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OXIDATIVE DETERMINATION OF SOME ANTIHISTAMINE DRUGS IN PURE FORM AND THEIR PHARMACEUTICAL PREPARATIONS BY USING PYRIDINIUM FLUORO CHROMATE (PFC) REAGENT

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ABSTRACT: In this paper Chromium (VI) based Pyridinium fluoro chromate (PFC) reagent has been used as an oxidant for the determination of some antihistamine drugs *e.g.* Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) in pure form and their pharmaceutical preparations such as Phenergan (Injection and tablet) and Avil (Tablet and injection) respectively. The main principle of this method is based on the fact, that each pharmaceutical drug contains a specific organic functional group, which on oxidation in the presence of selected oxidant (Here PFC is used as an oxidant) provides the new oxidized product. This type of oxidation reaction between the drug molecule and an oxidant establishes a stoichiometric relationship between the drug molecule and an oxidant. This relationship is the basis of quantitative estimation of drugs in pure form and their pharmaceutical preparations. In this research, oxidizing reagent Pyridinium fluoro chromate (PFC) oxidizes the sulfur atom of Promethazine hydrochloride (PMH) to the corresponding sulphoxide, whereas in case of Pheniramine maleate (PM) it oxides one hydroxyl (-OH) group of carboxylic (-COOH) group to corresponding aldehydic (-CHO) group. Thus an oxidant PFC establishes a 1:1 ratio with both Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) drug. Oxidative determination of these drugs was carried out by adopting the iodometric titration (Visual volumetric) method. The applied technique was very simple, convenient, accurate, precise and economical. To examine the accuracy and precision of results various statistical analysis such as percentage error, standard deviation (SD) and coefficient of variation (CV) was also calculated for each sample. The proposed method was validated by recovery analysis, by drug addition method.

INTRODUCTION: An antihistamine [1-4] is a kind of drug that is used to neutralize the effects of histamine, or inhibits its production in the body.

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Antihistamines do not stop the allergic reactions but protect tissues of the body from some of its effects. Histamine is generally present in rich amounts in the tissues of skin, lungs, liver and also in blood and is responsible for the allergy in the body.

Antihistamine drugs are mainly used to cure itching (pruritus), hives (urticaria), hay fever (seasonal allergic rhinitis), insect bites and stings. It is also used to reduce the feeling of sick (nausea) and sick

(vomiting) beside this also useful in the treatment of anxiety, bronchial asthma, and in some cases to relax patients before surgery. Here the selected drugs Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) belongs to first-generation antihistamines. The drug Promethazine hydrochloride (PMH) is chemically known as N, N-dimethyl-1 -phenothiazine-10 -ylpropan- 2-amine hydrochloride **Fig. 1** and Pheniramine maleate is chemically known as N, N-dimethyl-3-phenyl-3-(2-pyridyl) propylamine hydrogen maleate **Fig. 2**.

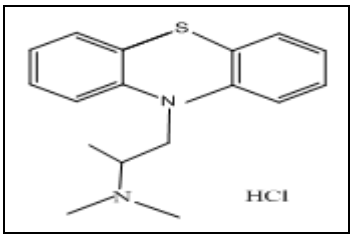

FIG. 1: STRUCTURE OF PROMETHAZINE HYDROCHLORIDE

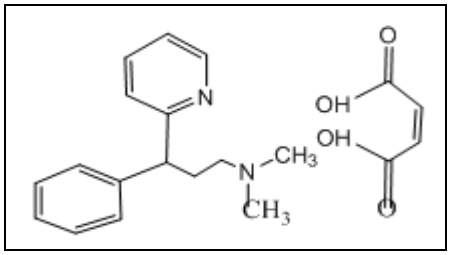

FIG. 2: STRUCTURE OF PHENIRAMINE MALEATE

Many researchers in their work have employed different oxidants for the determination of different pharmaceutical drugs such as Cu (III) [5-7] has been employed as an oxidant for the determination of antibiotic, antihypertensive and antibiotic, in pure form and their pharmaceutical preparations. Determination of Promethazine hydrochloride, in pharmaceutical drugs, was successfully achieved by using N-bromosaccharin [8] (NBS) as an oxidizing reagent. Similarly, an oxidant N-chlorosuccinimide [9] (NCS) reagent in acidic medium was used for the determination of some antineoplastic drugs. Reagent Pyridinium fluoro chromate [10, 11] (PFC) was used for the determination of Cyproheptadine hydrochloride and Fexofenadine hydrochloride drugs in pure and in their pharmaceutical preparations.

