Section A-Research paper
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USE OF BETA-CYCLODEXTRIN COMPLEX AND NOVEL SUPERDISINTEGRANT (KYRON-T) FOR FORMULATION OF MOUTH DISSOLVING FILM OF TELMISARTAN

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ABSTRACT:
Telmisartan, an antihypertensive agent which lies in BCS class II, is used for treating Hypertension. Due to the poor solubility of the API i.e. Telmisartan, Beta Cyclodextrin complexation was performed and the ratio of the Telmisartan to the Beta Cyclodextrin was 1:1.Inclusion complex was developed using Kneading Method. Further Mouth Dissolving Film was prepared by using "Solvent Casting Method" and Dose of the Telmisartan per film used was 40 mg. Various Excipients were used for the formulation such as film forming polymer (HPMC E5), Plasticizer (Povidone K 30), Surfactant (Tween 80), Superdisintegrant (Kyron –T), Saliva Stimulating agent (Trisodium Citrate), Sweetening agent (Aspartame) etc. HPMC E5 was used at various concentration i.e. 1200 mg/ film, 1600 mg/film and 2000 mg/film. Similarly Polacrilin Potassium (Kyron-T) was used at three level of concentration i.e. 2%, 5% and 8% of the amount of film forming polymer HPMC E5. Povidone K 30 (PVP K 30) was used at various amount i.e. 0.5 mg/film, 1.75 mg/film, 3 mg/film. Others materials were kept in constant quantity. Altogether Nine different formulations were prepared and one optimized formulation was also prepared. Formulated Mouth Dissolving film were analyzed for different parameters such as film's Folding Endurance, Film Thickness, Average weight of film, Degree of swelling, Disintegration time ,Percentage Absorption of moisture, Percentage Loss of moisture, Assay %, In-vitro dissolution rate. All the parameters are found to be within the acceptable limit. Folding Endurance, Film Thickness, Degree of swelling, Disintegration Time, In-vitro dissolution rate etc were found varied with variation applied during formulation but Assay %, Percentage

Moisture Absorption, Percentage Moisture Loss, Average weight etc. were found almost similar and did not show significant variation with respect to variation applied. Mouth Dissolving Film containing lower amount of film forming polymer, Intermediate amount of plasticizer and higher amount of superdisintegrant was found to provide the better result among other formulation. All the evaluation parameters were found optimized in the optimized formulation.

Keywords*: Solvent Casting Method, Antihypertensive agent, Complexation, Kneading Method, Optimization.*

INTRODUCTION:

Oral routes are considered to be the convenient route among other routes for the drug delivery. Different dosage forms have been designed for delivering the drug through the oral routes. Among them Mouth Dissolving Film are the recent advancement and are the future of modern pharmaceutics. Patients are highly benefitted through the use of Mouth Dissolving Film. Patient's acceptability is comparatively higher in these dosage forms. Since they are non-invasive in nature, they have become more patient friendly. (Pawar, et al. 2019) Modern Pharmacotherapeutics have started doing research in these dosage forms to develop the Mouth Dissolving Film of the drug for which they requires the immediate relief. Drugs for the treatment of Hypertension, Drugs for the treatment of Migraine, Drugs for lowering the cholesterol level, Drugs for the treatment of Diabetes etc. are the targets of the therapeutic scientist for the development of these dosage forms.

Problem/Difficulty for swallowing is the major concern that is prevalent in the Dysphagic patient. Dysphagia is the disease in which patients feel difficulty in swallowing. Especially patients with the lower age group i.e. Pediatric and the patients with higher age group i.e. Geriatric patients are also found to have difficulty in swallowing. For these populations, Mouth Dissolving Film are becoming the boon. Patients can take the drug easily without administration of the water and just by placing the Mouth Dissolving Film in the tongue. About 35 % of the total population now a days are suffered with the dysphagia which is seriously a major concern. (Patil, et al. 2014) When the Mouth Dissolving film are kept in the tongue, Saliva present in the tongue helps for wetting the Film and which in turns disintegrates the film thus releasing the required API. (Desu, et al. 2013)

Various materials are required for preparing Mouth/Oral Dissolving Film. Active Pharmaceutical/Therapeutics Ingredients, Polymer for film formation, Plasticizing agents, Surfactant/Wetting agent, Saliva stimulator, Various Buffers, Superdisintegrants etc. are the major components of the Mouth Dissolving Film. Film forming polymers can be natural or synthetic. Natural film forming such as Xanthan Gum, Guar Gum and Synthetic film formers such as Hydroxypropyl Methyl Cellulose, Polyvinyl Alcohol, Carboxy Methyl Cellulose are the major choice for the formulation. Plasticizers are used to provide the rigidity to the film and thus help in easy handling and storage of the formulation. PEG 400, PEG 4000, Povidone K 30 etc. are most commonly used plasticizers. Saliva stimulation and secretion is desirable while taking the Mouth Dissolving film so that stimulated saliva makes the Mouth Dissolving Film wet and

thus gets disintegrated easily. Citric Acid, Trisodium Citrate etc. are commonly used Saliva Stimulating agents. Role of the Superdisintegrant is most important during the formulation of Mouth Dissolving Film. They helps in quicker disintegration thus helps in fastest release of the drug through the dosage form. Both Synthetic/ Natural Superdisintegrant are found for development for Mouth/Oral Dissolving Film. Natural superdisintegrant such as Plantago Ovata, Fenugreek seed, Musa Paradisiaca etc and Synthetic superdisintegrants such as Croscarmellose Sodium, Polacrillin Potassium (Kyron-T), Crospovidone etc. are most commonly used Superdisintegrants for the Formulation of Mouth Dissolving Film. Surfactants are also used in order to increase the wettability of the formulation. Various Buffers are helps for the maintaining of appropriate pH of the formulation.

