity but granulation should prevent this. Content uniformity ensures that the same API dose is delivered with each tablet.

Some APIs may be tableted as pure substances, but this is rarely the case; most formulations include excipients. Normally, a pharmacologically inactive ingredient (excipients) termed a *binder* is added to help hold the tablet together and give it strength. A wide variety of binders may be used, some common ones including lactose, dibasic calcium phosphate, sucrose, corn (maize) starch, microcrystalline cellulose, povidone polyvinylpyrrolidone and modified cellulose (for example hydroxypropyl methylcellulose and hydroxyethylcellulose).

Often, an ingredient is also needed to act as a *disintegrant* to aid tablet dispersion once swallowed, releasing the API for absorption. Some disintegrant, such as starch and cellulose, are also excellent disintegrants.

Tablets can be made in virtually any shape, although requirements of patients and tableting machines mean that most are round, oval or capsule shaped. More unusual shapes have been manufactured but patients find these harder to swallow, and they are more vulnerable to chipping or manufacturing problems.

Tablet diameter and shape are determined by the machine tooling used to produce them - a die plus an upper and a lower punch are required. This is called a station of tooling. The thickness is determined by the amount of tablet material and the position of the punches in relation to each other during compression. Once this is done, we can measure the corresponding pressure applied during compression. The shorter the distance between the punches, thickness, the greater the pressure applied during compression and sometimes the harder the tablet.

Tablets need to be hard enough that they don't break up in the bottle, yet friable enough that they disintegrate in the gastric tract.

Tablets need to be strong enough to resist the stresses of packaging, shipping and handling by the pharmacist and patient. The mechanical strength of tablets is assessed using a combination of (i) simple failure and erosion tests, and (ii) more sophisticated engineering tests. The simpler tests are often used for quality control purposes, whereas the more complex tests are used during the design of the formulation and manufacturing process in the research and development phase. Standards for tablet properties are published in the various international pharmacopeias (USP/NF, EP, JP, etc.). The hardness of tablets is the principle measure of mechanical strength. Hardness is tested using a tablet hardness tester. The units for hardness have evolved since the 1930s, but are commonly measured in kilograms per square centimeter. Models of tester include the Monsanto (or Stokes) Hardness Tester from 1930, the Pfizer Hardness Tester from 1950, the Strong Cob Hardness Tester and the Heber lain (or Schleeniger) Hardness Tester.

Lubricants prevent ingredients from clumping together and from sticking to the tablet punches or capsule filling machine. Lubricants also ensure that tablet formation and ejection can occur with low friction between the solid and die wall, as well as between granules, which helps in uniform filling of the die.

Common minerals like talc or silica, and fats, e.g. vegetable stearin, magnesium stearate or stearic acid are the most frequently used lubricants in tablets or hard gelatin capsules.

Drug absorption from a solid dosage form after oral administration depends on the release of the drug substance from the drug product, the dissolution or solubilization of the drug under physiological conditions,

and the permeability across the gastrointestinal tract. Because of the critical nature of the first two of these steps, in vitro dissolution may be relevant to the prediction of in vivo performance.
The protocol of single point is developed for immediate release (IR) dosage forms and is intended to provide

- General recommendations for dissolution testing
- Approaches for setting dissolution specifications related to the biopharmaceutic characteristics of the drug substance
- Statistical methods for comparing dissolution profiles
- Process to help determine when dissolution testing is sufficient to grant a waiver for an in vivo bioequivalence study

1.4. This document also provides recommendations for dissolution tests to help ensure continuous drug product quality and performance after certain post approval manufacturing changes
Lornoxicam 8mg rapid disintegrating tablet, manufactured through direct compression process, comprises of Lornoxicam sodium equivalent to lornoxicam as an active ingredient while Avicel PH-102 (Microcrystalline Cellulose), sodium bicarbonate ($NaHCO_3$), Calcium hydrogen phosphate anhydrous, low substitute hydroxypropylcellulose, Hydroxypropylcellulose, Magnesium Stearate as its inactive ingredients / excipients. For its development six different formulations were proposed containing the same set of coating materials Opadry blue color, Dichloromethane, Isopropyl alcohol and Talcum powder .

II. Materials & Methods

2.1 Materials used as Excipients (Core tablets):

- Avicel PH – 102 (Microcrystalline Cellulose)
- Sodium bicarbonate ($NaHCO_3$)
- Calcium hydrogen phosphate anhydrous
- Low substitute hydroxypropylcellulose (HPC-L)
- Hydroxypropylcellulose (HPC)
- Lactose monohydrate
- Magnesium Stearate.

