Research Article

Formulation and development of osmotic drug delivery system using push-pull techniques for BSC Class I drug

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ABSTRACT

Background: Oxybutynin HCL is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Push-pull osmotic pump can be used for delivery of drugs having extremes of water solubility. Drug along with osmogents is present in the upper compartment whereas the lower compartment consists of polymeric osmotic agents. **Objective:** Osmotic drug delivery system based on push-pull technique has been formulated in the form of bilayer tablets using wet granulation method. **Method:** The tablets were coated with semi permeable membrane of cellulose acetate followed by film coating. Precompressional parameters of matrix tablets (bulk density, tapped density, Carr's, index Hausner's ratio, and angle of repose) are in the range of official standard, indicated that granules prepared. The post-compression parameters of extended release tablets (hardness, friability, weight variation, thickness, and drug content) were within the limits. The tablets were evaluated physic-chemically. **Results:** In FTIR study showed, there were no any interaction between the Oxybutynin HCl drug into HPMC, butylated hydroxyl toluene polymers, and into the all excipients at molecular level. The drug release pattern of final formulation was tested over the period of 18 h and it was found to be 81% which was comparable to that of reference product. The formulation F8 follows first-order release kinetics and the drug release mechanism was found to be non-Fickian anomalous diffusion. Oxybutynin release from the developed formulations was inversely proportional to the osmotic pressure of the release media, confirming osmotic pumping to be the major mechanism of drug release. **Conclusion:** The optimized formulation was found stable at accelerated and long-term conditions.

Keywords: BCS Class 1, bilayer, controlled release, osmogent, oxybutynin HCL, push pull system

Introduction

The pharmaceutical industry over the past decades has been facing tough challenges in brining (NCEs) to market for prevention and treatment of existing and newer diseases. Furthermore, the cost of developing NCEs is continually rising, and today it costs around US $ 1 billion to bring one NCE to market.[1] The earliest studies in the field of controlled drug delivery date back to the 1950s. Since then, a large number of drug products with controlled release (CR) characteristics, have been introduced. The incredible growth can be attributed to several advantages that these products offer, including improved patient compliance, better therapeutic efficiency, potential for cost saving, patentability, and opportunity for extending product lifecycle. Various technologies have been investigated to achieve different kinds of modified release, for example, sustained, delayed, pulsatile, targeted, and programmed release. Regardless of the delivery type, the main mechanisms associated with drug transport in these systems include diffusion, swelling, erosion, ion exchange, and osmotic effect.[2] Among the various CR drug delivery systems available in market, oral CR systems hold the major market share because of their obvious advantages of ease of administration and better patient compliance.[3] A number of design options are available to control or modulate the drug release from an oral dosage form. The majority of oral CR dosage forms falls in the following categories, matrix systems, reservoir systems, and osmotic systems. In matrix systems, the drug is embedded in a polymer matrix and the release takes place by partitioning of drag into the polymer matrix and the release medium. In contrast, reservoir systems have a drug core surrounded/coated by a rate controlling membrane. However, factors such as pH, presence of food, and other physiological factors may affect drug release from conventional CR systems (matrix and reservoir). Osmotic systems utilize the principles of osmotic

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pressure for the delivery of drags. Drag release from these systems is independent of pH and other physiological parameters to a large extent and it is possible to modulate the release characteristics by optimizing the properties of drag and system. Osmotic pumps are well known for delivering drag at a zero-order rate. Osmosis is the phenomenon that makes controlled drug delivery a reality. Osmotic pressure created due to imbibition of fluid from external environment regulates the delivery of drug from the osmotic device. There are various factors that govern a particular pattern of drug delivery such as nature of semipermeable membrane, diameter of delivery orifice, surface area of semipermeable membrane, and nature and concentration of osmogent.[3] Osmotic drug delivery systems for oral and parenteral use offer distinct and practical advantages over other means of delivery. The following advantages have contributed to the popularity of osmotic drug delivery systems.[4] Desired zero-order delivery rate is achieved with osmotic systems as shown by *in vitro* and *in vivo* experiments. Delivery may be delayed or pulsed, if desired. For oral osmotic systems, drug release is independent of gastric pH and hydrodynamic conditions. Higher release rates are possible with osmotic systems compared with conventional diffusion-controlled drug delivery systems. The release rate of osmotic systems is highly predictable and can be preprogrammed by modulating the release control parameters. A high degree of *in vivo in vitro* correlation is obtained in osmotic system. The release from osmotic systems is minimally affected by the presence of food in the gastrointestinal tract (GIT). Push-pull osmotic pump can be used for delivery of drugs having extremes of water solubility. Drug along with osmogents is present in the upper compartment whereas the lower compartment consists of polymeric osmotic agents.[5] The drug compartment is connected to the outside environment through a delivery orifice. After coming in contact with the aqueous environment, polymeric osmotic layer swells and pushes the drug layer, thereby delivering the drug in the form of a fine dispersion through the orifice.[6]