Mouth Dissolving Film can be prepared by using the different technique such as "Hot Melt Extrusion Methods" (Bhattarai and Gupta 2015)**,** "Solvent Casting Method", "Semisolid Casting Method" (Bala, et al. 2013), "Solid dispersion Extrusion Method" (Saxena and Singh 2022) and "Rolling Method" (Arya, et al. 2010)**.** All have their own advantage and disadvantages. Among them most commonly used method is "Solvent Casting" in which a polymer for film formation is soaked in water till the viscous solution is formed. Others ingredients like Plasticizers, Surfactants, Superdisintegrants, Saliva Stimulating agents etc. are then added under continuous stirring conditions. The solution shall be stirred continuously so that the uniformity of the drugs can be maintained. Further sonication for certain time helps in the uniform mixing of the formulation. Thus obtained solution is then subjected for casting into the petridishes and which is allowed 24 hours drying. (Raza, et al. 2019)

Mouth Dissolving Films offers the various advantages such as bypassing of "First Pass Metabolism", Protection of GI degradable drugs, Higher flexibility and portable for carrying, can be taken in the place with the scarcity of the water, quicker disintegration and enhanced dissolution in the mouth cavity and thus ultimately leads to faster action, More patient acceptability & compliance and are boon for the patients having difficulty in swallowing. (Saxena and Singh 2022)**.** Cold Sores or when Local anesthetic is desirable, role of mouth dissolving films comes into the existence. (Neeta, et al. 2012)

In contrast Mouth Dissolving Films has certain disadvantages too. Maintaining of the dose uniformity is the challenging part during formulation. Special packaging condition is required so they are a bit costly. They are somewhat Hygroscopic in the nature so requires protection from the various environmental conditions. (Ketul, et al. 2013)

Prepared Mouth Dissolving film should possess some special features such as: They must be possibly thin and should be attractive, they should show faster disintegration and they should be easily palatable. They should be unobstructive in nature and should provide the pleasant mouth feel. There should not be any residues that are left after administration in the Mouth. (Pawar, et al. 2019)

Not all the drugs are suitable for incorporating into the Mouth Dissolving Film. The intended drug should not have any noxious taste and should be pleasant. Comparatively small molecular weight is desirable. Drug must be hygroscopically stable and should not have any irritation effect to mucosal cells of Oral Cavity. (Siddiqui, Garg and Sharma 2011)

Mouth Dissolving Films after formulation are subjected for the evaluation in order to draw the conclusion of the research. Different Evaluation parameters are monitored such as Folding Endurance, Average Weight, Thickness, Degree of swelling, Percentage Absorption of moisture, Percentage Loss of moisture, Assay %, disintegration time, dissolution rate etc. and based on the result conclusion can be drawn.

Active Pharmaceutical Ingredient Telmisartan is an oral Antihypertensive agent which fall under BCS class II category. Thus solubility has been the rate limiting step. It has low aqueous solubility i.e. it is insoluble in water and its solubility is pH dependent. A drug gets solubilized at low or high pH and is insoluble at pH ranging from 3-7. (Kundu, et al. 2018) Bioavailability of the Telmisartan is very poor i.e. only 45% and it is due to the extensive first pass metabolism. It is highly lipophilic in nature and has the log P value of 3.2. Its molecular weight is 514.6 and it has melting point of 261-263^{o}C. Telmisartan is considered as best antihypertensive agent due to its therapeutic action.

MATERAILS AND METHODS:

Materials:

API, Telmisartan was procured from manufacturer, Virchow Drugs Pvt. Ltd. Similarly others materials such as Beta-Cyclodextrin (a Complexing agent) was purchased from Mengzhou Huaxing Biochemistry Co. Ltd. HPMC E5, Povidone K-30 Trisodium Citrate, Polacrillin Potassium (Kyron-T), Polysorbate-80 (Tween-80) and Aspartame was purchased from Zhejiang Joinway Pharmaceutical Co. Ltd, Boai NKY Pharmaceuticals Ltd, Sunil Chemicals, Corel Pharmachem, Clariant IGL speciality Chemicals P. Ltd, Nantong Changhai foods additive Co. Ltd Respectively. All the manufacturer were previously qualified through vendor validation procedure.

Methods:

Drug Solubility Study: Active Pharmaceutical Ingredient (Telmisartan) was subjected for the solubility study in different solvent like Water, Methanol, Methylene Chloride and 0.1 M sodium Hydroxide.

***Drug Excipients Compatibility Study*:** FTIR spectrophotometer was used for evaluating the Compatibility between the intended drug and excipients. Spectra obtained with of Pure drug Telmisartan, Telmisartan with Beta Cyclodextrin, Telmisartan with HPMC E5, Telmisartan with Povidone- K 30, and Telmisartan with Kyron- T were compared.

Determination of Calibration Curve: Samples of different concentration ranging from 4 to 20µg/ml were prepared and analyzed using the UV Spectrophotometer. Plotting of Calibration curve was done with Absorbance against concentration. Similarly samples of different

concentration ranging from 32 to 48 µg/ml were prepared and analyzed using HPLC. Calibration curve was plotted with concentration vs. Peak area.

Formulation of Inclusion Complex: API (Telmisartan) and Betacyclodextrin complex was prepared with the help of popular technique called kneading method. For this both the contents were subjected for mixing in the 1:1 ratio. Addition of distilled water was done to wet the mixture and thus formed wet mass was subjected for kneading thoroughly. Paste having the high consistency was obtained which was then dried at normal temperature of room. Mesh size #80 was taken and the sample was passed through it. Prepared sample was properly stored.