2.2 Materials used as Excipients (For coating of tablets):

- Opadry blue color
- Dichloromethane
- Isopropyl Alcohol
- Talcum Powder

Avicel 102

- Avicel 102 is the most common filler to use pharmaceutical oral dosage preparation because of inert in nature as microcrystalline cellulose and commonly available in all over the world.

Sodium bicarbonate ($NaHCO_3$)

- Sodium bicarbonate is common excipients which is being used for wetting of tablets that help to disintegrate the tablets quickly to reduce the disintegration time also worked as filler and very cheap in price

Calcium hydrogen phosphate anhydrous:

- Calcium hydrogen phosphate anhydrous is usually used for diluents of tablets and also supported the better and quick disintegration of the tablets.

Low substitute hydroxypropylcellulose:

- Low substitute hydroxypropylcellulose (L-HPC) is widely used as good disintegrator in tablets formulation of direct compression.

Hydroxypropylcellulose:

- Hydroxypropylcellulose is efficient binder used in the direct compression process

Magnesium stearate:

- It is also a pharmaceutical excipients and widely use for lubricant that is enhancing the product powder flow during tablets compression process on the compression machine.

Opadry blue:

- Opadry blue is used from many years for coloring and shining effect of the tablets for coating of tablets also gives the protection of light.

Talc*:*

- Talc powder used as glidant and lubricant and help to granules or tablets in proper flow and usually not count in the final weight of tablets because of dusty in nature if use during coating process.

Isopropyl alcohol:

- Isopropyl alcohol is good solubilizer and disinfectant. Widely used for the pharmaceutical industry as excipients due to miscible with water and safe in coating.

Dichloromethane:

- Dichloromethane is also pharmaceutical excipients that has been used for the coating solution and where we want to avoid water to the tablets.

2.3 Instrument:

- Analytical balance for accurate and precise weighing of standard, API, Excipients, materials, chemicals. HPLC for performing the assay of Lornoxicam tablets. Dissolution apparatus for performing the dissolution test in vitro studies. Type A glass wares volumetric flasks and pipettes for testing of Quantitative analysis of lornoxicam tablets. Ultrasonic bath for dissolving the standard and degassing of solution during analysis. pH meter for performing the pH during analysis. Magnetic stirrer for preparation of standard and sample solution of assay preparation.

2.4 Chemical And Reagents:

- Working Standard of Lornoxicam
- Methanol (HPLC grade)
- Purified water.
- Orthophosphoric acid
- Di ammonium hydrogen phosphate

2.5 Reagents Preparation:

Assay Of Lornoxicam 8mg Tablets:

Preparation Of Buffer For Mobile Phase:

Take 800ml of purified water in a beaker and add 3.3 gram Di ammonium hydrogen phosphate adjust pH to 7.2 ± 0.01 with dilute Orthophosphoric acid. Makeup the volume with purified water up to 1000ml and mix well.

Preparation Of Mobile Phase:

Prepare a mixture of buffer solution and Methanol (300:700). Filter through 0.2µm membrane filter and degas before use. **Diluent:** Mobile phase

Preparation of Standard Solution:

Weigh accurately about 25mg of Lornoxicam working standard into a 100ml volumetric flask. Add 20ml diluent to dissolve, shaking and sonicating if necessary to assure dissolution. Make up the volume with diluent and mix thoroughly. Pipette out 4ml of solution from prepared above into 25ml volumetric flask and dilute to volume with mobile phase up to the mark, mix and filter through a filter having a porosity of 0.45µm. This is the standard solution having conc. of 0.04mg/ml.

Preparation of Sample Solution;

Take 10 tablets and determine the average weight of the tablet than crush and fine them. Transfer a quantity of the powder 155.0mg into 200ml volumetric flask. Add 80ml diluent and sonicate for 5 minutes and shake for 30 minutes, allow it to cool at room temperature. Make up the volume with diluent, mix thoroughly. Filter through 0.45µm membrane filter in an HPLC vial. This is the sample solution having concentration of 0.04mg/ml. Prepare at least 02 samples in the same manner.