Other oxidants like Potassium permanganate [12-14] was used for the assay determination of pharmaceuticals like Pioglitazone hydrochloride in an acidic and basic medium, Diethylcarbamazine citrate and Albendazole in pharmaceutical drugs. Reagent Perchloric acid [15, 16] has been as an oxidant for the determination of lansoprazole in pharmaceutical capsules and isoniazid. Similarly in another experiment, Potassium iodate [17] and Cerium (IV) [18] was employed as an oxidant for estimation of ethionamide in pharmaceutical formulations. Oxidant diperiodatocuprate (III) [19] in an aqueous alkaline medium, has been used to oxidize aspartame.

Literature survey revealed that various techniques had been reported, by different researchers, for the determination of Promethazine hydrochloride (PMH) and Pheniramine maleate (PM). Techniques like Spectrophotometric [20-22] and Chromatographic techniques [23, 24] for Promethazine hydrochloride (PMH) whereas Potentiometric titration [25], Spectrophotometric [26] and Chromatographic [27, 28] technique has been employed by different researchers for the determination of Pheniramine maleate (PM) in bulk and its pharmaceutical formulations. Although different researchers have used various chromium (VI) based oxidant but up to till date no any researcher has employed Pyridinium fluorochromate as the oxidant, for the determination of both antihistamines, *i.e.* Promethazine hydrochloride (PMH) and Pheniramine maleate (PM). Besides this various technique as cited above, have been adopted by various researcher's for the assay determination of above said antihistamine drugs but all techniques involve sophisticated instruments and have been observed that these instrumental methods are generally not as accurate and precise, as the titrimetry in microanalysis.

In this paper, simple, accurate, precise, rapid and cost-effective visual titrimetric technique (Volumetric titration technique) has been described for the assay determination of these drugs in a form pure and in their formulations in the form of tablets and injections. This technique is easily adaptable to pharmaceutical companies for the quality control assessment of these drugs, in their routine quality analysis.

MATERIALS AND METHODS:

Apparatus: Graduated Pipette, Measuring cylinders, Burette, Iodine flask (Stoppered flask),

etc. were used to carry out volumetric titration successfully.

Materials: Double distilled water and all other chemicals used in the analysis were of analytical reagent grade and was used throughout the experiment. A pure pharmaceutical grade Promethazine hydrochloride (PMH) has been supplied by Akums Drugs and Pharmaceuticals Ltd, 304, Mohan Place, L.S.C., Block-C, Saraswati Vihar, New Delhi, India as gift sample and pure sample of Pheniramine maleate (PM)) supplied on request, as gift sample by Sanofi India Ltd, Ankleshwar, Distt-Bharuch, Gujarat, India as gift sample whereas for pharmaceutical preparations of Promethazine hydrochloride (PMH), tablet Phenergan-10 mg and Injection Phenergan -2 ml (Manufactured by Akums Drugs and Pharmaceuticals Ltd., Ranipur, Haridwar, Uttarakhand, India) and similarly for Pheniramine maleate (PM) tablet Avil-25 mg and injection Avil-10ml (Manufactured by Sanofi India Ltd., Ankleshwar, District Bharuch, Gujarat, India) has been purchased from commercial sources in the local market.

Reagents and Solutions:

A solution of Pyridinium Fluoro Chromate (0.03 N): Solution of 0.03N PFC was prepared by dissolving 0.497 gm of PFC in 150 ml glacial acetic acid (MERCK) and made up the volume with distilled water in 250 ml volumetric flask.

The prepared solution was standardized iodometrically with standard Sodium thiosulphate solution using starch as an indicator.

