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Formulation and Evaluation of Chewable Tablets of Loratadine by Wet Granulation Method

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Abstract
Chewable tablets are made especially for pediatric and geriatric patients. It improves the therapeutic efficacy and better bioavailability. Loratadine is a second-generation H1 histamine antagonist drug used to treat allergies. Loratadine is used for the symptomatic relief of allergy such as hay fever (allergic rhinitis), urticaria and seasonal allergies, including sneezing, itchy and runny nose, and tearing and redness of the eyes. It is a peripherally selective piperidine histamine receptor blocker, which competitively antagonizes histamine at the H1 receptor site. It stimulates the cells to release chemicals that produce effects associated with allergy and commonly acts on α-adrenergic receptor or 5-HT receptor.

Keywords: histamine receptor, α-adrenergic receptor, urticaria, Loratadine etc.

1. Introduction
Loratadine is a second-generation H1histamine antagonist under the therapeutic category of tricyclic antihistamine used to treat allergies. It is white to off white solid. The molecular weight is 382.883 g/mol. The melting point is 132 – 137 °C. The BCS class of the drug is class II. The empirical formula of loratadine is $C_{22}H_{23}ClN_2O_2$. [1] The IUPAC name of the drug is Ethyl 4-(8-chloro-5, 6-dihydro-11-H benzo [5, 6] cyclohepta (1, 2-b) pyridin-11-ylidine) 1-piperidinecarboxylate. The structural formula of the drug is given below:

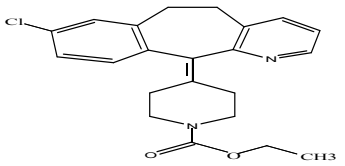

Fig 1: Structural representation of Loratadine Hydrochloride

2. Materials and methods
Loratadine hydrochloride, Lactose, Microcrystalline cellulose, Povidone K 30, Maize Starch, Colloidal Silicon dioxide, Magnesium Stearate, Talcum, Aspartame, Isopropyl Alcohol were provided by the Sky Lab, Rohtak as a gift sample.

3. Experimental methods [2, 3]
3.1 Formulation of chewable tablet by wet granulation method

Table 1: Formulation of trial batches using different concentration of excipients by Wet Granulation method

Batch No.	W 01	W 02	W 03	W 04	W 05	W 06
Ingredients	mg/tab	mg/tab	mg/tab	mg/tab	mg/tab	mg/tab
Loratadine	10	10	10	10	10	10
Lactose	155	100	70	90	85	85
Micro crystalline cellulose	-	50	60	50	50	50
Povidone K-30	20	10	20	15	15	10
Maize starch	120	153	154	150	150	150
Aspartame	20	12	25	20	15	25
Colloidal Silicon dioxide	6	7	-	6	5	5
Magnesium stearate	10	8	8	9	10	7
Talc	9	-	3	-	10	8
Isopropyl Alcohol	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Total	350	350	350	350	350	350

3.2 Preparation of chewable tablet by Wet Granulation Method

Loratadine tablet each weighing 350 mg containing 10 mg of Loratadine was formulated as follows:

- Intragranular and extragranular ingredients were weighed according to the formula.
- Intragranular (Loratadine, Lactose, Microcrystalline cellulose, Povidone-K30, Maize Starch, Aspartame, Colloidal silicon dioxide) ingredients were moistened with isopropyl alcohol and kneaded continuously until the subjective end point of suitable consistency was attained.
- The mixture was fed into Rapid mixture granulator and blended for 30 min. at 120 rpm.
- The granules were dried in Fluidized Bed Dryer at 55 °C and 40 air pressures.
- The extragranular Magnesium stearate and talc was weighed, sifted through sieve no. 60 and blended for 10 min. in quanta blender.
- The tablets were compressed into tablets using 16 station compression machine equipped with round and standard concave tooling of 8 mm with target weight of each tablet 350 mg.
- Six trial batches of Chewable tablets of Loratadine were formulated using Wet Granulation method as shown in table 1.

4. Evaluation of chewable tablet [4]

4.1 Precompression studies

Table 2: Bulk density, Tapped density, Angle of Repose, Hausner's ratio, Carr's index value of Different batches blend of Loratadine

Batch No.	Bulk Density	Tapped density	Angle of Repose	Hausner's ratio	Carr's index
W 01	0.487	0.663	38.1 (Passable)	1.36 (Passable)	26.54 (Passable)
W 02	0.496	0.635	38.7 (Passable)	1.28 (Passable)	21.8 (Passable)
W 03	0.520	0.669	38.5 (Passable)	1.29 (Passable)	22.3 (Passable)
W 04	0.492	0.630	26.05 (good)	1.28 (passable)	21.90 (passable)
W 05	0.498	0.635	31.8 (good)	1.27 (passable)	21.6 (passable)
W 06	0.530	0.629	29.5 (good)	1.18 (fair)	16.0 (fair)

From aforementioned results it was found that batches W 05 and W 06 exhibited acceptable flow properties with respect to angle of repose, Carr's index, Hausner's ratio.