Preparation of Film*:* It was prepared by the help of Solvent casting technique. Initially polymer i.e. HPMC E5 was soaked in the water properly and after proper soaking, Drug inclusion complex was then added slowly with continuous stirring with addition of small amount of water if required. Polacrillin Potassium (Kyron T) which is used for superdisintegration was added to the above solution with continuous stirring. Remaining excipients such as Trisodium Citrate (Saliva Stimulating agent), Tween-80 (Surfactant), Povidone-K 30 (Plasticizer) and Aspartame (Sweetening agent) were added with the continuous stirring. Viscous solution thus obtained was sonicated for about 10 minutes and after sonication, it was casted on the petridish and for 24 hours it was kept in oven. After properly drying, it was cut into area of 2*2 cm^2 and subjected for the evaluation.

Table 1: Formulation Table

Components	TF1	TF2	TF3	TF4	TF5	TF6	TF7	TF8	TF9
Telmisartan +Betacyclodextrin Complex (mg)	1330.4	1330.4	1330.4	1330.4	1330.4	1330.4	1330.4	1330.4	1330.4
HPMC E5 (mg)	2000	2000	2000	1600	1600	1600	1200	1200	1200
Povidone-K30 (mg)	0.5	1.75	3	0.5	1.75	0.3	0.5	1.75	3
Trisodium Citrate (ml)	10	10	10	10	10	10	10	10	10
Polacrilin Potassium (Kyron-T)	2%	5%	8%	2%	5%	8%	2%	5%	8%
Aspartame(mg)	75	75	75	75	75	75	75	75	75
Tween 80 (ml)	5	5	5	5	5	5	5	5	5
Purified Water (ml)	50	50	50	50	50	50	50	50	50

Note: Here the amount of the components is calculated for per petriplates used for the formulation using Solvent Casting Method. Radius of petriplates= 4.6 cm and Area=66.5 cm^2. Kyron-T amount is expressed in percentage of amount of HPMC E5.

Methods of Evaluation:

General Appearance: All Formulations including optimized formulation was evaluated for general appearance visually.

Taste: Prepared Mouth Dissolving films of all formulations from TF1 to TF9 including optimized formulation was tasted and the acceptability of the formulation in terms of taste was noted.

Average Weight: Six different Films of every formulations were taken out and they were individually weighed with the calibrated analytical balance and Average weight of the prepared films was calculated. (Throat, et al. 2021)

pH of Surface: Prepared Films were made wet with the distilled water and touched with the rod of pH meter. (Pawar, et al. 2019)

Thickness of the film: Six different films of each formulation from TF1 to TF9 were taken and film thickness was taken using micrometer screw gauge. Average thickness of the formulation was determined.

Folding Endurance: Folding Endurance was obtained by repeatedly breaking the film at same place until it breaks and the number of time was noted. (Upreti, et al. 2014)

Disintegration time: Disintegration time was determined using Disintegration test apparatus.

Degree of Swelling: Initial weight of prepared films was taken and kept in stainless steel wire which was weighed previously. These wires were submerged into Simulated saliva solution and final weight was taken after having constant weight. (Mankar, Biyani and Umekar 2020)

Percentage Moisture Absorption: Desiccator with aluminum chloride was taken and into this preweighed Mouth Dissolving Film were kept for Seventy two (72) hours and after defined time period, films were again weighed (Momin, et al. 2019)

Percentage Moisture Loss: Desiccator with Calcium Chloride was taken and into this pre-weighed Mouth Dissolving Film were kept for Seventy Two (72) hours and after defined time period, films were again weighed.

Assay: Standard and Sample solutions were prepared and subjected for analysis using the HPLC at 298 nm.

In-vitro Dissolution: Samples and standard were analyzed using UV spectrophotometer at wavelength of 296 nm.

RESULT

Solubility of Telmisartan: Telmisartan was not soluble in water, in methanol it was soluble slightly, in Methylene Chloride it was soluble sparingly and in 0.1 N Sodium Hydroxide it was soluble freely.

Solubility of Telmisartan-Beta Cyclodextrin Complex: Telmisartan-Beta Cyclodextrin complex was freely soluble in water.

Determination of Calibration Curve:

a) For UV Visible spectrophotometer

Table 2: Concentration Vs. Absorbance of UV

Concentration (mcg/ml)	Absorbance
4	0.2161
8	0.3945
12	0.5828
16	0.7841
20	0.9619

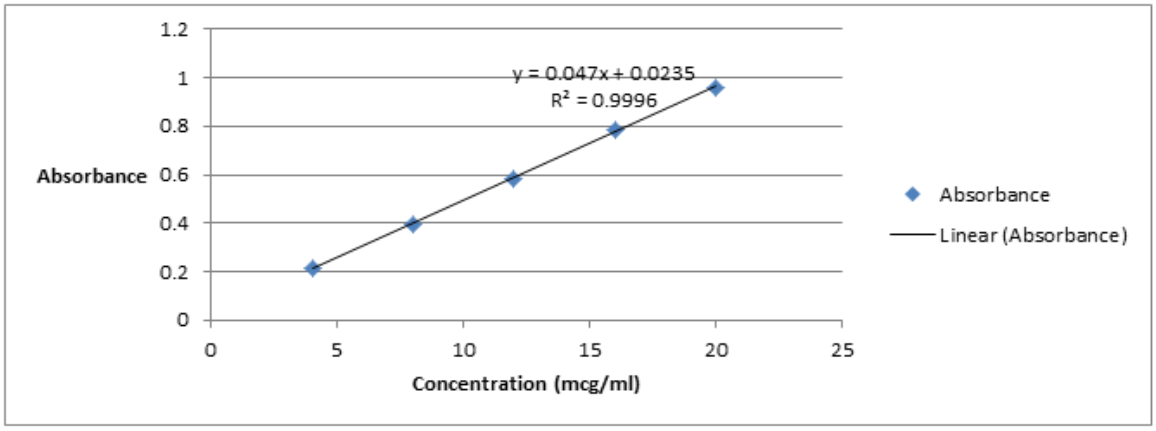

Figure 1: Calibration Curve of UV Visible Spectrophotometer

b) For HPLC

Table 3: Peak Area of Telmisartan at various concentration

Concentration (mcg/ml)	Peak Area
32	1847120
36	2078059
40	2308954
44	2518563
48	2761650