Oxybutynin HCL is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Oxybutynin is a racemic (50:50) mixture of R- and S- isomers. Antimuscarinic activity resides predominantly with the R-isomer. Oxybutynin acts as a competitive antagonist of acetylcholine at postganglionic muscarinic receptors, resulting in relaxation of bladder smooth muscle. The active metabolite, N desethyloxybutynin, has pharmacological activity on the human detrusor muscle that is similar to that of oxybutynin in *in vitro* studies.[7-10] The aim of the present investigation was to develop bilayer osmotic drug delivery system using push pull techniques for BSC Class 1 drug, that is, oxybutynin HCL.

Materials and Methods

Materials

Oxybutynin HCl was obtained as gift sample from Sun Pharma, Polyox WSR 303 and Polyox WSR N80 were obtained from Gopal enterprises, ferric oxide red and black were obtained from Jaideep Chemicals Private Limited, sodium chloride was obtained from Anish Chemicals, Butylated hydroxyl toluene (BHT) was purchased from Ratnagiri Chemicals Pvt. Ltd, HPMC was purchased from Jigchem Universal, Lactose monohydrate, and magnesium state was purchased from Lasa Supergenerics Ltd, cellulose acetate was purchased from G M Chemical, Opadry Pink and Yellow were obtained as gift samples from Colorcon Asia Private Limited, ethylene glycol was purchased from Golden Dyechem, Mumbai, ethanol and acetone were used as analytical grade reagents.

Methods

Preparation of pronged released bilayer tablets by wet granulation method

Push layer

Polyox WSR 303, ferric oxide red, and ferric oxide black and sodium chloride were sifted through #24 mesh. This dry mix was mixed in RMG for 10 min at slow impeller. BHT and HPMC were dissolved in IPA under continuous stirring until clear solution is formed under mechanical stirrer (Granulating fluid). Dry mix was granulated with granulating fluid. The wet mass was air dried for 10 min in suitable dryer followed by drying at 45°C ± 5°C till desired LOD achieved (NMT 1%). Dried granules were sifted through #24 meshes. #24 meshes retain granules were passed through 1 mm screen fitted to multi-mill and continued till all granules pass through # 24 mesh. Magnesium stearate was passed through # 60 meshes and added to size granules in suitable blender. Lubrication was done for 5 min at slow speed of blender. Formula composition is presented in Table 1.

Pull/drug layer

Adjusted quantity of oxybutynin HCl, Polyox WSR N80 and sodium chloride were passed through #24 meshes. Sifted powder transferred to the clean dry bowl of RMG and dry-mix for 10 min at slow impeller. Slowly added dispensed quantity of BHT and HPMC to IPA and stirring continued till clear solution formed under mechanical stirrer. Dry-mixed powder was granulated using granulating fluid. Wet mass was unloaded in dryer bowl and air dry for 10 min and continued the drying at 45°C ± 5°C till LOD achieved NMT 1%. Dried granules were sifted through #24 meshes. Oversized granules were passed through 1 mm screen fitted to multi-mill, continued the milling till all granules pass through # 24 meshes. Magnesium stearate was passed through # 60 meshes and added to size granules and lubricated for 5 min at slow speed in suitable blender. Formula composition is presented in Table 1.

Compression and coating

Bilayer tablets were compressed using two different blends, that is, pull layer and push later using 7.6 mm diameter round punches. The tablets were coated with cellulose acetate solution prepared in water and ethanol as solvent system until desired weight gain is achieved to form semi permeable coating. CA coated tablets were drill to from desired orifice using laser drilling machine. Drilled tablets were further coated with Opadry film coating dispersion till desired weight gain achieved. Formula composition is presented in Table 1.