(i) Chromatographic Condition

Mobile Phase : Buffer: Methanol (300: 700)

Flow rate	:	1.0ml / minutes.
Wavelength	:	290nm
Column	:	4.6 x 250mm C18, 5µ or equivalent
Temperature	:	40 °C
Injection volume	:	20µl
Retention Time	:	3 – 5 min

System Suitability:

% RSD of six replicates of standard	: Not more than 2.0
Tailing Factor	: Not more than 2.0

Preparation Of Dissolution Medium

Preparation of dissolution Medium

Take 500ml of purified water in a beaker and add 40.8 gram Potassium dihydrogen phosphate and 10gm NaOH adjust pH to 7.5 ± 0.01 (If required) with dilute Orthophosphoric acid or NaOH. Makeup the volume with purified water up to 6 liter and mix well.

Preparation of standard solution (Dissolution):

Weigh accurately about 25mg of Lornoxicam working standard into a 100ml volumetric flask. Add 40ml diluent to dissolve, shaking and sonicating if necessary to assure dissolution. Make up the volume with purified water and mix thoroughly. Pipette out 2ml of solution from prepared above into 50ml volumetric flask and dilute to volume with purified water up to the mark and mix thoroughly. This is the standard solution having concentration of 0.01mg/ml. Use dissolution medium as blank.

Preparation of sample solution:

Transfer 1 tablet in dissolution vessel and proceed as dissolution procedure. At the end of each time interval, withdraw 8ml of these fluids from each vessel and filter.

2.6 Dissolution Parameters

Method	:	USP II paddle Method.
Rotation Speed	:	50 rpm.
Dissolution Medium	:	Phosphate Buffer pH 7.5
Reference standard	:	Lornoxicam
Temperature	:	37 ± 0.5ºC.
Sampling intervals	:	30 minutes
No. of tablets	:	6 tablets of each test

2.7 Procedure:

- Take 900ml of medium in each vessel of the apparatus.
- When the temperature achieved, place one tablet in each vessel of the dissolution apparatus.
- Cover the vessels and operate for 30 minutes at 50rpm.
- At the end of time period withdraw about 8ml of these fluids from each vessel and filter through a filter paper. This is sample solution having concentration of 0.009mg/ml.

2.8 Acceptance Criteria:

a) Assay value should be between 95% and 105%
b) Disintegration Time should be less than 3 minutes
c) Invitro Dissolution should be more than 85% within 30 minutes

III. Indentations And Equations

Formula For Assay:

$$\%Lornoxicam = \frac{Ares\ of samples}{Area\ of\ Standard} x \frac{Weight\ of\ standard}{100} x \frac{4}{25} x \frac{200}{Weight\ of\ sample} x \frac{Average\ weight}{8} x\ Potency$$

Where as:

Ar. sp. = Area of sample.

Ar.std. = Area of standard.
Wt. Std. = Weight of Standard.
Wt.sp = Weight of sample.
Av.wt = Average weight of the tablets.
Potency = Potency of working standard Lornoxicam
Factor = 0.04 (Dilution Factor).

Formula For Dissolution

$$\% \, Dissolved \, Lornoxicam = \frac{Absorption \, of \, sample}{Absorption \, of \, Standard} \, x \, \frac{Weight \, of \, standard}{100} \, x \frac{4}{25} \, x \frac{2}{50} \, x \, \frac{900}{8} \, x \, Potency$$

Where:
Abs. sp. = Absorbance of sample.
Abs. std. = Absorbance of standard.
Wt. std . = Weight of standard.
Potency = Potency of working standard Lornoxicam
Factor = 0.045 (Dilution Factor)

IV. Figures And Tables

Summary Of Ingredients

TABLE 1

Ingredient (Core tablets, mg/tab)	**T-01**	**T-02**	**T-03**	**T-04**	**T-05**	**T-06**
Lornoxicam	8	8	8	8	8	8
Microcrystalline cellulose (Avicel 102)	113.5	113.5	113.5	86.5	86.5	86.5
Lactose monohydrate	22.5	22.5	22.5	22.5	22.5	22.5
Croscarmellose sodium	1.5	2.5	3	0	0	0
Povidone K-30	3	2	1.5	0	0	0
Sodium hydrogen carbonate ($NaHCO_3$)	0	0	0	27	27	27
Low substitute hydroxypropylcellulose	0	0	0	1.5	2.5	3
Hydroxypropylcellulose	0	0	0	3	2	1.5
Magnesium stearate	1.5	1.5	1.5	1.5	1.5	1.5
Total	**150**	**150**	**150**	**150**	**150**	**150**
Ingredient (Film Coating Material, mg/tab)	**T-01**	**T-02**	**T-03**	**T-04**	**T-05**	**T-06**
Opadry Blue	5	5	5	5	5	5
Talc	1.8	1.8	1.8	1.8	1.8	1.8
Dichloromethane	0.20	0.20	0.20	0.20	0.20	0.20
Isopropyl alcohol	12	12	12	12	12	12
Total	**19**	**19**	**19**	**19**	**19**	**19**