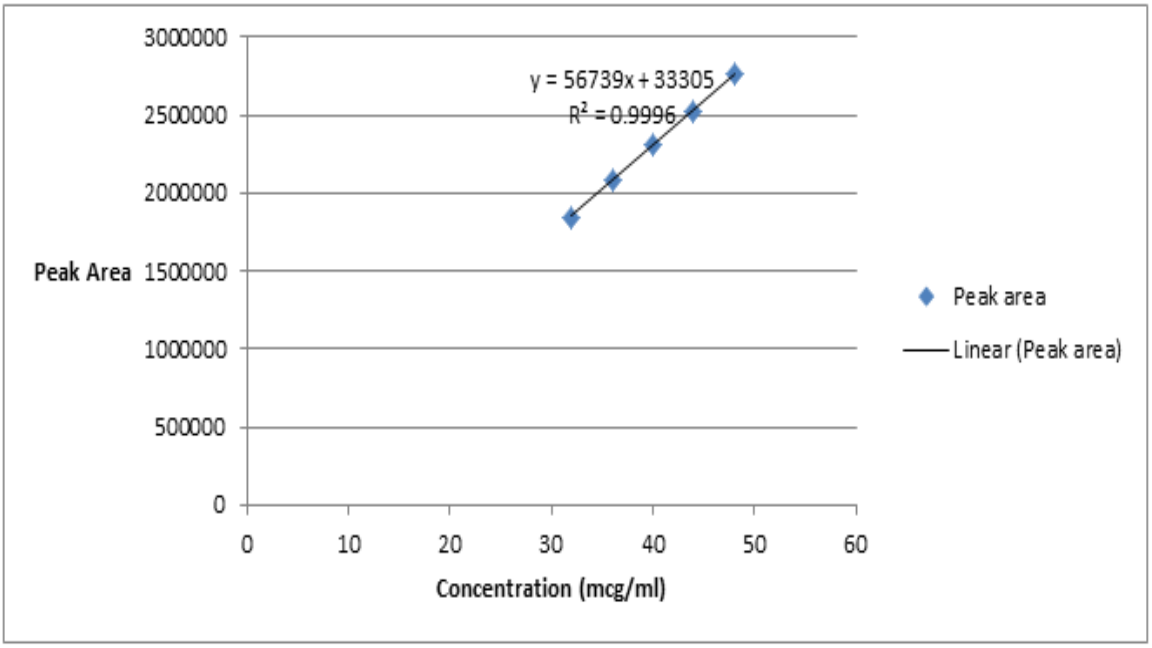

Figure 2: HPLC Calibration Curve

Drug Excipients Compatibility: Telmisartan was found to be compatible with Beta cyclodextrin, HPMC E5, Povidone K 30 and Kyron –T.