4.2 Post-compression evaluation

Table 3: Evaluation parameters of tablets from different batches

Batch No.	Average weight (mg)	Thickness (mm)	Friability (%)	Hardness (kp)	Drug content
W 01	345.3	3.64	0.19	2.3	98.45
W 02	344.2	3.48	0.13	2.1	102.2
W 03	345.6	3.4	0.11	1.8	98.09
W 04	343.9	3.7	0.12	1.6	101.34
W 05	343.2	3.6	0.09	1.2	99.4
W 06	343.6	3.5	0.06	1.1	99.7

From aforementioned results of post compression parameters of formulated batches were found to be satisfactory.

4.3 *In-vitro* drug release studies

In vitro drug release rates of loratadine from chewable tablets were determined using USP type 2 apparatus (paddle). Trial formulation batches were prepared using wet granulation method and its release profile were compared to select the manufacturing process for further studies. Release profile of formulations (W 01 to W 06) is given in table 7.13. The cumulative % drug release was shown in Fig. 7.11.

Table 4: *In-vitro* Release profile of wet granulation trial batches (W 01 to W 06)

Time (min.)	% Cumulative drug release (Dissolution medium 0.1 N HCl)					
	W 01	W 02	W 03	W 04	W 05	W 06
0	0	0	0	0	0	0
5	5.81	7.10	13.71	14.23	18.87	27.79
10	20.5	24.64	36.21	38.06	42.19	49.98
20	42.3	53.52	65.00	68.33	71.64	85.58
30	60.19	71.30	77.18	80.79	87.89	100.00
45	78.27	87.75	89.39	93.46	100.00	100.00

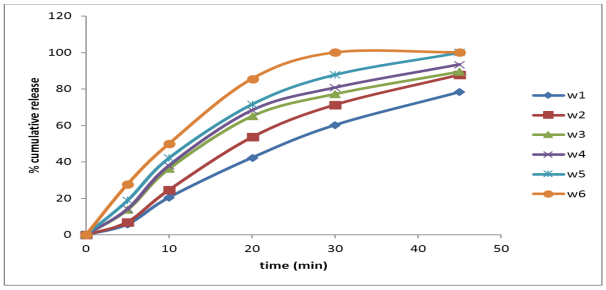

Fig 2: % cumulative drug release rate of wet granulation method (W 01 to W 06)

5. Comparison of Finally Selected Formulation with Marketed Formulation (Claritin)

The release profile of final optimized batch from wet granulation method (W 06) was compared to commercially marketed product. Release profile of both batches was given in table 5 and % cumulative drug release was shown in fig. 3.

Table 5: In-vitro drug release of final batch & commercial marketed product (Claritin)

Time (min.)	% cumulative drug release (Dissolution medium 0.1 N HCl)	
	W 06	Claritin tablet
0	0	0
5	27.79	18.5
10	49.98	32.25
20	85.58	65.14
30	100.00	79.94
45	100.00	98.66

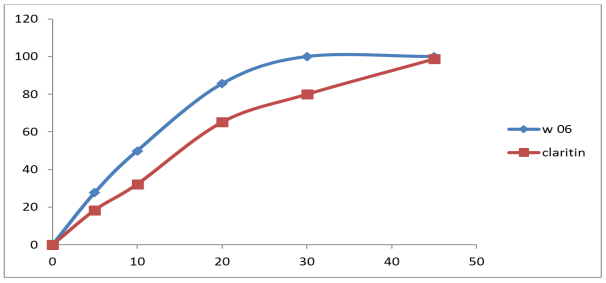

Fig 3: Comparison of % cumulative drug release rate of marketed formulation with final formulation (W 06)

6. Summary

The present research work involved the formulation and evaluation of chewable tablet of loratadine by wet granulation method. Six formulations were developed keeping different concentration of excipients. Superdisintegrants Povidone (Polyvinylpyrrolidine) was used in varying concentrations. One of the selected best formulations (W 06) was compared with that of the marketed conventional tablet formulation of Loratadine (Claritin) for its in vitro drug release performance.

7. Conclusion

The absorbance maxima of Loratadine were found to be 279 nm. Formulation was prepared by wet granulation. Comparison of formulation (W 06) with the marketed tablet formulation of loratadine (Claritin) showed better drug release profile. On the basis of present research finally, it can be concluded that the Chewable tablet of loratadine may be used in clinical practice for treatment of allergic infections.

8. References

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