Characterization of tablets

Weight variation

Weight variation was determined by weighing 20 tablets of each formulation on an electronic balance (AG 64, Mettler-Toledo GmbH, Greifensee, Switzerland).[11]

Table 1: Oxybutynin HCl pronged released tablets formulation trials

Sr. No.	Ingredient	Grade	Function	T1	T2	T3	T4	T5	T6	T7	T8	T9
Pull/drug layer												
	Drymix											
1.	Oxybutynin HCl	NA	Active pharmaceutical Ingredient	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00	10.00
2.	Polyethylene oxide 200k	Polyox N80	Osmogent (pull layer)	70.90	60.90	75.90	70.90	70.90	70.90	70.90	70.90	70.90
3.	Sodium chloride	NA	Osmogene	6.00	6.00	6.00	6.00	6.00	6.00	6.00	4.00	8.00
4.	Lactose Monohydrate	Pharmatose 200M	Diluent	8.50	18.50	3.50	8.50	8.50	8.50	8.50	10.50	6.50
	Bindre solution											
5.	Butylhydroxytoluene	NA	Antioxidant	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10	0.10
6.	Hydroxypropyl methylcellulose	Hypromellose 5 cps	Binder	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00	9.00
7.	IPA	NA	Solvent	QS	QS	QS	QS	QS	QS	QS	QS	QS
	Lubrication											
8.	Magnesium stearate	Veg	Lubricant	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50	0.50
Weight of pull/drug layer				105.0	105.0	105.0	105.0	105.0	105.0	105.0	105.0	105.0
Push layer												
	Drymix											
1.	Polyethylene oxide 2000k	Polyox WSR 303	Osmogen (push layer)	41.04	41.04	41.04	36.04	46.04	41.04	41.04	41.04	41.04
2.	Sodium chloride	NA	Osmogene	14.40	14.40	14.40	19.40	9.40	14.40	14.40	14.40	14.40
3.	Black iron oxide (E172)	NA	Colorant	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
4.	Yellow oxide (E172)	NA	Colorant	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35	0.35
	Bindre solution											
5.	Butylhydroxytoluene	NA	Antioxidant	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06	0.06
6.	Hydroxypropyl methylcellulose	Hypromellose 5 cps	Binder	3.60	3.60	3.60	3.60	3.60	3.60	3.60	3.60	3.60
7.	IPA	NA	Solvent	QS	QS	QS	QS	QS	QS	QS	QS	QS
	Lubrication											
8.	Magnesium Stearate	Veg	Lubricant	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20	0.20
Weight of push layer				60.00	60.00	60.00	60.00	60.00	60.00	60.00	60.00	60.00
Weight of tablets				165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00	165.00
	Semipermeable/CA coating											
1.	Cellulose acetate	398-10	Semipermeable coating material	28.50	28.50	28.50	28.50	28.50	24.50	32.50	28.50	28.50
2.	Polyethylene glycol	PEG 3350	Plasticizer	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50	1.50
3.	Purified Water	NA	Solvent	QS	QS	QS	QS	QS	QS	QS	QS	QS
4.	IPA	NA	Solvent	QS	QS	QS	QS	QS	QS	QS	QS	QS
5.	Opadry Pink	NA	Film-coating material	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00	6.00
Weight of coated tablets				201.00	201.00	201.00	201.00	201.00	197.00	205.00	201.00	201.00

Hardness determination

The hardness of ten tablets was measured using a hardness tester before coating (6-D, Dr Schleuniger Pharmatron Inc., Manchester, NH).[11]

Friability

Friability was determined by testing ten tablets in a Roche Friability Tester. Accurately weighed ten tablets were placed in Roche Friabilator and rotated at 25 rpm for 4 min. The tablets were then de-dusted and re-weighed to determine the loss in weight. Friability was then calculated as percent weight loss from the original tablets.

Percentage friability was calculated using the following equation.

Friability = ([WO–W]/WO) ′ 100

Where; WO = weight of the tablet at time zero before the revolution.

W = weight of the tablet after revolutions at 4 min.

