INTERNATIONAL RESEARCH JOURNAL OF PHARMACY
www.irjponline.com ISSN 2230 – 8407
Research Article

# FORMULATION AND EVALUATION OF ISONIAZID AND ETHAMBUTOL HYDROCHLORIDE COMBINATION TABLETS

Margret Chandira R*, Jayakar B, Palanisamy P.
Vinayaka Mission's College of Pharmacy, Vinayaka Missions University, Salem, Tamil Nadu, India

Article Received on: 12/12/11 Revised on: 25/01/12 Approved for publication: 14/02/12

*Email: palanisamy2907@gmail.com

**ABSTRACT**
Ethambutol hydrochloride and Isoniazid Drugs are used as Antituberculosis agents. It is mainly used in the initial Treatment of pulmonary tuberculosis. Here in present study compressed tablet of Ethambutol hydrochloride and Isoniazid prepared by using HPMC, HPC, and PVPK -30 as binders. Compressed tablets of Ethambutol hydrochloride and Isoniazid were prepared by wet granulation method. Among different trials of F1 to F9 with wet granulation, the trial F1 showed satisfactory in-vitro drug release profile as compared to that of innovator for formulation. The cumulative percentage of drug release of formulation F1 (Isoniazid) And F1 (Ethambutol) were 99.53 and 99.43 respectively. The result of stability studies of batch F1 indicate that it is stable at 40°C ± 2°C / 75% RH ± 5 % relative humidity as there was no significant differences observe for dissolution and assay after two months.
**Keywords:** Antituberculosis agents, Effect of Binders, % Drug release.

## INTRODUCTION

### Ideal properties of tablets

The objectives of the design and manufacture of the compressed tablet is to deliver orally the correct amount of drug in the proper form, at or over the proper time and in the desired location. Beside the physical and chemical properties of medicinal agents formulated as a tablet, it should posses following characteristics.

- Should be an elegant product having its own identity, while being free of defects such as chips, cracks, discoloration, contamination and the like
- Should have the strength to withstand rigors of mechanical shocks encountered in its production, packaging, shipping and dispensing
- Should have the chemical and physical stability to maintain its physical/chemical attributes over time
- It must be able to release the medicinal agents in the body in a predictable and reproducible manner
- Must have suitable chemical stability over a time so as not to allow alteration of the medicinal agents.

### Aim and objective

The aim of the present study was to Formulate and Evaluate of Isoniazid and Ethambutol hydrochloride tablets.

- To provide a therapeutic amount of drug to the proper site in the body promptly achieve and maintain the defined drug concentration.
- To provide rapid disintegration, systemic effect.
- To produce faster onset of action.
- Rapid drug release.
- To achieve better patient compliance.
- This system minimizes or eliminates side effects, provides patient compliance, economically and promptly achieves and maintains desired effect.
- It can be achieved by planning for trails until the desired release pattern obtained.
- Stability studies as per ICH guidelines for the drug substances and drug product.

## MATERIALS AND METHODS

Ethambutol was procured by Lupin Tarapure (Aurangabad, India); Isoniazide was procured by Sharon Biomedicine (Aurangabad, India); Talc, Magnesium stearate was gifted by S.D. Chemical (India); HPC was gifted by Shineltsu LTD (India); Maize starch was gifted by Vats International (India); PVP K30 was gifted by Madichem enterprise Co-LTD (India); Hydrogen prophycilluose, gelatin was gifted by Dow Chemicals (India).

**Formulation of Isoniazid and Ethambutol Tablets** (Table 1, 2 & 3)

**Table 1: Formulation of Isoniazid and Ethambutol Tablets (Innovator)**

| Sn | Ingredients | Unit formula (mg) |
|---|---|---|
| 1. | Ethmbutol | 800.00 |
| 2. | Isoniazid | 300.00 |
| 3. | Dibasic calcium Phosphate | 90.50 |
| 4. | Maize starch | 36.157 |
| 5. | Maize starch (paste) | 2.22 |
| 6. | Lake of sunset yellow | 0.80 |
| 7. | Gelatin | 20.00 |
| 8. | Magnesium stearate | 13.33 |
| 9. | Talc | 10.00 |
| 10 | Maize Starch | 12.00 |
| 11. | **Total weight of Tablet** | **1285** |

### Evaluation of tablet

All the tablets were evaluated for following official and unofficial parameter

1) Weight variation
2) Thickness
3) Hardness
4) Friability Test
5) Disintegration Test
6) Assay
7) Dissolution study

### Weight variation

20 tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation test if not more than two of the individual tablets weight derivative from the average weight by more than the percentage shown. (Table 4)

### Thickness

Five tablets were selected at random from individual formulations and thickness was measured by using vernier

caliper scale, which permits accurate measurement. Thickness should be controlled within a ± 0.5% variation of standard value.
The results are shown in Table 7.

**Hardness**

Five Tablets was selected at random from individual formulations and hardness was measured using Scheluniger hardness tester. The results are shown in Table 7.

