

changes to glucose concentration. The permeability ratio of insulin ($P_{50}:P_{200}:P_{400}$) was found to be 1:3:7.4, 1:2.6:7, 1:2.6:6.9 for cycles 1, 2 and 3 respectively. The average P_{50} , P_{200} , P_{400} for three cycles was 1.1×10^{-5} , 3.06×10^{-5} and 7.85×10^{-5} . It is evident from the data that the insulin release depends on the external glucose concentration and when the glucose concentration was increased from 50 to 200 mg% the insulin release increases by three times and when increased to 400 mg% the release increases by almost 7 times.

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Spectrophotometric Determination of Ambroxol Hydrochloride

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A rapid, sensitive and simple spectrometric method is developed for the estimation of ambroxol hydrochloride. It is based on the reaction of p-N-dimethylamino-cinnamaldehyde reagent with aromatic amino group of ambroxol in acidic medium. The yellow chromophore with λ_{max} at 503 nm, obeyed Beer's law in the concentration range of 1-110 $\mu\text{g/ml}$.

Ambroxol hydrochloride, an expectorant is useful in the treatment of respiratory problems. The drug is official in BP¹. Chemically ambroxol hydrochloride is trans-4-[(2-amino-3,5-dibromobenzyl)amino]cyclohexanol hydrochloride. Literature cites determination of ambroxol hydrochloride by spectrophotometric², HPLC³⁻⁵ and GC methods⁶⁻⁷ in pharmaceutical formulations. Officially, ambroxol is assayed by potentiometric titration¹ method. In the present study, the presence of aromatic amino group in

ambroxol was exploited, for a condensation reaction with 3-(4'-N,N-dimethylaminophenyl)-prop-2-en-1-al, more commonly referred to as p-N-dimethylamino-cinnamaldehyde reagent (PDAC).

A Shimadzu UV 1601 Spectrophotometer with 1 cm matched quartz cell was used for developing the method. Toluene and methanol of analytical grade were used in the proposed method. A solution of 0.1% w/v PDAC was prepared in methanol. A standard solution of ambroxol hydrochloride was prepared by dissolving 100 mg of ambroxol hydrochloride in methanol and then the volume

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TABLE 1: ASSAY OF AMBROXOL FORMULATION AND RECOVERY STUDY

Assay		Recovery study			
Formulation	Amount found per tablet (mg±SD)*	Amount of standard added (µg)	Total amount found (µg±SD)*	Amount of standard recovered	% Recovery
Ambrolite	29.81±0.6	100	403±2.1	103	103.0
Acolyt	30.42±1.3	200	495±1.9	195	97.50
Ambrodil	29.53±1.1	300	596±2.7	296	98.67

*Average of three determinations

was made up to 100 ml with methanol to get a concentration of 1000 µg/ml.

To obtain the standard curve, the following procedure was adopted. In a series of 10 ml volumetric flasks, to aliquot volumes of 0.2, 0.4, 0.6, 0.8 and 1 ml of standard solution of ambroxol hydrochloride, 3 ml of PDAC, 2 ml of toluene and 0.2 ml of sulphuric acid were added. The solutions were allowed to stand for 5 min and the volume was then made up to 10 ml with methanol. The absorbance of yellow colored chromophore was measured at 503 nm against the reagent blank. The method was validated for fixing optimum concentration and volume required for maximum absorbance, stability of color and order of mixing.

The proposed validated method was extended for the determination of ambroxol hydrochloride in different tablet formulations. The following formulations purchased from the market and having strength of 30 mg of ambroxol hydrochloride per tablet were analysed by the proposed method: Ambrolite (Tablets India Limited), Acolyt (Modi Mundi Pharma) and Ambrodil (Aristo). A total of 20 tablets were weighed separately and powdered. An amount of tablet powder equivalent to 100 mg of ambroxol hydrochloride was weighed into a separate 100 ml volumetric flask and dissolved in methanol. The volume was then made up to 100 ml with methanol in each case. The solutions were filtered through Whatman paper no. 42. These solutions were then analyzed by the same method as described above. The results of assay are recorded in the Table 1.

To ensure the accuracy and the reproducibility of the proposed method, recovery experiments were carried out by adding a known amount of standard drug to previously analysed tablet formulation at three different levels. For the recovery study, marketed sample of Ambrolite was used. A

volume of 0.3 ml of the sample solution was added into three sets of volumetric flasks, each containing standard solution in the concentration of 100, 200 and 300 µg. The flasks were processed in the same way as described before to develop the colour. From the amount of total drug found from the calibration curve, recovery of standard was calculated and expressed as percentage. The percentage recovery ranged from 97.5 –103%. The results are presented in the Table 1.

The colour was stable for two hours. The Beer's law was obeyed in the concentration range of 1–110 µg/ml. Molar absorptivity was found to be 8.3×10^3 l/mol.cm and Sandell's sensitivity was found to be $0.49876 \mu\text{g}/\text{cm}^2/0.001$ absorbance unit. The regression equation ($y=a+bx$) was obtained by a linear least square treatment of the results, established slope of 0.3446 and intercept 0.002 with standard deviation of 0.06 and coefficient of variance 0.005. The data from recovery study indicated no interference of excipients present in the formulation. The developed method was thus found to be sensitive, accurate, precise and reproducible and can be used for the routine determination of ambroxol hydrochloride in tablet formulations.

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