Summary Of Results T-01

TABLE 2

Friability (%) @ 100 Rev	**D.T Core tab**	**D.T Coated tab**
0.08	112 sec	122 sec

TABLE 3

S. No.	**Thickness (mm)**	**Hardness (Kp)**	**Weight variation**
1	2.87	7.8	151
2	2.86	7.1	156
3	2.85	8.2	154
4	2.87	9.5	159
5	2.90	7.8	157
6	2.91	8.9	158
7	2.88	7.9	158
8	2.92	7.1	156
9	2.89	7.9	157
10	2.85	7.9	156
Min	2.85	7.1	151
Max	2.92	9.5	159
Mean	2.880	8.0	156.20
SD	0.024	0.732	2.30
RSD	0.851	9.145	1.47

Assay Calculation:
(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 4

Assay	
Weight of standard	26.4
Weight of sample	148.00
Area of standard	1,676.45503
Area of sample	1,471.98877
Average weight	156.20
Factor	3.9676
Results	97.07

Dissolution Calculation:
(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 5

Dissolution		
Sample	**Abs spl**	**%Dissolution**
1	0.256	70.15
2	0.258	70.70
3	0.249	68.24
4	0.273	74.81
5	0.252	69.06
6	0.279	76.46
Min		68.24
Max		76.46
Mean		71.57
SD		3.30
%RSD		4.62

Summary Of Results

T-02 TABLE 6

Friability (%) @ 100 Rev	**D.T Core tab**	**D.T Coated tab**
0.07	98 sec	109 sec

S. No.	**Thickness (mm)**	**Hardness (Kp)**	**Weight variation (mg)**
1	2.84	9.3	156
2	2.90	8.9	156
3	2.86	7.4	157
4	2.88	8.6	153
5	2.87	8.4	156
6	2.88	7.2	156
7	2.85	7.5	154
8	2.88	8.1	152
9	2.88	7.7	155
10	2.86	8.4	154
Min	2.84	7.2	152
Max	2.90	9.3	157
Mean	2.870	8.2	154.90
SD	0.018	0.692	1.60
RSD	0.615	8.486	1.03

Assay Calculation:
(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 7

Assay	
Weight of standard	26.40
Weight of sample	148.20
Area of standrad	1,676.45503
Area of sample	1,575.28418
Average weight	154.90
Factor	3.9676
Results	102.87

Dissolution Calculation:
(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 8

Dissolution		
Sample	**Abs spl**	**%Dissolution**
1	0.287	78.65
2	0.300	82.21
3	0.319	87.42
4	0.296	81.12
5	0.290	79.47
6	0.304	83.31
Min		78.65
Max		87.42
Mean		82.03
SD		3.15
%RSD		3.84

Summary Of Results T-03

TABLE 9

Friability (%) @ 100 Rev	**D.T Core tab**	**D.T Coated tab**
0.06	87 sec	98 sec

TABLE 10

S. No.	**Thickness (mm)**	**Hardness (Kp)**	**Weight variation (mg)**
1	3.09	5.7	151.00
2	2.89	8.4	156.00
3	2.85	6.9	156.00
4	2.87	8.3	154.00
5	2.87	7.7	154.0
6	2.88	9.4	153.00
7	2.85	7.3	155.00
8	2.91	7.9	154.00
9	2.87	9.3	155.00
10	2.89	8.3	153.00
Min	2.85	5.7	151
Max	3.09	9.4	156
Mean	2.897	7.9	154.10
SD	0.070	1.106	1.52
RSD	2.425	13.969	0.99

Assay Calculation:
(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 11

Assay	
Weight of standard	26.40
Weight of sample	150.20
Area of standard	1,676.45503
Area of sample	1,572.87537
Average weight	154.10
Factor	3.9676
Results	100.82

Dissolution Calculation:
(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 12

Dissolution		
Sample	**Abs spl**	**%Dissolution**
1	0.260	71.25
2	0.263	72.07
3	0.252	69.06
4	0.300	82.21
5	0.265	72.62
6	0.261	71.52
Min		69.06
Max		82.21