**Friability Test**

Tablet select 20 tablets from pooled sample, weight The tablets on calibrated balance and note down weight of 20 tablets (w1).add these tablets to the friability test apparatus, operate apparatus for 100 rotations, upon completion examine the tablets for the physical changes and remove the half broken tablets from the sample and weight on the calibrated balance .(w2)calculate the friability in % as follow:

$$\% \text{ friability} = (w1-w2) \times 100 / w1$$

The results are shown in Table 7.

**Disintegration Test**

Disintegration time for Tablets was determined using 6 tablets. Place one tablet in each six tubes of the basket, add disc to each tube and operate the apparatus using water at $37^0 \pm 2^0$C as the immersion fluid at the end of 15 mins, lifts the basket from the fluid and observe the tablets. all the tablets should disintegrates. Record the disintegration time in mins and seconds. Disintegration time for the Tablets should not be more than 15 min.
The results are shown in Table 7.

**ASSAY**

**Assay of isoniazid**

**Chromatographic conditions**

Column: 15cm x 4.6 cm**,** packed with octadecyisilyl silica gel
Column temperature: 30 c
Wavelength: 254 nm
Flow rate: 1 ml /min
Injection volume: 20 µl

**Buffer solution PH 6.8**

Dissolve 1.4 g of disodium hydrogen orthophosphate anhydrous in 1000 ml of water; adjust pH 6.8 with dilute phosphoric acid.

**Mobile phase**

Mix 960 ml of buffer solution with 40 ml of acetonitrile Filter through 0.45µ filter and degas.

**Test solution**

Weight and powder 20 tablets.171.0 mg powdered tablets containing about 40 mg of isoniazid, dissolve in 50.0 ml of methanol and dilute to 500 ml diluents.

**Diluents**

Dissolve 1.4 g of disodium hydrogen orthophosphate anhydrous in 1000 ml of water; adjust pH 6.8 with dilute phosphoric acid and sufficient water to produce 1000ml.

**Reference solution**

Weight accurately about 40 mg of isoniazid WS, dissolve in 50.0 ml of methanol and dilute to 500.0 ml with the diluents.

**Procedure**

Inject the reference solution in five replicate into the chromatograph and measure responses for the major peaks. If system suitability passes then inject test solution .Record the responses for the major peaks and calculate the content of tablet.

**System suitability**

| | |
|---|---|
| Tailing factor | : NMT2.0 |
| Theoretical plates | : NLT1500 |
| R.S.D | : NMT 2.0% |

**Calculation**

Calculate the isonizid content in tablets as % as follows

$$\frac{AT \times WS \times 500 \times P \times W \times 100}{AS \times 500 \times WT \times 100 \times 300}$$

The results are shown in Table 7.

**Assay of Ethambutol Hydrochloride**

**Chromatographic conditions**

Column: 15cm x 4.6 cm**,** packed with nitrile groups chemically bounded to porous silica particles.
Wavelength: 200nm
Flow rate: 1.0 ml /min
Injection volume: 50 ul

**Buffer solution PH 7.0**

1000 ml of water add 1.0 ml triethylamine, mix thoroughly .adjust pH to 7.0 with phosphoric acid.

**Mobile phase**

Prepare a mixture of above buffer 7.0 Acetonirile (50:50) filter and degas.

**Test solution**

Weight and powder 20 tablets. Weight accurately 96.0 mg powdered tablets into 100 ml volumetric flask. Add about70 ml of diluents, dissolve and dilute to 100 ml with diluents shake well.

**Diluents**

Dissolve 1.4 g of disodium hydrogen orthophosphate anhydrous in 1000 ml of water; adjust pH 6.8 with dilute phosphoric acid and sufficient water to produce 1000ml.

**Reference solution**

Weight accurately about 60 mg of isoniazid WS into 100 ml volumetric flask. Dissolve in 70 ml of diluent and dilute to 100 ml with diluents and mix.

**Procedure**

Inject 50 µl the reference solution in five replicate into the chromatograph and measure responces for the major peaks. If system suitability passes then inject test solution .Record the responces for the major peaks and calculate the content of tablet.

**System suitability**

| | |
|---|---|
| Tailing factor | : NMT3.0 |
| Theoretical plates | : NLT1500 |
| R.S.D | : NMT 2.0% |

**Calculation**

Calculate the Ethambutol Hydrochloride content in tablets as % as follows:

$$\frac{AT \times WS \times 100 \times P \times W \times 100}{AS \times 100 \times WT \times 100 \times 800}$$

**Where,**

AT = Mean area of test preparation
AS = Mean area of standard preparation
WS= wt. of standard in mg
WT= wt. of sample in mg
P = Potency of standard
W = Avg. weight of tablets
The results are shown in Table 7.