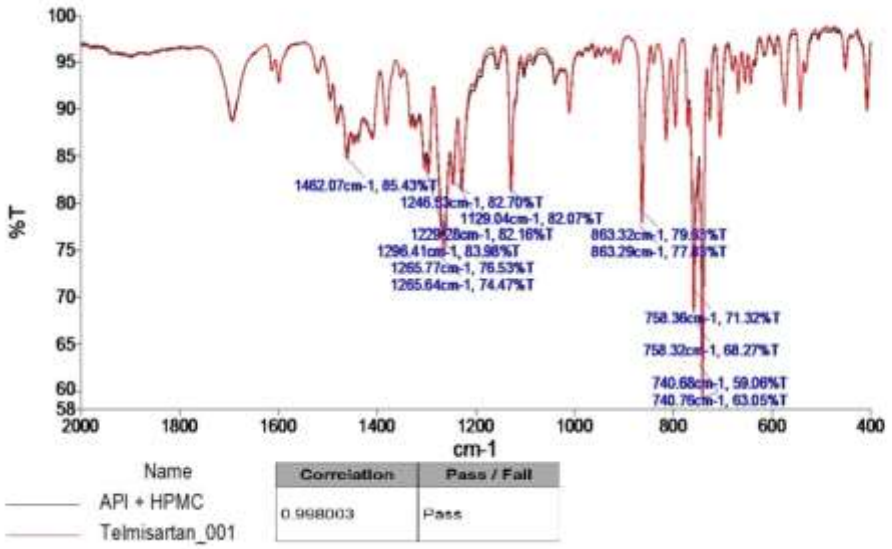

Figure 3: FTIR spectra of API and combination of API & HPMC E5

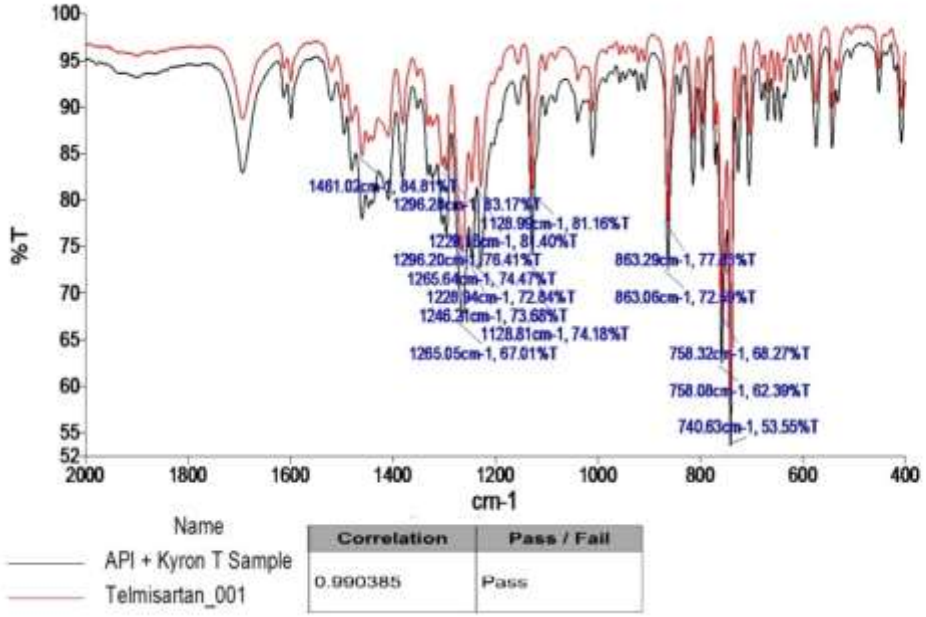

Figure 4: FTIR spectra of API and combination of API & Kyron T

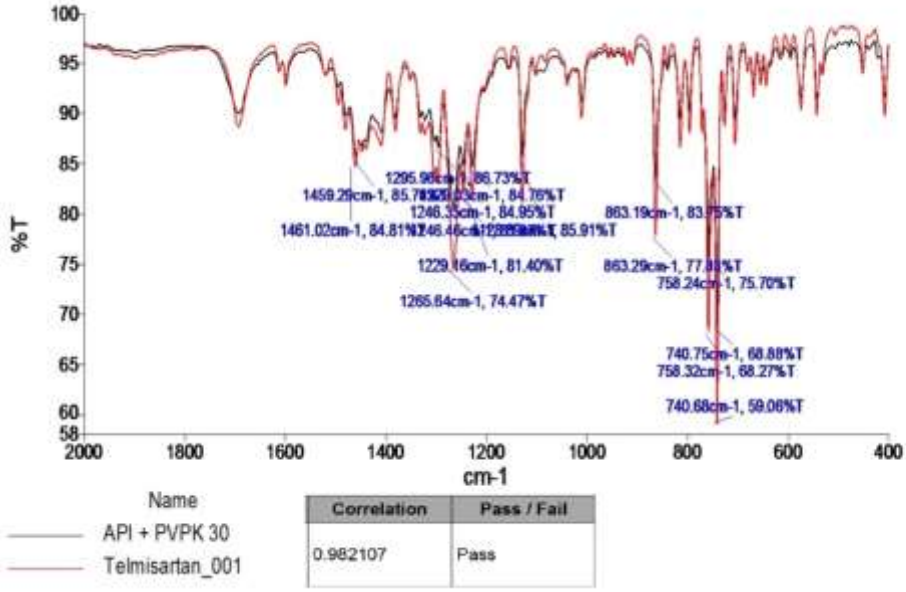

Figure 5: FTIR spectra of API and combination of API & Povidone K 30

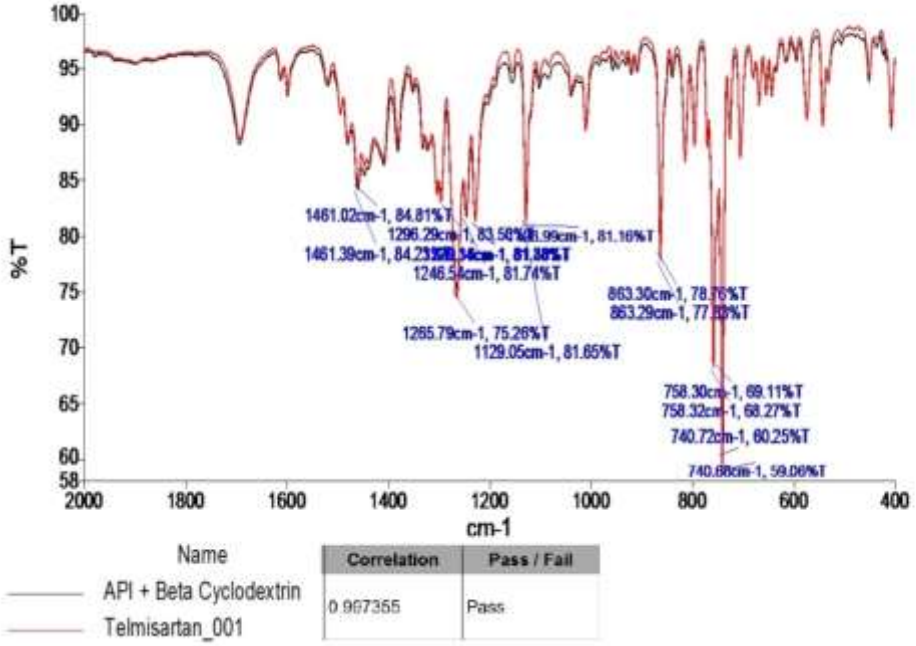

Figure 6: FTIR spectra of API and combination of API & Beta Cyclodextrin

General Appearance: All formulations were found clear & transparent.

Taste: Taste of all the formulation was found acceptable.

Average Weight: All the formulations were found to be uniform. Average weight ranging from 201.0 to 201.4 was obtained.

Table 4: Observed Average weight of formulations

S.N.	Formulation	Average Weight (mg) ±SD
1.	TF1	201.2±0.83
2.	TF2	201.4±0.89
3.	TF3	201.4±0.54
4.	TF4	201.2±0.44
5.	TF5	201.4±0.54
6.	TF6	201.2±0.54
7.	TF7	201.2±0.83
8.	TF8	201.0±1.00
9.	TF9	201.2±0.83

Surface pH: Surface pH ranging from 7.8 to 8.5 was obtained.