Mean	73.12
SD	4.62
%RSD	6.31

Summary Of Results T-04

TABLE 13

Friability (%) @ 100 Rev	D.T Core tab	D.T Coated tab
0.06	76 sec	80 sec

TABLE 14

S. No.	Thickness (mm)	Hardness (Kp)	Weight variation (mg)
1	2.89	8.1	155
2	2.87	8.5	157
3	2.86	7.5	155
4	2.88	7.3	155
5	2.88	7.0	156
6	2.89	7.7	157
7	2.90	8.8	158
8	2.86	7.7	159
9	2.90	8.0	157
10	2.90	9.7	159
Min	2.86	7.0	155
Max	2.90	9.7	159
Mean	2.883	8.0	156.80
SD	0.016	0.796	1.55
RSD	0.544	9.911	0.99

Assay Calculation:

(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 15

Assay	
Weight of standard	26.40
Weight of sample	131.80
Area of standard	1,676.45503
Area of sample	1,280.24011
Average weight	156.80
Factor	3.9676
Results	95.16

Dissolution Calculation:

(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 16

Dissolution		
Sample	Abs spl	%Dissolution
1	0.261	71.52
2	0.263	72.07
3	0.252	69.06
4	0.307	84.13
5	0.265	72.62
6	0.261	71.52
Min		69.06
Max		84.13
Mean		73.49
SD		5.35
%RSD		7.29

Summary Of Results T-05

TABLE 17

Friability (%) @ 100 Rev	D.T Core tab	D.T Coated tab
0.12	55 sec	62 sec

TABLE 18

S. No.	Thickness (mm)	Hardness (Kp)	Weight variation (mg)
1	2.89	8.6	156
2	2.89	7.8	157

3	2.90	9.4	157
4	2.90	8.5	157
5	2.91	8.0	160
6	2.89	8.0	158
7	2.88	7.4	157
8	2.89	9.5	157
9	2.91	7.9	157
10	2.90	9.0	159
Min	2.88	7.4	156
Max	2.91	9.5	160
Mean	2.896	8.4	157.50
SD	0.010	0.711	1.18
RSD	0.334	8.454	0.75

Assay Calculation:
(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 19

Assay	
Weight of standard	26.40
Weight of sample	152.20
Area of standard	1,676.45503
Area of sample	1,561.33899
Average weight	157.50
Factor	3.9676
Results	100.95

Dissolution Calculation:
(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 20

Dissolution		
Sample	Abs spl	%Dissolution
1	0.331	90.71
2	0.299	81.94
3	0.358	98.11
4	0.349	95.64
5	0.351	96.19
6	0.309	84.68
Min		81.94
Max		98.11
Mean		91.21
SD		6.65
%RSD		7.29

Summary Of Results T-06

TABLE 21

Friability (%) @ 100 Rev	**D.T Core tab**	**D.T Coated tab**
0.77	30 sec	38 sec

TABLE 22

S. No.	**Thickness (mm)**	**Hardness (Kp)**	**Weight variation (mg)**
1	2.87	8.1	155
2	2.88	7.9	160
3	2.88	8.5	157
4	2.87	7.9	154
5	2.88	8.1	156
6	2.87	7.5	156
7	2.85	6.9	156
8	2.87	9.1	155
9	2.87	7.7	155
10	2.86	7.0	158
Min	2.85	6.9	154
Max	2.88	9.1	160
Mean	2.870	7.9	156.20

SD	0.009	0.657	1.75
RSD	0.329	8.344	1.12

Assay Calculation:

(Ar.spl x wt. std x 4 x 200 x Av. Wt x Pot. Std) / (Ar. Std x 100 x 25 x wt. spl x 8)

TABLE 23

Assay	
Weight of standard	26.40
Weight of sample	152.20
Area of standard	1,676.45503
Area of sample	1,567.66772
Average weight	156.20
Factor	3.9676
Results	100.52

Dissolution Calculation:

(Abs.spl x wt. std x 2 x 900 x Pot. Std) / (Abs. Std x 100 x 50 x 8)

TABLE 24

Dissolution		
Sample	**Abs spl**	**%Dissolution**
1	0.377	103.31
2	0.395	108.25
3	0.328	89.89
4	0.383	104.96
5	0.363	99.48
6	0.391	107.15
Min		89.89
Max		108.25
Mean		102.17
SD		6.77
%RSD		6.62

V. Conclusion

There are few tests which are critical as far as tablets quality is concern disintegration time (sec), assay (%) and in-vitro dissolution (%) however the most critical parameter is in-vitro dissolution which is directly depends on the bio availability. Therefore the formulation of the T-06 is considered the best among all the formulation

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