A solution of Sodium Thio Sulphate (0.01 N): A 0.01 N stock solution of sodium thiosulphate (0.01N) was prepared by dissolving 3.16 gm of sodium thiosulfate (Anhydrous) AR grade of HI MEDIA in distilled water of 1000 ml volumetric flask and made up to the mark with distilled water.

The stock solution prepared in this way was standardized by using 0.01 N potassium dichromate (Moly Chem) solution iodometrically by using starch as an indicator.

Solution of Potassium Dichromate (0.01 N): A 0.01 N stock solution of $K_2Cr_2O_7$ was prepared by dissolving 0.245 gm of $K_2Cr_2O_7$ (A.R Grade of Moly Chem) in distilled water of 500 ml volumetric flask.

Potassium Iodide (10%): The Potassium iodide used for an experiment is of AR grade of RANKEM. 10% w/v aqueous solution was prepared in distilled water.

Starch Solution (1%): A solution of 1% of W/V aqueous solution of starch (LOBA Chemie) was prepared in boiling distilled water. The paste formed this way was filtered and kept to cool for some minutes. Always fresh starch solution has been prepared for accurate results.

Preparation of Drug Solutions:

Preparation of Pure Solution of Promethazine Hydrochloride (PMH) and Pheniramine Maleate (PM): Taken 100 mg pure compound of Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) in two 100 ml volumetric flask separately, supplied on request, as gift sample by Akums Drugs and Pharmaceuticals Ltd, 304, Mohan Place, L.S.C., Block-C, Saraswati Vihar, New Delhi, India and Sanofi India Ltd, Ankleshwar, District Bharuch, Gujarat, India respectively. Solutions of both the flask were first dissolved in minimum quantity of distilled water.
Both solutions of the volumetric flask have been shaken thoroughly, for twenty minutes so that compound may dissolve adequately. After getting a homogenous solution, the flask was made up to the mark with distilled water.

Preparation of Solution for Pharmaceutical Formulations:

For Phenergan -10 mg Tablet Containing Promethazine Hydrochloride (PMH) and Avil-25 mg Tablet Containing Pheniramine Maleate (PM): The 20 Phenergan- 10 mg tablets manufactured by Akums Drugs and Pharmaceuticals Ltd., Ranipur, Haridwar, Uttarakhand, India and 20 tablets of Avil- 25 mg manufactured by Sanofi India Ltd, Ankleshwar, District Bharuch, Gujarat, India has been obtained from local commercial source, and both types of these tablets were ground into an excellent power separately. The powder equivalent to 100 mg of sample, was taken, in two 100 ml calibrated flask individually and dissolved in the same process as described above for the pure solution of PMH and PM.

For Phenergan -2 ml Injection Containing Promethazine Hydrochloride (PMH) and an Avil-10 ml Injection Containing Pheniramine Maleate (PM): The contents of 20 ampoules Phenergan- 2 ml injection manufactured by Akums Drugs and Pharmaceuticals Ltd., Ranipur, Haridwar, Uttarakhand, India and similarly 20 ampoules Avil-10 ml injection manufactured by Sanofi India Ltd., Ankleshwar, District Bharuch, Gujarat, India were mixed properly and volume of these injections equivalent to 100 mg of the pure sample were taken separately and diluted up to the mark with distilled water in 100 ml calibrated flask, so that concentration of flask become 1 mg/ml.

Method: Aliquots of drug samples containing 1 to 5 mg were taken in 100 ml stoppered conical flask (Iodine flask) and to this 5 ml of 0.03 N PFC reagent (Prepared in 60% acetic acid) was added to it. Again 10 ml of 5N sulphuric acid was added to the same reaction mixture of said flask. Thereafter reaction mixture was shaken thoroughly, to mix the contents of flask properly and kept to stand the whole solution of flask for required reaction time at room temperature (25-30 ºC) so that reaction between the contents of flask may be completed. After the completion of reaction 5 ml of 10% KI was added to the same reaction mixture, and the whole reaction mixture was shaken again and adequately allowed to stand for one minute. The unconsumed PFC was determined by iodometric titration by using starch as an indicator.