**DISSOLUTION STUDY**

**USP Dissolution apparatus: Type II (Paddle)**

Media: Water
Volume of dissolution medium: 900ml
Speed of paddle rotation: 100RPM
Temperature: $37^0 \pm 0.5^0$C
Sampling point: 5, 10, 15, 20, 30, 45 min.

**PART A**

**Test solution**

In clean bowls place 900 ml of deairted water .Allow into attain temperature $37^0 \pm 0.5^0$C .place one tablet of in each bowl and start the instrument. At the end of specific interval time withdraw 10 ml of sample solution from a zone midway between the surface of medium, top surface of the rotating paddle and not less than 1 cm from bowl wall. Filter through Whatmann filter paper, discarding first few ml of filtrate, in separate marked test tubes .dilute 10 ml of filtrate to 20 ml with water.

**Reference solution**

Weight accurately 44 mg of Ethmbutol HCL WS into 100ml volumetric flask, dissolve in 70 ml of dissolution medium and diluted to 100 ml with the same solvents and mix.

**Procedure**

Inject the reference solution in five replicate into the chromatograph and measure responses for the major peaks. If system suitability passes then inject test solution .Record the responces for the major peaks and calculate the content of tablet.

**Calculation**

$$\% = \frac{AT \times WS \times 900 \times 20 \times P \times 100}{AS \times 100 \times 1 \times 10X \times 100 \times 800}$$

The results are shown in Table 8

**PART B**

**Test preparation**

Dilute 2 ml of the filtrate obtained in part A to 50 ml.

**Procedure**

In vitro dissolution study was carried out using USP II apparatus Paddle assembly in 900ml water for 45 mins. Temp of the dissolution medium was kept at $37 \pm 0.5^0$C and paddle was set at 100 rpm. Determine the amount of isoniazid dissolve from ultraviolet absorbance at the wavelength at 263 nm of the test solution. The concentration was determined from the standard curve of isoniazid .Cumulative percentage of drugs release was calculated using the equation obtained from a standard curve.

**The results are shown in** Table 9.

**RESULT AND DISCUSSION**

**Evaluation of powder**

**Pre-formulation studies**

Preformulation study was done initially and results directed for the further cource of formulation. Based on preformulation studies different batches of Isoniazid and Ethambutol HCL were prepared using selected excipients.

Powder were evaluated for tests Angle of repose, bulk density, tapped density, compressibility index,Hausner ratio before punched of tablet.

**In Vitro Dissolution studies**

Table shows the data for in Cumulative % release of Ethambutol HCL from tablet batches F1, F2, F3, F4, F5, F6, F7, F8, F9 respectively. (Table 8)

**In Vitro Dissolution studies**

Table shows the data for in Cumulative % release of isoniazid from tablet batches F1, F2, F3, F4, F5, F6, F7, F8, F9 respectively.

**Table 2: Formulation of Isoniazid and Ethambutol Tablets (Batch F1 to F5)**

| SN | Ingredient | F1 (mg) | F2( mg) | F3 (mg) | F4 (mg) | F5 (mg) |
|---|---|---|---|---|---|---|
| 1. | Ethmbutol | 800.00 | 800.00 | 800.00 | 800.00 | 800.00 |
| 2. | Isoniazid | 300.00 | 300.00 | 300.00 | 300.00 | 300.00 |
| 3. | **Maize starch** | **92.80** | **106.65** | **119.5** | **92.80** | **106.65** |
| 4. | **Pvpk-30** | **52.40** | **38.55** | **25.7** | - | - |
| 5. | **HPMC** | **-** | **-** | - | **52.40** | **38.55** |
| 6. | **HPC** | **-** | **-** | **-** | **-** | **-** |
| 7. | Lake of sunset yellow | 0.80 | 0.80 | 0.80 | 0.80 | 0.80 |
| 8. | Magnesium stearate | 13.00 | 13.00 | 13.00 | 13.00 | 13.00 |
| 9. | Talc | 10.00 | 10.00 | 10.00 | 10.00 | 10.00 |
| 10. | Colloidal silicon dioxide | 8.00 | 8.00 | 8.00 | 8.00 | 8.00 |
| 11. | Maize Starch | 8.00 | 8.00 | 8.00 | 8.00 | 8.00 |
| 12. | **Total weight of Tablet** | **1285** | **1285** | **1285** | **1285** | **1285** |

**Table 3: Formulation** of **Isoniazid and Ethambutol Tablets (**Batch F6 toF9)

| SN | Ingredient | F6 (mg) | F7 (mg) | F8(mg) | F9(mg) |
|---|---|---|---|---|---|
| 1. | Ethmbutol | 800.00 | 800.00 | 800.00 | 800.00 |
| 2. | Isoniazid | 300.00 | 300.00 | 300.00 | 300.00 |
| 3. | **Maize starch** | **119.5** | **92.80** | **106.65** | **119.5** |
| 4. | **Pvpk-30** | - | - | - | - |
| 5. | **HPMC** | **25.7** | - | - | - |
| 6. | **HPC** | **-** | **52.40** | **38.55** | **25.7** |
| 7. | Lake of sunset yellow | 0.80 | 0.80 | 0.80 | 0.80 |
| 8. | Magnesium stearate | 13.00 | 13.00 | 13.00 | 13.00 |
| 9. | Talc | 10.00 | 10.00 | 10.00 | 10.00 |
| 10. | Colloidal silicon dioxide | 8.00 | 8.00 | 8.00 | 8.00 |
| 11. | Maize Starch | 8.00 | 8.00 | 8.00 | 8.00 |
| 12. | **Total weight of Tablet** | **1285** | **1285** | **1285** | **1285** |