Tablet was showing good in friability testing.[11]

Effect of weight gain

To study the effect of weight gain of the coating on drug release, core tablets of oxybutynin final formulation were coated to obtain tablets with different weight gains (5%, 8%, and 12% wt/wt).[11]

FTIR spectroscopy

The chemical structure of the oxybutynin HCl, associated polymers and excipients were analyzed using FTIR spectrophotometer (FTIR-8400, Shimadzu, Asia Pacific Pvt. Ltd. Singapore) by KBr pellet method. Sample (1 mg) was mixed with KBr (40 mg) and formed into a disk by applying force in a manual press. Spectra were recorded in the scan range of 4000–400 cm^{-1}.

In vitro dissolution study (multimedia dissolution)

Drug release from tablets was performed *in vitro* using 0.1N HCl, pH 4.5 acetate buffer and pH 6.8 phosphate buffer for 18 h in dissolution test App. (model FC 6X12R Electrolab TDT — 08 L, India) Volume-900mL, Paddle with 50 rpm, and temperature 37 ± 0.5°C. Dissolution medium 10 ml was withdrawn at predetermined time intervals and replenished with same volume of fresh dissolution media to maintain the sink condition. The samples were filtered through a Whatman filter paper no. 41. The oxybutynin HCl, content of each sample after suitable dilution was assayed by UV spectroscopy at λ max of 202 nm using a 1 cm cell. The drug release was compared with reference product.[12]

Determination of release kinetics

The cumulative amount of drugs released from the optimized system at different time intervals was fitted to zero-order kinetics using least squares method of analysis to find out whether the drug release from the systems provides a constant drug release pattern. The correlation coefficient between the time and the cumulative amount of drug released was also calculated to find the fitness of the data to zero-order kinetics.[3,9]

Stability study

The developed formulations were stored for stability testing as per ICH guidelines. The chemical stability of the formulations was assessed by estimation of the percent drug remaining in the formulations; drug release pattern and physical stability were evaluated by monitoring any change in pH, appearance, spray pattern, leakage rate, and average weight per actuation.[9]

Results and Discussion

FTIR analysis

The FTIR peak values of oxybutynin HCl, HPMC, BHT and the all excipients are very much closed to FTIR spectra of optimized oxybutynin HCl tablet push-pull technique, indicating no existence of the interaction between the oxybutynin HCl, HPMC, and BHT, and the all excipients are shown in Figure 1.

In vitro dissolution study (multimedia dissolution)

In vitro dissolution of all formulations and reference product was carried out in 0.1 N HCl. It has been observed that trial 1 batch was found comparatively same dissolution profile as compare to reference product. Other formulations such as T2, T3, T5, T7, and T8 were found slower as compare to reference product while remaining formulations were observed faster than reference product. Comparative drug release profile is shown in Table 2 and graphically presented in Figure 2.

Among all these formulations trial 1 was considered as optimized formulation based on comparative dissolution profile with reference product. After swallowing of tablet by oral route it passes through various pH conditions throughout the GIT. So trial 1 final optimized formulation was carried out in multimedia dissolution (*in-vitro*). The results are presented in following table.

It has been observed that optimized formulation showed similar drug release profile in all three media when compared with reference product. These results clearly indicated the similarity of test product with reference product in all three selected media. Comparative dissolution profile is shown in following Figures 3-5.

Effect of ratio of drug to osmogent

To optimize the amount of osmogent to be used in the formulation and to study the effect of drug-to-osmogent ratio, core formulations were prepared with varying concentration of osmogen and it was clear from

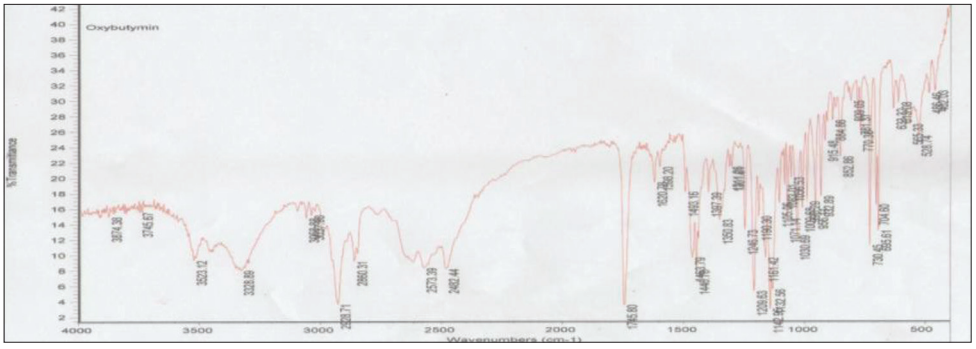

Figure 1: FTIR spectra of oxybutynin hydrochloride prepared formulation

Table 2: Dissolution data (media- 0.1N HCl, volume-900 mL, paddle with 50 rpm)