Similarly, blank experiment was also performed using all the regents under the identical condition, except the drug sample. The amount of PFC consumed for the given drug sample was calculated by the difference in the titre values of sodium thiosulphate solution for a blank and actual experiment. To validate the adopted method, the recovery of the drug sample was calculated with the amount of PFC consumed for the sample. Later on, for accuracy and precision percentage error, the coefficient of variation and standard deviation of each drug sample were calculated. Finally, Standard Drug Addition method was also performed to evaluate the authenticity of the method.

Expressions Used in Calculation: The expression used to determine the amount of drug present in the measured aliquot for each experiment is as follows:

$$\text{Weight (mg) of sample} = \frac{M_W \text{ X } N\ (V_B - V_S)}{n} \quad \ldots.(1)$$

Where, M_w = Molecular weight of the sample, N = Normality of sodium thiosulphate solution. V_B = Volume of sodium thiosulphate solution for blank. $V_{s.}$ = Volume of sodium thiosulphate solution for sample, n = Stoichiometry of the reaction.

By using the above mentioned method and expression the determination of Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) has been carried out for 1-5 mg of a pure sample of PMH and PM. Similarly, for their pharmaceutical formulations (*i.e.*, PHENERGAN- 10 mg and injection PHENERGAN- 2 ml and AVIL- 25 mg and AVIL- 10 ml) but convenience, the results as recorded in **Table 1** has been considered only for 1, 3 and 5 mg of sample size.

For the justification and validation of the proposed method, the recovery experiment was carried out by using standard drug addition method **Table 2** and **3**. In this experiment, a known amount of the pure compound is taken, and to this, varying amounts of the pharmaceutical preparations of the same compounds are added. Finally, the total amount of the sample was calculated by the expression:

$$\% \text{ Recovery} = \frac{N(\sum PQ - (\sum P)(\sum Q)}{N(\sum P^2) - (\sum P)^2} \times 100 \quad \ldots\ldots(2)$$

Where, N= $\sum N$ = Total number of observations, P = Amount of drug added, Q = Amount of drug obtained by calculation, $\sum P = \sum NP$, $\sum Q = \sum NQ$, $\sum PQ = \sum(NP)(Q)$, $\sum P^2 = \sum(NP)(P)$.

RESULTS AND DISCUSSION: The results as recorded in **Table 1** were carried out for PMH and PM aliquots of 1 ml to 5ml, but for convenience only 1, 3 and 5 mg has been shown. All sample sizes of both the drugs, *i.e.* PMH and PM always established a stoichiometric ratio for PMH: PFC and PM: PFC to be 1:1. This stoichiometric ratio is similar for both, i.e. for a pure sample of drug and for pharmaceutical formulations. This stoichiometric ratio 1:1 remains constant for even under varying reaction conditions, *i.e.* in varying reaction time, the concentration of the reagent, reaction temperature, and reaction medium, *etc*.

It has also been observed that 0.03N concentration of PFC and reaction 10 minutes for PMH whereas 15 min for PM, at room temperature, is the most appropriate condition for the determination of both the drugs. The effect of reaction medium has also been studied and has been observed that in the absence of sulphuric acid the reaction proceeds very slow, and concentration of 5N sulphuric acid gives accurate results. Method validation of the proposed method was carried out by recovery experiment and calculation. Recovery analysis for both the drugs, *i.e.* PMH and PM have been carried out by drug addition method by using the expression (2) as above. The results for recovery experiment were recorded in **Table 2** and **Table 3**. The recovery of drug calculated for this is 99.51% for Promethazine hydrochloride (PMH) whereas 99.55% for Pheniramine maleate (PM)

