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FORMULATION AND EVALUATION OF OXYMETAZOLINE AS NASAL DECONGESTANT

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ABSTRACT

Nasal drug delivery systems offer rapid onset of action, improved patient compliance, and localized therapeutic effects, making them suitable for the treatment of nasal congestion. Oxymetazoline hydrochloride, a selective α-adrenergic receptor agonist, is widely used as a topical nasal decongestant due to its potent vasoconstrictive action on nasal mucosa. The present study aimed to formulate and evaluate oxymetazoline hydrochloride nasal spray using different concentrations of propylene glycol as a solubilizing agent. Five formulations (F1–F5) were prepared and evaluated for physicochemical properties, drug content, viscosity, spray characteristics, droplet size distribution, sterility, and irritancy. The formulations exhibited acceptable pH values (6.9–7.4), uniform drug content, clarity, and non-irritant behavior. Among all formulations, F5 showed optimum viscosity, highest drug content (98.45%), appropriate droplet size distribution, and stability. The results indicate that oxymetazoline hydrochloride can be effectively formulated as a stable, safe, and efficient nasal decongestant, with formulation F5 identified as the optimized batch.

KEYWORDS: Oxymetazoline hydrochloride, Nasal decongestant, Nasal spray formulation, Alpha-adrenergic agonist, Spray evaluation, Droplet size distribution.

1. INTRODUCTION

Nasal congestion is a common symptom associated with allergic rhinitis, sinusitis, and upper respiratory tract infections. It occurs due to inflammation and vasodilation of blood vessels in the nasal mucosa, leading to edema and

airway obstruction. Topical nasal decongestants are frequently used to provide rapid relief by causing vasoconstriction of the nasal blood vessels.

Oxymetazoline hydrochloride is an imidazoline derivative that acts as a selective α_1-adrenergic receptor agonist and partial α_2-agonist. Its mechanism involves vasoconstriction of arterioles in the nasal mucosa, thereby reducing swelling and improving airflow. Due to minimal systemic absorption when administered nasally, oxymetazoline is preferred for short-term management of nasal congestion.

The effectiveness of nasal spray formulations depends on several factors, including pH, viscosity, droplet size, spray pattern, and pump performance. Proper formulation ensures uniform drug delivery, patient comfort, and therapeutic efficacy. This study focuses on the formulation of oxymetazoline hydrochloride nasal spray using varying concentrations of propylene glycol and evaluation of its physicochemical and performance characteristics to identify an optimized formulation.

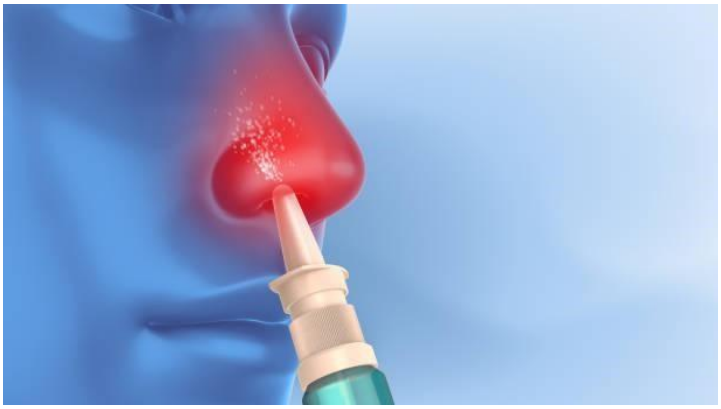

Fig. 1: Nasal Decongestant.

2. DRUG PROFILE

Oxymetazoline

Oxymetazoline is a selective alpha 1 adrenergic receptor agonist and alpha 2 adrenergic receptor partial agonist. It is a topical decongestant, used in the form of oxymetazoline hydrochloride. It was developed from xylometazoline at E. Merck Darmstadt by Fruhstorfer in 1961.

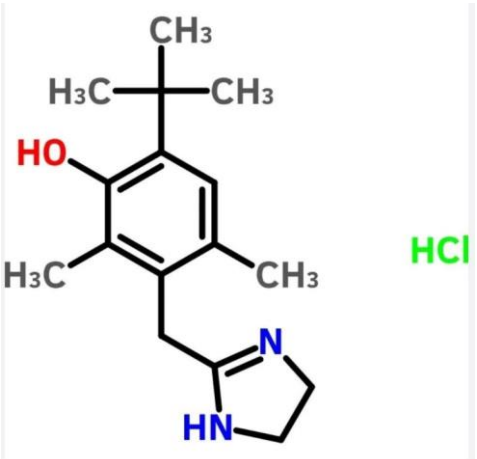

Fig 1: Structure of Oxymetazoline.