Batch no	IGBS100	Trial 1- Final batch	Trial 2	Trial 3	Trial 4	Trial 5	Trial 6	Trial 7	Trial 8	Trial 9
% CA coating (h)	Reference product	18.18%	18.1	18.1	18.1	18.1	15.7	20.6	18.1	18.1
1	1	1	1	0	6	0	4	1	1	1
2	12	13	10	5	33	6	25	9	17	16
4	23	24	18	10	54	13	44	16	35	34
6	36	35	28	15	74	19	61	28	52	53
8	48	50	40	22	87	25	76	39	67	68
10	60	60	52	28	93	35	86	50	77	80
12	71	72	61	34	96	44	90	60	79	87
14	81	82	70	40	98	55	93	68	83	89
16	86	85	78	46	99	63	94	74	86	90
18	89	92	84	49	99	72	93	78	87	92

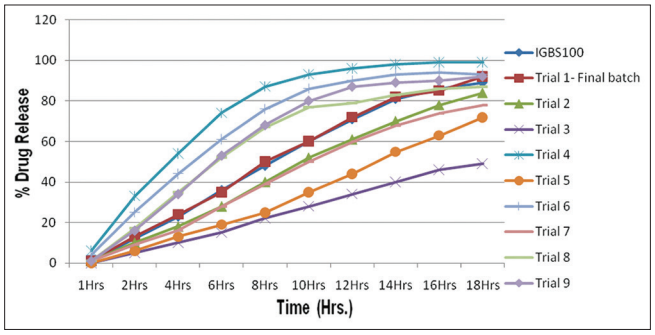

Figure 2: Comparative dissolution profile in 0.1N HCl

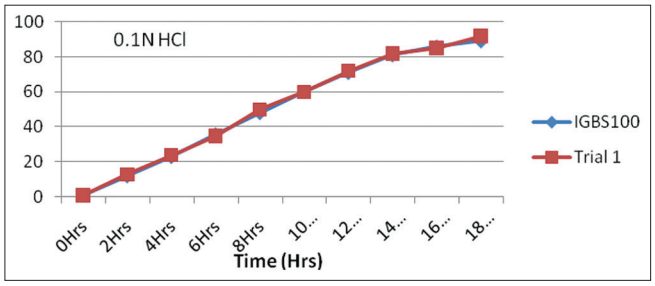

Figure 3: Multimedia dissolution data (volume-900 mL, paddle with 50 rpm) (0.1N HCl)

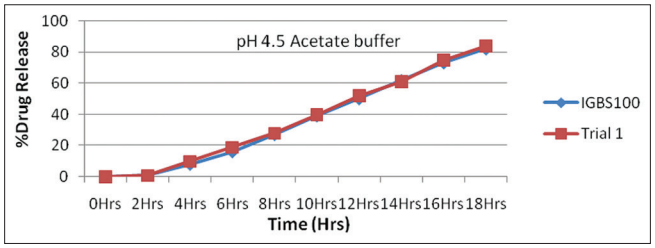

Figure 4: Multimedia dissolution data (volume-900 mL, paddle with 50 rpm) (pH 4.5 acetate buffer)

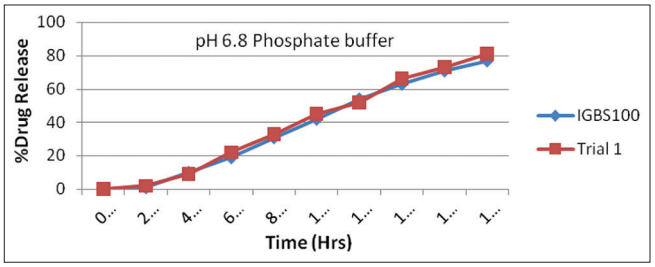

Figure 5: Multimedia dissolution data (Volume-900 mL, paddle with 50 rpm) (pH 6.8 Phosphate buffer)