TABLE 1: DETERMINATION OF PROMETHAZINE HYDROCHLORIDE (PMH) AND PHENIRAMINE MALEATE (PM) WITH 0.03 N PFC

S. no.	Amount of aliquots taken (mg)	Amount present (mg)	Reaction time (min)	Molecularity	Amount obtained by calculation (mg)	Error %	SD (mg)	CV (mg)
Pure Promethazine hydrochloride (PMH)								
1	1	0.996	10	1	0.987	− 0.90	0.0026	0.2634
2	3	2.985	10	1	2.962	− 0.77	0.0028	0.0945
3	5	4.970	10	1	4.945	− 0.60	0.0035	0.0708
Phenergan tablet (Manufactured by Akum Drugs Ltd.,) formulation of PMH								
1	1	0.969	10	1	0.961	− 0.83	0.0025	0.2601
2	3	2.906	10	1	2.886	− 0.69	0.0032	0.1109
3	5	4.843	10	1	4.816	− 0.56	0.0024	0.0498
Phenergan injection (Manufactured by Akums Drugs Ltd.,) formulation of PMH								
1	1	0.976	10	1	0.967	− 0.92	0.0020	0.2068
2	3	2.928	10	1	2.905	− 0.79	0.0017	0.0585
3	5	4.880	10	1	4.852	− 0.57	0.0009	0.0185
Pure Pheniramine maleate (PM)								
1	1	0.998	15	1	0.991	− 0.70	0.0052	0.5247
2	3	2.991	15	1	2.973	− 0.60	0.0031	0.1043
3	5	4.986	15	1	4.963	− 0.46	0.0029	0.0584
Avil tablet (Manufactured by Sanofi India Ltd.,) formulation of PM								
1	1	0.977	15	1	0.968	− 0.92	0.0028	0.2893
2	3	2.930	15	1	2.906	− 0.82	0.0022	0.0757
3	5	4.885	15	1	4.856	− 0.59	0.0010	0.0206
Avil Injection (Manufactured by Sanofi India Ltd.,) formulation of PM								
1	1	0.988	15	1	0.977	− 1.11	0.0031	0.3173
2	3	2.963	15	1	2.940	− 0.78	0.0026	0.0884
3	5	4.941	15	1	4.918	− 0.47	0.0033	0.0671

TABLE 2: RESULTS OF RECOVERY STUDIES BY STANDARD ADDITION METHOD FOR PMH

S. no.	Number of observ-ations N	Amount of pure PMH Present (mg)	Amount of PMH added (in an injection) (mg) P	A total amount of drug obtained by calculation (mg)	Amount of drug obtained by calculation (mg) Q	PQ	P^2	Recovery %
1	3	0.996	0.972	1.960	0.964	0.937	0.945	99.51
2	3	0.996	1.945	2.927	1.931	3.756	3.783	
3	3	0.996	2.917	3.894	2.898	8.453	8.509	
4	3	0.996	3.889	4.865	3.870	15.050	15.124	
5	3	0.996	4.862	5.831	4.842	23.542	23.639	
	15		14.585		14.505	51.738	52.000	
	∑N		∑P		∑Q	∑PQ	$\sum P^2$	

TABLE 3: RESULTS OF RECOVERY STUDIES BY STANDARD ADDITION METHOD FOR PM

S. no.	Number of observ-ations N	Amount of pure PM Present (mg)	Amount of PM added (in an injection) (mg) P	A total amount of drug obtained by calculation (mg)	Amount of drug obtained by calculation (mg) Q	PQ	P^2	Recovery %
1	3	0.998	0.988	1.976	0.978	0.966	0.976	99.55
2	3	0.998	1.977	2.961	1.963	3.881	3.909	

3	3	0.998	2.963	3.942	2.945	8.726	8.779
4	3	0.998	3.952	4.927	3.932	15.539	15.618
5	3	0.998	4.941	5.910	4.924	24.329	24.413
	15		14.821		14.742	53.441	53.695
	∑N		∑P		∑Q	∑PQ	$\sum P^2$

Possible Course of Reaction: The drug Promethazine hydrochloride (PMH) belongs to Phenothiazine class, and its structure consists of the tricyclic ring system, in which two aromatic rings are linked by branched alkyl chain, a sulphur atom and terminal nitrogen atom **Fig. 1**. In another word we can say that the sulphur atom present between two aryl rings is the bridging entity, between the two aryl rings. The nitrogen atom present in the drug PMH is not basic.