**Table 4: Percentage deviation allowed under weight variation**

| Percentage deviation allowed under weight variation test | |
|---|---|
| **Average weight of tablets (X mg)** | **Percentage deviation** |
| X< 80mg | 10 |
| 80 < x < 250 mg | 7.5 |
| x> 250 mg | 5 |

**Table 5: Preformulation study of pure drug and binders**

| Parameter | Isoniazid | Ethambutol HCl | Gelatin | HPMC | PVPK 30 | HPC |
|---|---|---|---|---|---|---|
| Angle of repose | 24 | 22 | 19 | 39 | 26 | 32 |
| Bulk density **(g/ml)** | 0.46 | 0.31 | 0.34 | 0.60 | 0.29 | 0.45 |
| Tapped density **(g/ml)** | 0.55 | 0.41 | 0.40 | 0.77 | 0.39 | 0.52 |
| Compressi-bility Index(%) | 16.36 | 23.80 | 15.00 | 22.07 | 25.64 | 13.46 |
| Hauners ratio | 1.19 | 1.31 | 1.17 | 1.28 | 1.34 | 1.15 |

**Table 6: preformulation studies of blend**

| Batch No. | Angle of Repose | Bulk Density(g/ml) | Tapped Density(g/ml) | Carr's Index(%) | Hausner Ratio |
|---|---|---|---|---|---|
| **INNOVATOR** | 28.56 | 0.624 | 0.671 | 1.07 | 9.69 |
| **F1** | 22.84 | 0.607 | 0..667 | 1.098 | 8.99 |
| **F2** | 29.65 | 0.605 | 0.682 | 1.127 | 11.29 |
| **F3** | 28.46 | 0.611 | 0.679 | 1.111 | 10.01 |
| **F4** | 27.38 | 0.593 | 0.692 | 1.1167 | 14.30 |
| **F5** | 28.62 | 0.564 | 0.642 | 1.138 | 12.14 |
| **F6** | 26.51 | 0.56 | 0.658 | 1.160 | 13.82 |
| **F7** | 25.21 | 0.572 | 0.654 | 1.143 | 12.53 |
| **F8** | 27.45 | 0.584 | 0.672 | 1.150 | 13.09 |
| **F9** | 26.65 | 0.575 | 0.682 | 1.186 | 15.68 |

**Table 7: Physico-chemical Evaluation of tablets**

| Batch No. | Weight variation | Thickness (mm) | Hardness (n) | Friability (%) | Disintegration time | Assay | |
|---|---|---|---|---|---|---|---|
| | | | | | | ETB HCL | INH |
| **INNOVATOR** | 1288±3 | 6.7±0.2 | 160±9 | 0.2 | 9min17sec | 99.14 | 100.03 |
| **F1** | 1290.5±2 | 7.0±0.2 | 150±5 | 0.04 | 9min15sec | 99.16 | 100.47 |
| **F2** | 1288.7±3 | 7.0±0.3 | 130± 8 | 0.05 | 8min05sec | 98 | 99.91 |
| **F3** | 1285.2±5 | 7.0±0.3 | 100± 10 | 0.03 | 7min37sec | 98.58 | 98.04 |
| **F4** | 1285±3 | 7.0-7.10 | 150± 10 | 0.028 | 9min07sec | 99.20 | 100.16 |
| **F5** | 1284±5 | 6.9±0.3 | 130± 9 | 0.028 | 8min10sec | 98.97 | 100 |
| **F6** | 1285±3 | 6.9±0.2 | 120± 8 | 0.01 | 7min06sec | 98.95 | 99.68 |
| **F7** | 1285±3 | 6.7±0.2 | 160± 9 | 0.02 | 9min20sec | 99.08 | 100.1 |
| **F8** | 1285±5 | 6.9±0.1 | 130± 5 | 0.06 | 7min43sec | 98.52 | 98.28 |
| **F9** | 1285±3 | 6.9±0.2 | 110± 10 | 0.062 | 7min03sec | 99.8 | 99.14 |