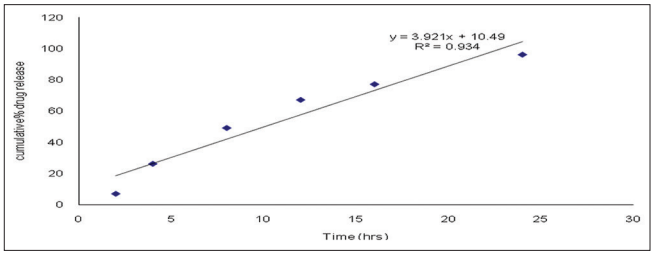

Figure 6: Zero-order of best formulation (cumulative % drug release)

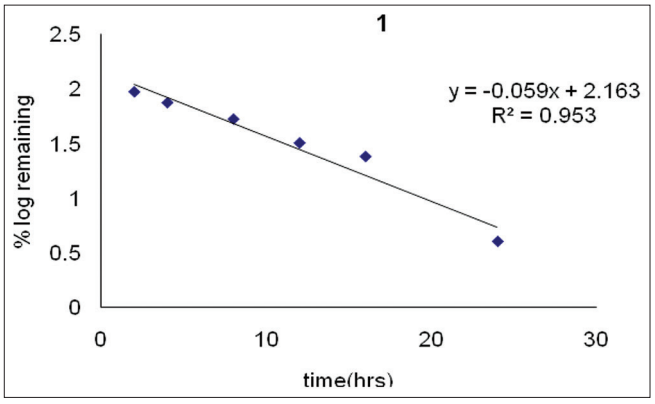

Figure 7: Zero-order of best formulation (% log remaining)

Figure 2 that osmogent enhances the release of drug and thus had a direct effect on drug release. This finding is evidenced from formulation final that was devoid of any osmogent in the core and showed 81% drug release at 24 h. However, the use of osmogent enhanced the release beyond 81% drug release at 24 h depending on the amount of osmogent present in the core formulation, which might be due to the increased water uptake and hence increased driving force for drug release.[13]

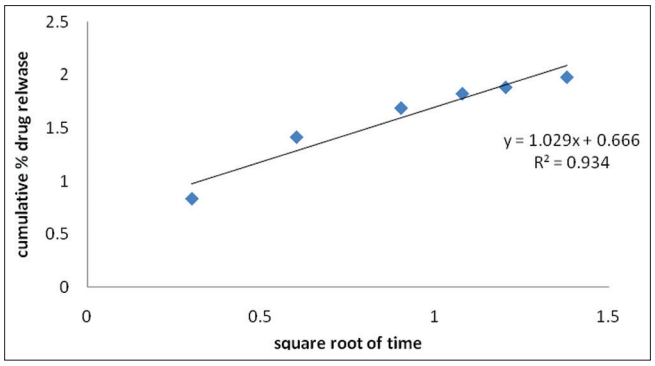

Figure 8: Higuchi of best formulation

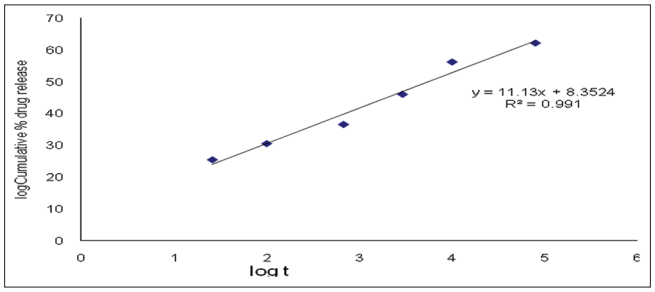

Figure 9: Korsmeyer–Peppas of best formulation

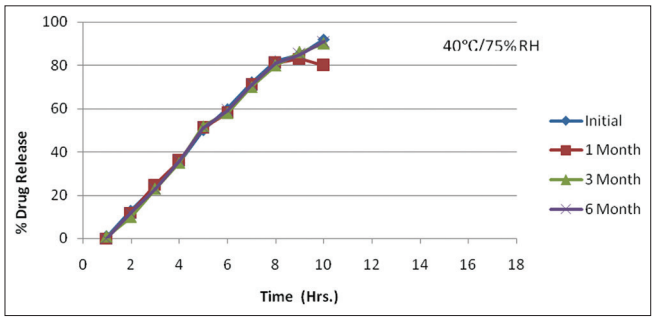

Figure 10: Dissolution data (media- 0.1N HCl, volume-900 mL, paddle with 50 rpm)- stability study (40°C/75% RH)