Table 5: Observed Surface pH of Formulations

S.N.	Formulation	Average pH
1.	TF1	7.9
2.	TF2	8.1
3.	TF3	7.8
4.	TF4	8.2
5.	TF5	8.2
6.	TF6	7.8
7.	TF7	8.5
8.	TF8	7.9
9.	TF9	8.0

Thickness of the film: Thickness ranging from minimum of 0.16mm to 0.39mm was obtained.

Table 6: Observed Thickness of Formulations

S.N.	Formulation	Average Thickness (mm) ±SD
1.	TF1	0.38±0.01
2.	TF2	0.39±0.01
3.	TF3	0.38±0.02
4.	TF4	0.25±0.02
5.	TF5	0.26±0.01
6.	TF6	0.25±0.01
7.	TF7	0.18±0.01
8.	TF8	0.17±0.01
9.	TF9	0.16±0.01

Folding Endurance: Folding Endurance ranging from minimum of 132 to 151.55 was obtained.

Table 7: Observed Folding Endurance of Formulations

S.N.	Formulation	Average Folding Endurance ±SD
1.	TF1	134.17±0.75
2.	TF2	140.00±0.63
3.	TF3	150.33±0.52
4.	TF4	134.33±0.82
5.	TF5	140.83±0.75
6.	TF6	149.67±1.03
7.	TF7	132.00±0.63
8.	TF8	142.33±1.03
9.	TF9	151.55±1.38

Disintegration Time: Average Disintegration time ranging from minimum of 26.33 sec to maximum of 54.00 sec was obtained.

Table 8: Observed DT of Various Formulations

S.N.	Formulation	Average Disintegration Time (Sec)±SD
1.	TF1	51.67±0.82
2.	TF2	42.17±0.75
3.	TF3	26.33±0.82
4.	TF4	53.33±1.03
5.	TF5	41.50±1.05
6.	TF6	27.50±1.05
7.	TF7	54.00±0.63
8.	TF8	42.33±0.82
9.	TF9	28.67±0.52

Degree of Swelling: Degree of swelling ranging from minimum value of 0.022 to 0.063 was obtained.

Table 9: Observed Degree of Swelling of Various Formulations

S.N.	Formulation	Average Degree of Swelling ±SD
1.	TF1	0.025±0.01
2.	TF2	0.024±0.01
3.	TF3	0.022±0.01
4.	TF4	0.048±0.01
5.	TF5	0.052±0.01
6.	TF6	0.052±0.01
7.	TF7	0.063±0.01
8.	TF8	0.063±0.01
9.	TF9	0.057±0.01

Percentage Moisture Absorption: Percentage Moisture Absorption ranging from minimum of 0.30 to maximum of 0.35 was obtained.

Table 10: Observed percentage moisture absorption of Various Formulations

S.N.	Formulation	Percentage moisture absorption ±SD
1.	TF1	0.32±0.02
2.	TF2	0.30±0.01
3.	TF3	0.32±0.02
4.	TF4	0.32±0.01
5.	TF5	0.32±0.02
6.	TF6	0.34±0.03
7.	TF7	0.35±0.01
8.	TF8	0.32±0.01
9.	TF9	0.31±0.01

Percentage Moisture Loss: Percentage Moisture loss ranging from minimum of 0.24 to maximum of 0.35 was obtained.

Table 11: Observed percentage moisture Loss of Various Formulations

S.N.	Formulation	Percentage moisture Loss ±SD
1.	TF1	0.25±0.01
2.	TF2	0.34±0.01
3.	TF3	0.35±0.01
4.	TF4	0.28±0.01
5.	TF5	0.25±0.01
6.	TF6	0.32±0.01
7.	TF7	0.33±0.01
8.	TF8	0.24±0.01
9.	TF9	0.28±0.01

Assay: Assay percentage ranging from minimum of 99.61% to maximum of 102.62% was obtained.

Table 12: Observed Assay value of Various Formulations

S.N.	Formulation	Average Assay (%)
1.	TF1	99.61
2.	TF2	100.11
3.	TF3	100.07
4.	TF4	100.22
5.	TF5	101.33
6.	TF6	101.85
7.	TF7	102.16
8.	TF8	101.91
9.	TF9	102.62