**Table 8: Cumulative % release study of Ethambutol HCL of various Formulation**

| Time in min | % Cumulative Drug Release | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **INNOVATOR** | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
| 5 | 35.30 | 34.90 | 32.04 | 30.40 | 35.40 | 32.80 | 30.00 | 35.04 | 31.48 | 30.69 |
| 10 | 54.20 | 55.01 | 52.03 | 50.32 | 55.41 | 51.55 | 49.40 | 55.48 | 51.54 | 50.04 |
| 15 | 63.80 | 64.40 | 61.88 | 59.56 | 63.30 | 61.43 | 60.50 | 64.81 | 60.81 | 60.65 |
| 20 | 78.60 | 78.90 | 75.30 | 73.00 | 77.20 | 74.48 | 72.90 | 77.41 | 75.00 | 72.80 |
| 30 | 88.3 | 88.71 | 85.70 | 83.80 | 87.48 | 84.70 | 83.16 | 88.04 | 84.81 | 82.30 |
| 45 | 97.36 | 99.43 | 95.51 | 92.30 | 97.00 | 95.63 | 92.04 | 96.64 | 95.56 | 91.49 |

**Table 9: Cumulative % release study of Isoniazid various formulation**

| Time in min | % Cumulative Drug Release | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | INNOVATOR | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 5 | 36.40 | 35.00 | 32.14 | 31.50 | 36.50 | 33.90 | 31.10 | 36.14 | 32.58 | 31.70 |
| 10 | 55.30 | 56.11 | 53.13 | 51.42 | 56.51 | 52.56 | 50.40 | 56.58 | 52.65 | 51.14 |
| 15 | 64.90 | 65.50 | 62.98 | 60.66 | 64.30 | 62.53 | 61.60 | 65.90 | 61.91 | 61.75 |
| 20 | 79.70 | 79.00 | 70.40 | 74.00 | 78.30 | 72.59 | 73.00 | 78.51 | 76.00 | 73.90 |
| 30 | 89.4 | 89.81 | 86.80 | 84.90 | 88.58 | 65.80 | 84.26 | 89.14 | 85.91 | 83.40 |
| 45 | 97.46 | 99.53 | 95.61 | 93.40 | 96.40 | 95.74 | 93.00 | 96.88 | 95.05 | 92.50 |

**Table 10: Cumulative % release study of (F1 and Innovator)**

| Time in min | % Cumulative Drug Release | | | |
|---|---|---|---|---|
| | INNOVATOR | | F1 | |
| | ETB | INH | ETB | INH |
| 5 | 35.30 | 36.40 | 34.90 | 35.00 |
| 10 | 54.20 | 55.30 | 55.01 | 56.11 |
| 15 | 63.80 | 64.90 | 64.40 | 65.50 |
| 20 | 78.60 | 79.70 | 78.90 | 79.00 |
| 30 | 88.3 | 89.4 | 88.71 | 89.81 |
| 45 | 97.36 | 97.46 | 99.43 | 99.53 |