- **Formula**: $C_{16}H_{24}N_2O$
- **Molecular weight**: 260.39 g/mol
- **Trade name**: Afrin, Ocuclear, Drixine
- **Elimination half life**: 5-6 hours
- **Dependence liability**: Moderate
- **Mechanism of Action**: Oxymetazoline is a selective α adrenergic receptor agonist — primarily acting on: α_1-adrenergic receptors (strong activation) α_2 adrenergic receptors (partial agonist activity)
- **Effect:** Causes vasoconstriction of arterioles in the nasal mucosa. This reduces blood flow, leading to decreased swelling, mucosal edema, and nasal congestion relief.
- **Absorption:** Minimal systemic absorption when used topically (nasal). However, overuse or damaged mucosa can increase absorption and systemic effects.
- **Distribution**: Limited data; expected to stay mostly local at site of application. May cross mucosal barriers in small amounts.
- **Metabolism:** Primarily hepatic metabolism (likely via monoamine oxidase — MAO — and possibly CYP enzymes). Exact pathways not fully defined in humans.
- **Elimination:** half-life (t½) Approximately 5–8 hours (systemic exposure data limited).
- **Excretion:** Metabolites excreted mainly in urine.
- **Bioavailability:** Very low with topical/nasal administration (<5%), higher with oral exposure (not recommended orally).

3. MATERIALS AND METHODS

3.1 FORMULATION OF NASAL DECONGESTANT

Table 1: Preparation of Nasal Decongestant.

S. NO	FORMULATION	F1	F2	F3	F4	F5
1	OXYMETAZOLINE	0.4	0.4	0.4	0.4	0.4
2	BENZALKONIUM CHLORIDE	0.02	0.02	0.02	0.02	0.02
3	PROPYLENE GYLCOL	_	_	0.8	1.2	1.4
4	EDTA	0.006	0.006	0.006	0.006	0.006
5	DIBASIC SODIUM PHOSPHATE	1.0	1.0	1.0	1.0	1.0
6	DISTILLED WATER	30ml	30ml	30ml	30ml	30ml

Procedure

- **Step 1:** All the five batches of the prepared formulation contains 4mg of Oxymetazoline per ml.
- **Step 2:** Total quantity of 30ml of formulation for 4mg of Oxymetazoline and 0.006gm of EDTA were dissolved in the proposed ratio of solubilizer and sonicated for the period of 30 mins.
- **Step 3:** The Propylene glycol in different proportion of the volume was made up 15ml.
- **Step 4:** Then add 0.02% of Benzalkonium chloride pH 6 was adjusted with 0.IM of sodium hydroxide with Dibasic sodium phosphate was prepared.
- **Step 5:** Cooled at room temperature, volume make up to 30ml with Distilled water.
- **Step 6:** Stored in cool place.

3.2 EVALUATION PARAMETERS

3.2.1 Physical Paramete

The prepared decongestant were inspected visually for their color, odour. The pH was measured using a pH meter, which was calibrated before each use with standard buffer solutions of pH 4, 7, 9. The electrode was inserted in to the sample 10 min priors to taking the reading at room temperature.

- **Colors:** All the formulation were tested for color by visual inspection. They were checked against white.
- **Odours:** The odors of all formulation were checked by mixing them in water.
- **pH:** Weighed 30ml formulation were transferred in 10 ml of the beaker and measured it by using the digital pl meter. pH of the topical gel formulation should be between 3-9 to treat the skin infections.

3.2.2 Drug Content

Weighed 10 ml of formulation were transferred in 250 ml of the volumetric flask containing 20 ml of alcohol and stirred for 30 min. The volume was made up to 100 ml and filtered. I ml of the above solution was further diluted to 10 ml with alcohol and again 1 ml of the above solution was further diluted to 10 ml with alcohol. The absorbance of the solution was measured spectrophotometrically at 260 nm. Drug content was calculated by the following formula

$$\text{Drug content} = \text{Absorbance/Slope} \times \text{Dilution Factor} \times 1/1000$$

3.2.3 Irritancy Test

Mark an area (Isq.cm) on the left hand dorsal surface. The solution was sprayed into the specified area and time was noted. Irritancy, erythema, edema, was checked if any for regular intervals up to 24 hrs and reported.

3.2.4 Viscosity Measurement

Viscometer can be used to measure the viscosity of prepared formulations. They are rotated at 0.3. 0.6 and 1.5 rotations per minute. At each speed, the corresponding dial reading is noted. The viscosity is obtained by multiplication of dial reading with factor given in the viscometer catalogues.

3.2.5 Appearance & Clarity

The formulated solutions were evaluated as in-house test for appearance (color) as well as their clarity. The color and clarity were visually examined against black and white surface in inspection.

3.2.6 Spray Content Uniformity

The spray content uniformity as important parameter for nasal spray, was studied to investigate the spray discharged from the nosepiece for the drug substance content. The examination was carried out for multiple spray form single container and in different container for the same. This test will determine an overall performance evaluation of the formulate batch, which will assess the pump selection. The acceptance criteria was nominated as the amount of drug substance not outside of 80-120 percent of label claim for more than 1 of 10 containers , none of the determination is outside of 75-125 percent of the label claim , and the mean is not outside 85- 115 percent label claim.