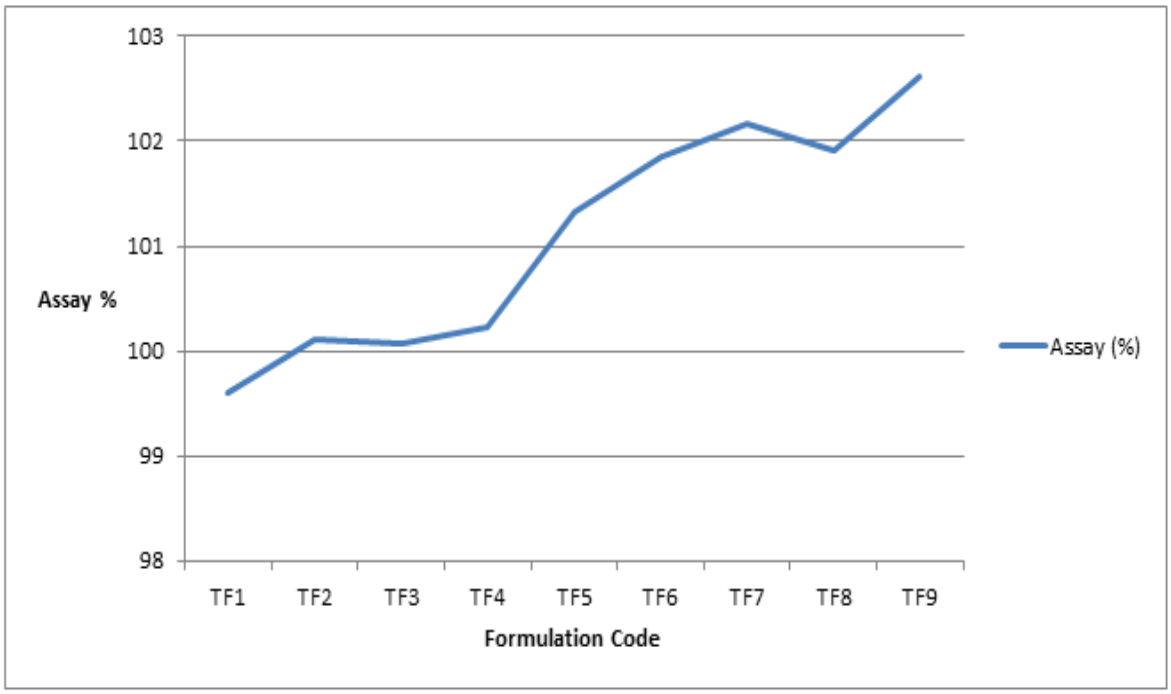

Figure 7: Assay % of various formulations

In-vitro Dissolution: % Drug release ranging from minimum of 14.69% at 3 mins to maximum of 100.78% at 15 mins was obtained.

Table 13: % Observed Drug Release of Various Formulations in different time interval

S.N	Formulation Number	3 Mins	6 Mins	9 Mins	12 Mins	15 Mins
1.	TF1	14.69	32.00	51.49	74.41	87.49
2.	TF2	17.08	38.15	55.56	76.89	92.49
3.	TF3	15.99	33.40	54.29	75.42	89.55
4.	TF4	18.16	39.42	57.09	76.73	94.37
5.	TF5	20.41	41.59	59.68	80.52	98.01
6.	TF6	19.66	40.76	58.81	78.64	95.65
7.	TF7	21.81	43.93	63.03	81.07	99.62
8.	TF8	22.64	44.26	65.85	83.25	100.78
9.	TF9	21.64	44.45	66.64	83.44	100.22

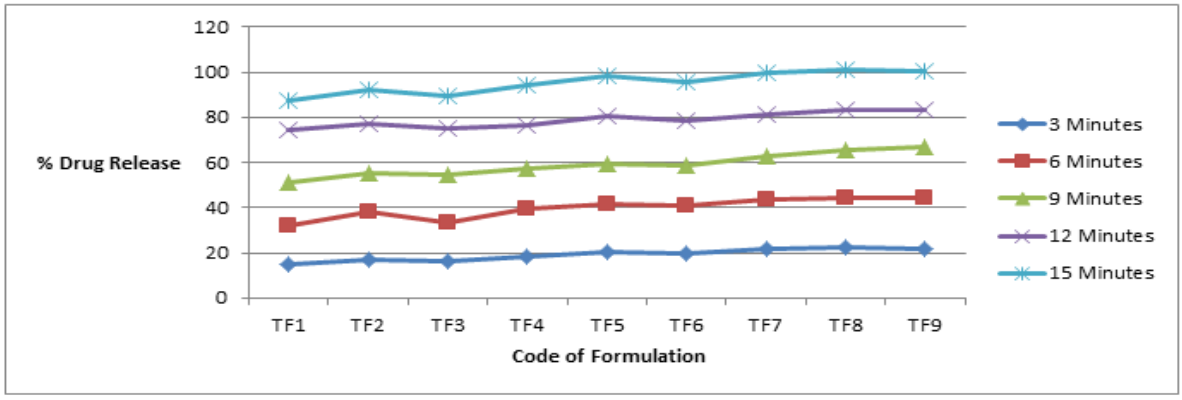

Figure 8: % Drug release of various formulations

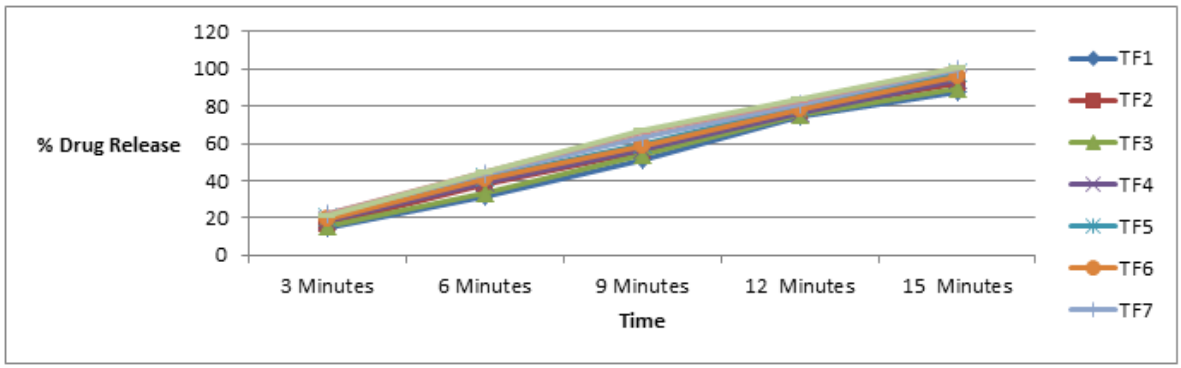

Figure 9: Drug release profile of various formulations at different time

Design of optimized formulation: Optimized formulation was designed keeping the minimum concentration of film forming Polymer i.e. HPMC E5, Intermediate amount of Plasticizer, Povidone K 30 & Higher concentration of Superdisintegrant i.e. Kyron-T.