**Dissolution profile of F1, F2, F3 batch (ETB)**

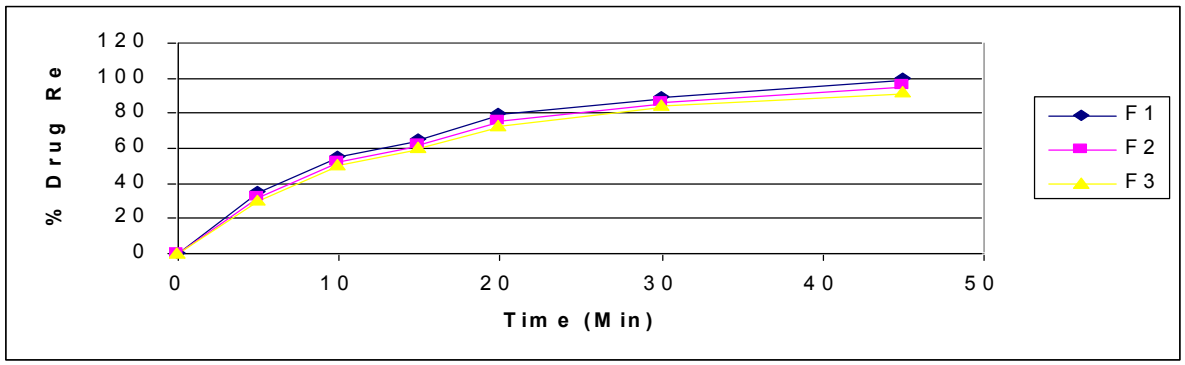



**Fig 1: Graph of cumulative % drug release for F1, F2, F3 batches (ETB)**

**Dissolution profile of F4, F5, F6 batch (ETB)**

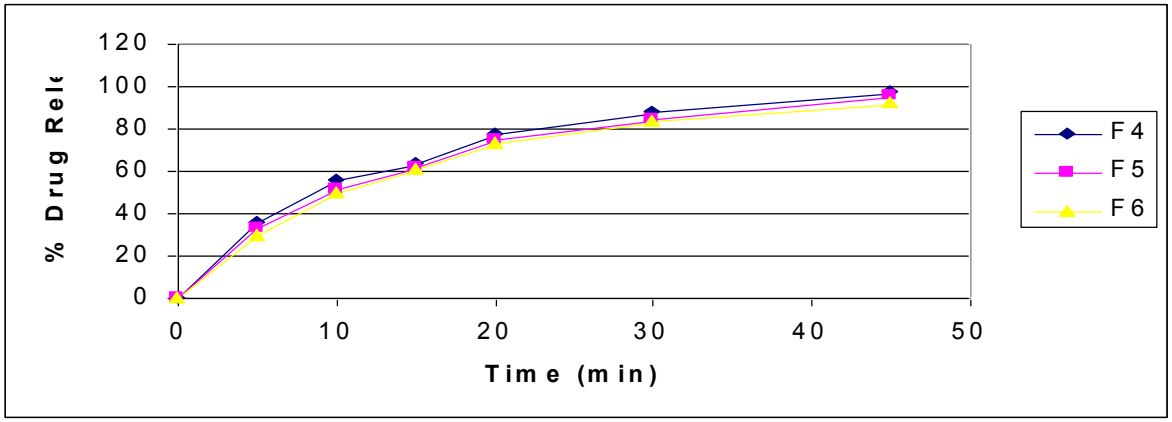



**Fig 2: Graph of cumulative % drug release for F4,F5,F6 batches(ETB)**

**Dissolution profile of F7, F8, F9 batch (ETB)**

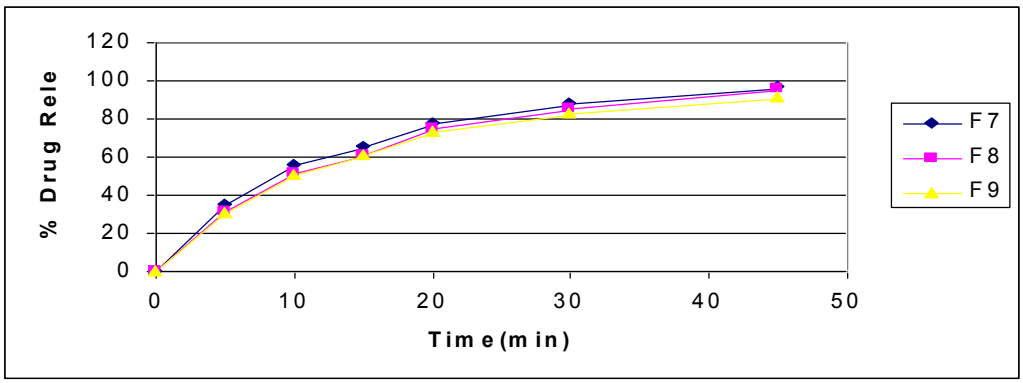



**Fig 3: Graph of cumulative % drug release for F7,F8,F9 (ETB)**

**Dissolution profile of F1, F4, F7 batch (ETB)**

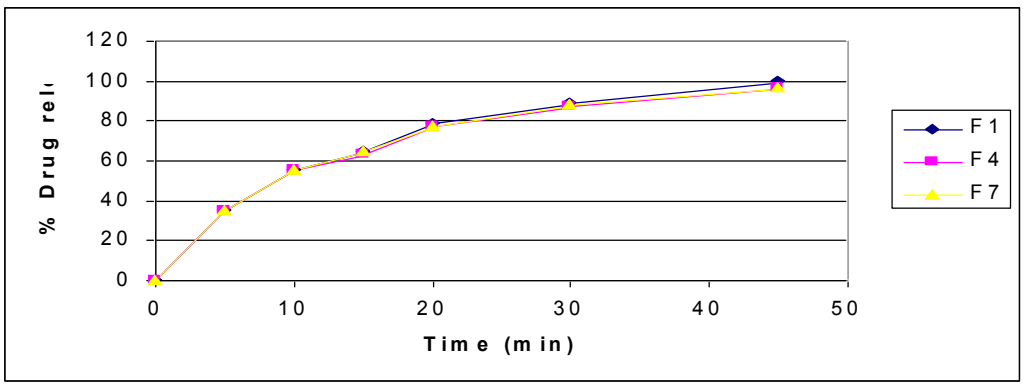