3.2.7 Pump Delivery

The pump delivery as well as spray content uniformity are related constraints implicating substantial effect on the product enactment. The formulation was evaluated for pump-to-pump reproducibility and the metering capability of the pump. The formulation was filed into the container closure, which was further actuated for 10 times in a pre-weighed bottle. The weight of the bottle was reweighed after 10 actuations and the difference was calculated.

3.2.8 Spray Pattern

The characterization of spray is the pathway through which the performance of the pump and the nozzle of container closure system need to be evaluated. In the evaluation of the spray pattern, the spray distance between the nose- piece and the collection surface. orientation of the nose-piece, and visualization procedure are specified. Spray Pattern of prepared nasal spray formulation was measured by the Spray view system. The parameters of spray pattern assessment are height at 30mm, evacuation time 15000 millisecond, inclination as 65.40 and summation mode as automatic.

3.2.9 Droplet Size Distribution

The in-vivo deposition of the formulation in cavity is affected by droplet size analysis of the formulation spray. The major factor that influences the droplet size is the delivery device and the formulation. The USDA guideline for nasal aqueous spray formulation states that there must be appropriate control for droplet size distribution of the delivered plume. The droplet size distribution can be controlled in terms of D10, D50, and D90 by utilization of laser diffraction

3.2.10 Sterility

Sterility is one of the most mandatory requirement for nasal preparation. The support for the test is that at fortunate conditions (temperature as well as nutrition) the microorganisms will grow, which can be recognized by turbidity in the medium. The method used was as per USP general chapter sterility tests.

4. RESULTS AND DISCUSSION

Table 2: Evaluation of Nasal Drops.

S.NO	FORMULATION	APPEARANCE	PH	DRUG CONTENT	VISCOSITY
1	F1	CLEAR	6.9	89.01	13.33±0.57
2	F2	CLEAR	7.4	89.99	14.33±1.15
3	F3	CLEAR	7.2	88.31	15.33±0.57
4	F4	CLEAR	7.4	95.13	17.00±1.00
5	F5	CLEAR	7.4	98.45	18.33±0.57

Table 3: Evaluation of Nasal Drops.

S.NO	FORMULATION	SIZE OF DROPLET	STABILITY	IRRITATION	PERCENTAGE CONTENT
1	F1	51.90±3.28	-	NIL	95.41±0.89
2	F2	51.63±4.72	-	NIL	95.81±0.62
3	F3	52.42±2.97	-	NIL	96.60±1.29
4	F4	56.59±3.19	-	NIL	95.34±0.72
5	F5	57.77±3.63	STABLE	NIL	98.86±0.93

DISCUSSION

- The nasal decongestant formulation was developed by utilizing factorial design approach. The drug-excipient compatibility study endorsed no interaction between oxymetazoline and the excipients.
- The parameters for solution formulation such as drug content, pH, viscosity, sterility and pray evaluation like spray content uniformity, pump delivery, spray pattern, and weight loss were evaluated.
- The results for spray content uniformity were in the range of 95-102%, while PH in the range of 6.9 to 7.4. The osmolality of spray was 1.118, while perimeter and area of spray pattern were found to be 57.42 mm and 258.8 mm2 respectively for optimized formulation.
- The least value for repriming was 97.6% while the extreme value was 102.2% indicating one actuation was satisfactory for repriming. The results for droplet size test were obtained in the range of 57.77 to 60.90µm.

- The present work was carried out to Formulate and evaluate oxymetazoline hydrochloride. The Evaluation of Oxymetazoline Hydrochloride Nasal Decongestant performed with the clarity test will be transparent. Viscosity of various formulated Nasal drop was found in range of 18.33 to 19.42 centipoises.
- The percentage drug content of formulations was found satisfactory. The *In-vitro* release of oxymetazoline HCl was prolonged release of drug ranges from 98.45% of released within 7 hour. Among the five formulations the best formulation is F5 formulation.

5. CONCLUSION

The present study successfully formulated and evaluated oxymetazoline hydrochloride nasal decongestant using different concentrations of propylene glycol. All formulations exhibited satisfactory physicochemical properties, drug content uniformity, clarity, sterility, and non-irritant nature. Evaluation of spray characteristics confirmed acceptable pump delivery, spray pattern, and droplet size distribution essential for effective nasal deposition. Among the five formulations, F5 demonstrated superior performance in terms of stability, viscosity, drug content, and droplet size, making it the most optimized formulation. The study concludes that oxymetazoline hydrochloride can be effectively delivered through a nasal spray system, providing a safe and efficient treatment option for nasal congestion.

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