Table 14 : Table of formulation for optimized Formulation

S.N	Components	Amount
1	Telmisartan+ Beta-Cyclodextrin	1330.4 mg
2	HPMC E5	1200 mg
3	Povidone-K 30	1.75 mg
4	Trisodium Citrate	10 ml
5	Polacrilin Potassium (Kyron-T)	8 %
6	Tween 80	5 ml
7	Aspartame	75 mg
8	Distilled Water	50 ml

Table 15: Optimized formulation evaluation

S.N	Evaluation Parameters	Observation
1.	General Appearance	Clear and Transparent
2.	Taste	Acceptable
3.	Thickness	0.2 mm
4.	Folding Endurance	140
5.	Surface pH	8.2
6.	In-Vitro Disintegration Time	28 Sec
7.	Degree of swelling	0.065
8.	Percentage Moisture Absorption	0.031
9.	Percentage Moisture Loss	0.029
10.	Assay (%)	100.71

Drug Release (%) of the Optimized Formulation						
S.N	Formulation Number	3 Mins	6 Mins	9 Mins	12 Mins	15 Mins
1	Optimized Formulation	23.24	47.81	65.97	83.82	100.53

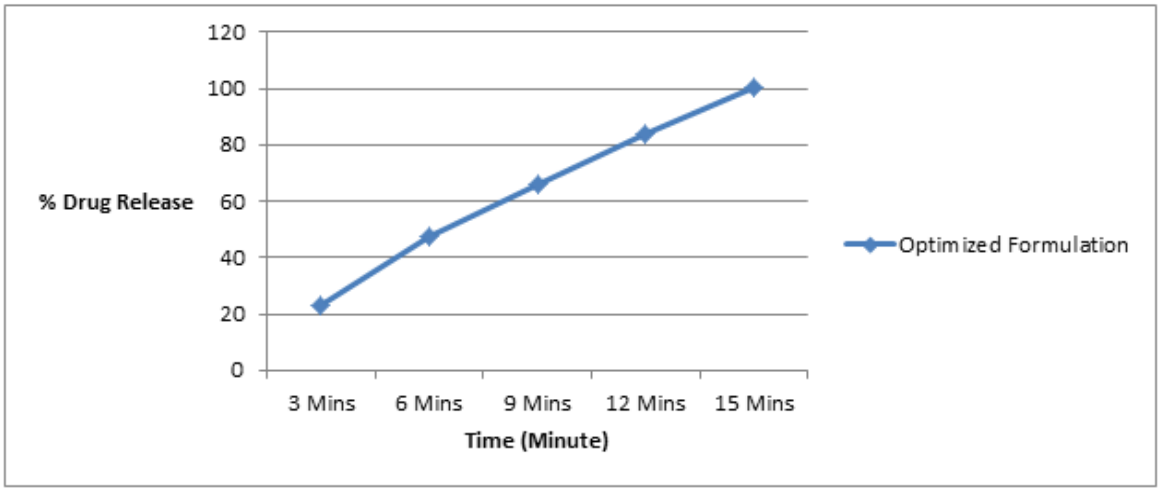

Figure 10: Percentage Drug Release of Optimized Formulation in different time Interval

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DISCUSSION

Solubility of the Telmisartan gets increased when the inclusion complex is formed with the Beta Cyclodextrin and pH is adjusted at basic level.

Active Pharmaceutical ingredient (Telmisartan) is compatible with various excipients such as HPMC E5, Povidone K 30, Beta Cyclodextrin, Kyron T etc. Thus can be used for the routine formulation process.

Alternation of the variable i.e. concentration of various excipients does not affect the assay % of the formulation significantly as almost identical values are obtained for all the formulations.

Variation in Polymer concentration affects the different parameters such as Thickness, Degree of swelling, % Drug release of the formulation. Formulation containing higher amount of polymers will have comparatively more thickness, will have less degree of swelling and retards the release pattern of the drug out of the formulation whereas Formulation containing lower amount of film forming polymers will have comparatively less thickness, will have more degree of swelling and enhance the release of the active moiety out of the formulation.

Higher or Lower concentration of Super disintegrating agent affects the different parameters such as Disintegration time which affects ultimately the release pattern of drug. Films containing Higher concentration of super disintegrating agent like Kyron-T will have comparatively lower disintegration time and thus will have better drug release profile whereas the Formulation containing Lower concentration of super disintegrating agent will have comparatively higher time of disintegration and affects the drug's release profile in negative logarithm.

Alternation in Plasticizer's concentration affects the different parameters such as Folding Endurance, Time of Disintegration and ultimately the Drug's release profile. Films containing higher amount of Plasticizers gives the higher rigidity to the film with higher Folding Endurance and it increases the disintegration time & ultimately affects Drug's release rate in negative logarithm. Similarly formulation containing lower amount of Plasticizers such as Povidone K 30 will produce the less rigid film with comparatively less value of Folding Endurance which may leads to the brittleness of the film upon storage. Thus Intermediate concentration or amount of plasticizers must be incorporated for the film formation.

CONCLUSION:

Mouth Dissolving Film containing lower amount of film forming polymer, Intermediate amount of plasticizer and higher amount of superdisintegrant was found to provide the better result among other formulation. All the evaluation parameters were found optimized in the optimized formulation. Thus while designing the formulation we shall be focused for taking comparatively lower amount of film forming polymer i.e. HPMC E5, Intermediate amount of plasticizer i.e. Povidone K 30 and higher amount of superdisintegrant i.e. Kyron-T. Trisodium Citrate can be considered as best Saliva Stimulating agent for the film of Telmisartan as it solves the problem of insolubility of the Telmisartan by maintaining the pH in alkaline state.

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CONFLICT OF INTEREST:
There is no any financial and intellectual conflict in this work.

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