**Fig 4: Graph of cumulative % drug release for F1,F4,F7 batches(ETB)**

**Dissolution profile of F1, F2, F3 batch (INH)**

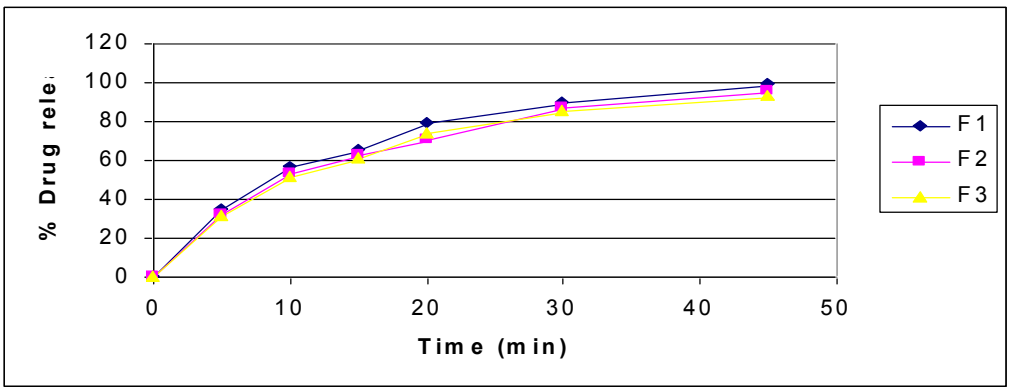



**Fig 5: Graph of cumulative % drug release for F1,F2,F3 (INH)**

**Dissolution profile of F4, F5, F6 batch (INH)**

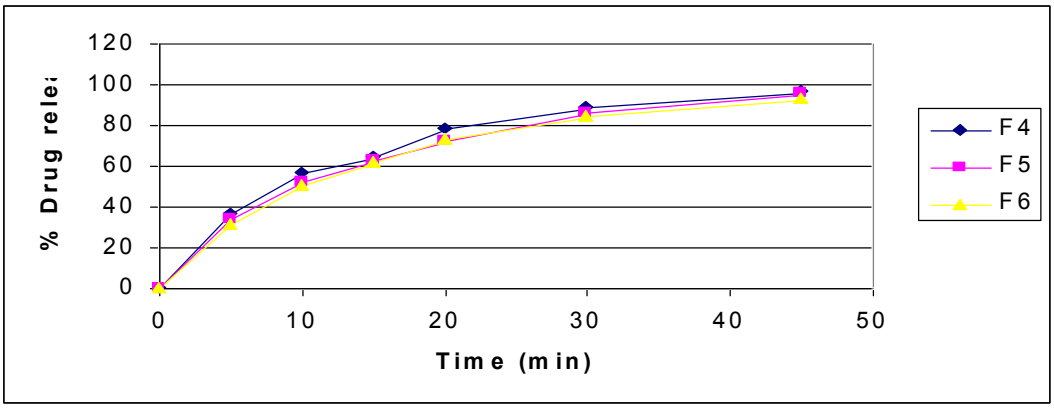



**Fig 6: Graph of cumulative % drug release for F4,F5,F6 (INH)**

**Dissolution profile of F7, F8, F9 batch (INH)**

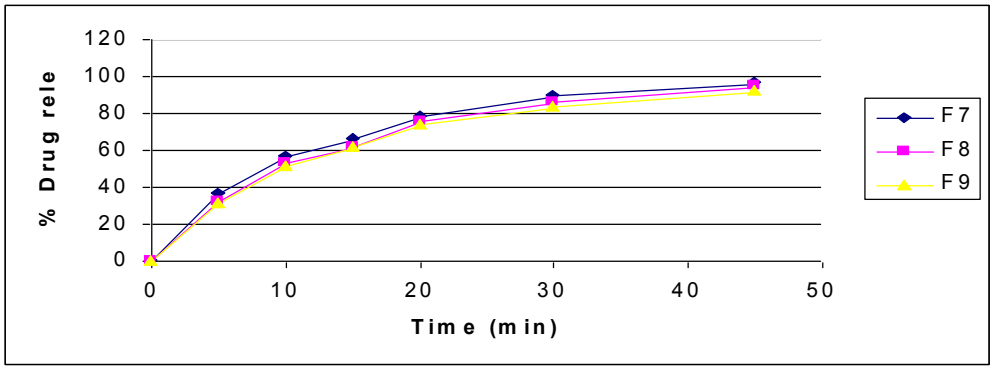



**Fig 7: Graph of cumulative % drug release for F7,F8,F9 (INH)**

**Dissolution profile of F1, F4, F7 batch (INH)**

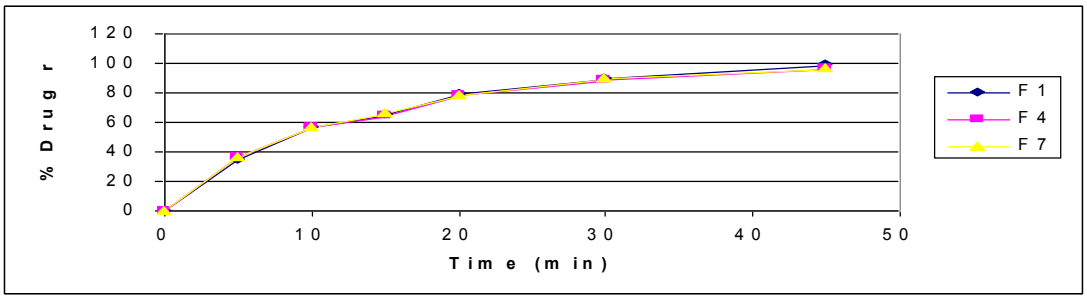
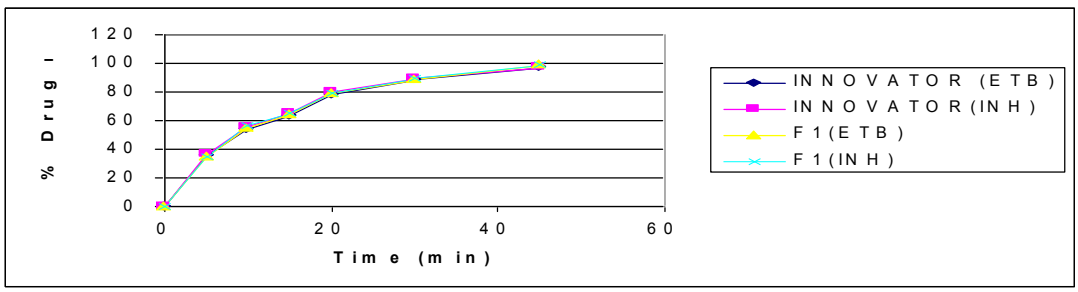