Hence, the oxidizing reagent PFC oxidizes the sulfur atom present between the two aryl ring to the corresponding sulphone but not nitrogen atom as they are not basic. Thus sulfur atom of the drug PMH, during oxidation reaction with oxidizing reagent PFC consumes one equivalent of PFC per mole and forms sulphoxide and due to this PMH with PFC establishes the stoichiometric ratio of 1:1. This reaction between drug PMH and PFC takes ten minutes for its completion. By stoichiometric ratio established between PFC and pharmaceutical drug Promethazine hydrochloride (PMH) and after the survey of different literature, the scheme for the proposed reaction is expressed in **Fig. 3**.

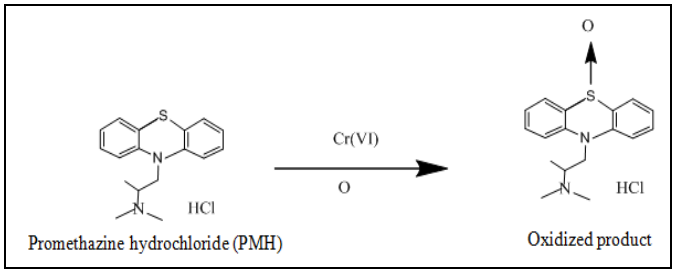

FIG. 3: POSSIBLE OXIDATION REACTION

The other drug Pheniramine maleate (PM) is the maleate salt of pheniramine. This pheniramine consists of two aryl rings in which one is phenyl group and the other one is 2-pyridyl rings, and these both aryl rings are linked by terminal dimethylamino moiety. As mentioned above, since Pheniramine maleate is the maleate salt of pheniramine, hence this pheniramine always exits with the maleic molecule. The oxidizing reagent PFC does not react with the pheniramine molecule, whereas it reacts with the hydroxyl (- OH) group present in the carboxylic group of a maleic molecule. Here oxidizing reagent PFC reacts with one hydroxyl (-OH) group of one carboxylic (-COOH) group out of two carboxylic groups present in the maleic acid molecule.

PFC oxidizes the reacting hydroxyl (-OH) group to it's corresponding aldehydic (-CHO) group while remaining one carboxylic (-COOH) of maleic molecule became unaffected. Thus, drug Pheniramine maleate (PM) with an oxidant, PFC establishes a stoichiometric ratio of 1:1. This reaction between drug PM and PFC takes fifteen minutes for its completion. By the stoichiometric ratio established between PFC and pharmaceutical drug Pheniramine maleate (PM) and after the survey of different kinds of literature, the proposed reaction may be expressed as:

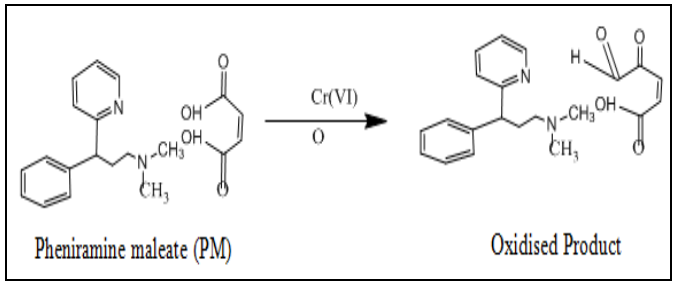

FIG. 4: POSSIBLE OXIDATION REACTION

CONCLUSION: It has been observed that reagent Pyridinium fluoro chromate (PFC) is a versatile oxidizing reagent and is effectively capable in oxidizing above antihistamine drugs. The oxidizing reagent Pyridinium fluoro chromate establishes 1:1 stoichiometric ratio with both drugs, *i.e.* with Promethazine hydrochloride (PMH) and Pheniramine maleate (PM). The adopted technique, i.e. visual volumetric technique is simple, rapid, accurate and precise and most economical analytical method was developed and validated.

The selected method is suitable for routine analysis of both the drugs, *i.e.* Promethazine hydrochloride (PMH) and Pheniramine maleate (PM) in bulk drugs as well as formulations for pharmaceutical laboratories, as this method does not have any sophisticated instruments and is easily procurable at meager expenses. Thus, due to accuracy, reproducibility, simplicity, and cost-effectiveness

of this method, suggest its application in the quality control laboratories where the modern and expensive instruments are not available.

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CONFLICT OF INTEREST: There is no conflict of interest.

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