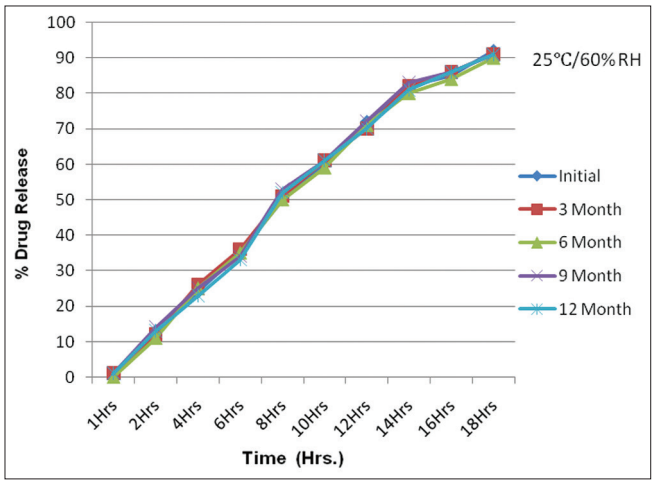

Figure 11: Dissolution data (media- 0.1N HCl, volume-900 mL, paddle with 50 rpm)- stability study (25°C/60% RH)

Effect of pH

The optimized formulation, final formulation was subjected to *in vitro* release studies in buffers with different pH. As can be seen from multimedia dissolution results and graphs shown above, there is no significant difference in the release profile, demonstrating that the developed formulation shows pH-independent release.[14]

Effect of osmotic pressure

To confirm the major mechanism of drug release, release studies of the optimized formulation were conducted in media of different osmotic pressure.[9] To increase the osmotic pressure of the release media (pre-equilibrated to 37°C ± 1°C), mannitol (osmotically effective solute) was added in SGF (without enzymes). Release studies were performed in 900 mL of media using USP dissolution apparatus (75 rpm). To avoid any interference in the analysis by lactose, residual drug analysis methodology was used for the construction of release profile. At predetermined time points, formulations were withdrawn from each vessel and cut open, and the contents were dissolved in sufficient volume of SGF. The samples were analyzed to determine the residual amount remaining in each formulation. The accuracy of this method was checked in SGF, where results after direct measurement of drug into the release media were similar to the results of residual drug analysis method. The effect of osmotic pressure on the optimized formulation was studied in media of different osmotic pressure, and the dissolution parameters with varying osmotic pressure are depicted in Table 3. The drug release rate decreased with increase in osmotic pressure in the media. It is evident that the drug release from the formulation decreased as the osmotic pressure of the media increased. This finding confirms that the mechanism of drug release is by the osmotic pressure.[15]

Drug release kinetics

The fitness of the data to first-order kinetics was assessed by determining the correlation coefficient between the time and the amount of drug to be released from the formulations. The results are presented in Table 4.

To understand the mechanism of drug release from the optimized system final formulation, the data were treated according to first-order (log cumulative percentage of drug remaining vs. time) along with zero-order (cumulative amount of drug released vs. time) pattern using least squares method of analysis, when the data were plotted according to the first-order equation shown in Figures 6-9.

Stability studies

Final formulation formulations were packed in strips of 0.04-mm thick aluminum foil laminated with polyvinyl chloride and stored in ICH certified stability chambers maintained at 40°C and 75% relative humidity for 3 months. The tablets were withdrawn periodically and evaluated for drug content, hardness, burst strength, and release studies.

Table 3: Multimedia dissolution data (volume-900 mL, paddle with 50 rpm)

Media	0.1N HCl		pH 4.5 Acetate buffer		pH 6.8 Phosphate buffer	
Batch no	IGBS100	Trial 1	IGBS100	Trial 1	IGBS100	Trial 1
% CA coating (h)	Reference product	Final batch	Reference product	Final batch	Reference product	Final batch
0	1	1	0	0	0	0
2	12	13	1	1	1	2
4	23	24	8	10	10	9
6	36	35	16	19	19	22
8	48	50	27	28	31	33
10	60	60	39	40	42	45
12	71	72	50	52	54	52
14	81	82	62	61	63	66
16	86	85	73	75	71	73
18	89	92	82	84	77	81