**Fig 8: Graph of cumulative % drug release for F1, F4, F7 (INH)**




## SUMMARY AND CONCLUSION

The present study was undertaken with an aim to formulate develop and evaluate Isoniazid and ethambutol HCL tablets using different Binders. Preformulation study was done initially and result directed for the further course of formulation. Based on preformulation studies different batches of Isoniazid and ethambutol HCL were prepare using selected excipients. Powders were evaluated for tests Angle of repose, Bulk density, tapped density, compressibility index, and Hausner ratio before being punched as tablets. Various formulation of tablets of Isoniazid and ethambutol HCL were developed using various Binders viz, HPMC, PVPK -30, HPC in different proportions and combinations by Wet Granulation technique. The tablets were evaluated for physical characterization, in vitro release study and stability studies. Observations of all formulation for physical characterization had shown that, all of then comply with the specifications of official pharmacopoeias and/or standard references. Result of in vitro release profile indicated that formulation (F1) was the most Promising formulations as the drug release from this formulation was high as compared to other formulations. The cumulative % of drug release of formulation F1 (INH) and F1(ETB) were 99.53 and 99.43 respectively. Stability study was conducted on tablets of Batch F1 stored at $40^0 \pm 2^0$C/75±5% RH for two months. Tablets were evaluated for hardness, friability, in-vitro release profile and drug content. After Two month no significant changes were observed in any of the studied parameters during the study period, thus it could be concluded that formulation was stable. From the above results and discussion it is concluded that formulation of tablets of Isoniazid and ethambutol HCL containing PVPK-30 batch F1 can be taken as an ideal or optimized formulation compressed tablet as it fulfils all the requirements for tablet.

## ACKNOWLEDGMENT

Authors are thankful to Prof.(Dr.) B.Jayakar, principal Vinayaka missions college of pharmacy, Salem,Tamilnadu and providing all the facilities for this research Project.

## REFERENCES

1. Lachman, L., Liberman, H.A., Kanig J.L.,(1990) The Theory and Practice of Industrial Pharmacy, 3rd Edn, 3rd Indian Reprint, Varghese Publishing House, Bombay, 1990, 296-345,346-373.
2. Lieberman, H. A., Lachman, L. and Schwartz. B., Pharmaceutical dosage form: Tablet Volume 1, 2nd Edn, 179-181, 274-275.
3. Bogda, M.J.,2002. Tablet compression machine theory, design and process trouble shooting in- encyclopedia of pharmaceutical technology, 2, Marcel Dekker Inc Newyork, 2669 – 2674.
4. Tousey, M.D., Pharmaceutical technology, tabletting and granulation (Available from: http://www.pharmtech.com).
5. Aulton, M.,2007. The design & manufacturing of medicines, 3 rd edition, 410-424
6. Rubric, E.M., Schwartz J.D.,2001. Oral solid dosage form in: Remington- the science and practice of pharmacy' 20th edition, Lippincott Williams and Wilkins, 1, 859 – 871.

7. R.S.Satoskar, S.D.Bhandarkar, Pharmacology and Pharmacotherapeutics,20th edition,734-740
8. Rowe RC,Sheskey PJ ,Handbook of pharmaceutical excipients,4 th edition London ,Pharmaceutical press and American Pharmaceutical Association,2003
9. United States Pharmacopoeia XXIV NF 19, (2000), United States Pharmacopoeial Convention, Rockville, 2235-2236.
10. United State Pharmacopoeia -30:National Formulary -25, Vol.1, Asian edition, United State Pharmacopoeial Convention, Inc; 2007, p.645.
11. United State Pharmacopoeia -30:National Formulary -25, Vol.1, Asian edition, United State Pharmacopoeial Convention, Inc; 2007, p.644.
12. ICH guidelines Q1A (R2), Guidance for industry, stability testing of new drug substance and products (Available on: http:// http://www.ich.org).

**Source of support: Nil, Conflict of interest: None Declared**