Table 4: Kinetic studies of tablets

Release kinetics	R^2	Intercept	Slope
Zero-order	0.934	10.49	3.29
First-order	0.953	4.964	–0.14
Higuchi	0.934	11.0	25.61
Korsmeyer–Peppas	0.991	0.66	0.74

Table 5: Comparative stability data of dissolution

Batch no	Final batch							
Pack	HDPE with 1 g Silica gel pouch							
Condition	40□/75% RH				25□/60% RH			
Interval (h)	Initial	1 M	3 M	6 M	3 M	6 M	9 M	12 M
1	1	0	1	0	1	0	1	1
2	13	12	10	12	12	11	14	13
4	24	25	23	23	26	25	25	23
6	35	36	35	36	36	35	34	33
8	50	51	52	51	51	50	53	52
10	60	58	58	59	61	59	61	61
12	72	71	70	71	70	71	72	70
14	82	81	80	81	82	80	83	81
16	85	83	86	85	86	84	86	86
18	92	80	90	91	91	90	91	91

The formulations were found to be stable in terms of drug content and dissolution stability shown in Figures 10 and 11 and Table 5.

The impurity profile was also found to be within acceptable limit over the period of 6 M in case 40°C/75% RH and for 12 h in case of 25°C/60% RH. The assay was also found to be within range throughout the stability period. No significant change was observed

Table 6: Assay and related substances data – initial and stability study

Batch no	Final batch								
Pack	HDPE with 1gm Silica gel pouch								
Condition	40°C/75% RH					25°C/60% RH			
Interval	Limits (%)	T0	1 M	3 M	6 M	3 M	6 M	9 M	12 M
Related substances									
Impurity-A	NMT 0.15	ND	ND	ND	ND	ND	ND	ND	ND
Impurity-B	NMT 0.15	0.02	0.04	0.04	0.06	0.04	0.04	0.06	0.09
Impurity-C	NMT 0.15	0.01	0.03	0.06	0.07	0.03	0.06	0.08	0.1
Impurity-D	NMT 1.0	0.08	0.1	0.19	0.48	0.12	0.15	0.18	0.36
Impurity-E	NMT 0.15	ND	ND	ND	ND	ND	ND	ND	ND
Single unknown maximum	NMT 0.2	0.02	0.06	0.07	0.1	0.04	0.05	0.08	0.11
Total impurity	NMT 2.0	0.24	0.2	0.34	0.63	0.2	0.3	0.3	0.6
Assay	95–105	101.5	101.8	100.5	100.9	102.5	100.5	101.5	101.1

shown in Table 6. This stability study implies the robustness of the formulation and it can be well accepted.

Conclusion

The FTIR peak values of oxybutynin HCl, HPMC, BHT and the all excipients are very much closed to FTIR spectra of optimized oxybutynin HCl tablet push-pull technique, indicating no existence of the interaction between the oxybutynin HCl, HPMC, BHT and the all excipients. *In vitro* dissolution profile of release tablets containing oxybutynin hydrochloride from the final formulation, drug release at 2nd 4th, 6th, 8th, 10th, 12th, 14th, 16th, and 18th h was found to be 2%, 9%, 22%, 33%, 45%, 52%, 66%, 73%, and 81%, respectively. The kinetic of drug release for final formulation was calculated and plotted. The formulation F8 follows first-order release kinetics and the drug release mechanism was found to be non-Fickian anomalous diffusion. The optimized formulation was compared with marketed product and showed similar release profile. The plot of time versus percentage of drug was release and was also given after the table the brief description about table and graph was also given for all formulations. Precompressional parameters of matrix tablets (bulk density, tapped density, Carr's, index Hausner's ratio, and angle of repose) are in the range of official standard, indicated that granules prepared. The post-compression parameters of extended release tablets (hardness, friability, weight variation, thickness, and drug content) were within the limits. A porous osmotic pump-based drug delivery system can be designed for CR of highly water-soluble drug oxybutynin. It is evident from the results that the rate of drug release can be controlled through osmotic pressure of the core, level of pore former, and membrane weight with release to be fairly independent of pH and hydrodynamic conditions of the body. Oxybutynin release from the developed formulations was inversely proportional to the osmotic pressure of the release media, confirming osmotic pumping to be the major mechanism of drug release.

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