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Qualitative Analysis of Patent and Suspected Generic Medicine through TLC

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Abstract

Pharmaceuticals expenditures concern not only consumers but also government payers, private health plans and employees as well. Generic drug offer opportunities for significant cost savings over brand name drug products patent. TLC has been used as an analytical technique for the identification and separation of two type medicines i.e., the patent and the generic which composed of the same ingredients. The examination of each medicine was placed on the TLC aluminum plate silica gel 60 F_{254} as the stationary phase under experimental conditions. Ten samples each of patent and suspected generic medicine was analyzed by using were on various surfactants mediated solvent systems. U.V chamber was used out for better visualizations at three different conditions i.e., visible light, light of short wavelength (254nm) and long wavelength (365 nm) and thus the Rf (retention factor) of each patent and suspected generic medicines were calculated respectively for the purpose of identification of constituents and active ingredients. The results obtained from the TLC method, visual, U.V light and through Rf value examination, samples group – S_A, S_B, S_D, S_E, S_G and S_J Sample were found to differ with the Rf value of just by ± 0.05 considering the error in examination or considered as genuine medicines whereas S_C, S_F, S_H, S_I differed in color of spots developed in the TLC plate. The Rf with more than ± 0.5 considered the some amount of adulterant, excess active ingredient, any other ingredient may

have been added hence considered as a fake medicines or suspected medicines. The proposed TLC method was a suitable, simple, reliable, easy, inexpensive and less time consuming method for qualitative study of such patent and generic medicines.

Key words: Patent, generic, medicines, TLC, R_f value.

1. Introduction

A patent medicine is a medicine which is designed to be sold directly to the public, with no prescription required. Pharmaceuticals companies, when designing a drug obtain a patent so that no other company can manufacture the same drug. This patent typically last for 17 -20 yrs. After the patent expired, any other company can manufacture the same drug **(Mital, 2010**). This is where generic drug comes in. A generic drug is a drug defined as "a drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use." It has also been defined as a term referring to any drug marketed under its chemical name without advertising. A generic drug must contain the same active ingredients as the original formulation **(Sharma 2007).** According to US Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range

to the brand-name counterpart with respect to to pharmacokinetic and pharmacodynamic properties.

By extension, therefore, generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy, and intended use. Generic drugs are usually sold for significantly lower prices than their branded equivalents. One reason for the relatively low price of generic medicines is that competition increases among producers when drugs no longer are protected by patents.

According to Special law on counterfeit drugs, Sec 3 states that counterfeit drug/medicine refers to medicinal products with the correct ingredients but not in the amounts as provided hereunder, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient, which results in the reduction of the drug's safety, efficacy, quality, strength or purity. It is a drug which is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products. Counterfeiting can apply to both branded and generic products with counterfeit products.

Thin layer chromatography may be used to separate the ingredients/constituents and identified on the basis of Rf values. The most commonly used adsorbent in TLC is silica gel and the flat surface is a plain rectangular or square glass plate. The separation of the components of a mixture depends on adsorption-desorption equilibrium between compounds adsorbed on the solid stationary phase and in the moving liquid phase. Once the spot are located, their R_f values can be used to identify the common ingredients.

2. Methodology

The samples of patent and suspected generic medicines of same composition were collected from different pharmaceutical shops. 10 samples of each patent and generic medicine were collected i.e., S_1, S_2, S_3, S_4……S_{20} of ten groups. Qualitative analyses of these medicines were performed by the TLC method. The medicines of both patent and generic were accurately weight to finely powder and were extracted by swirling with solvents. The mixtures were filtered through filter paper.Standard TLC plate was taken and a vertical line, of 2cm from both the edges were drawn. With the help of the micro-pipette extract of both the patent and generic sample were spotted at least 1.5cm apart. The TLC plates were placed horizontally in the chamber containing the solvents and are made to run for 6-7 min. Different solvents were used to separate the constituent of the compound. Thus the plates were removed from the chamber and kept in oven at 60^o for 30 minutes. So as to allow the solvents to evaporate. The plates were then visualized under U.V chamber by three conditions i.e., visible light, short wave U.V. light (254nm) and long wave U.V. light (365nm). The R_f values of spot all the samples of patent and suspected medicines were calculated for the purpose to identify the purity, whether the particular drug consists of proper active ingredients.

According to table after analysis at different parameter it was found that S_C group sample S_6 have two spot and two R*f* values, whereas sample S_5 of same group have one R*f* value and single spot after separation, Same time similar type of finding with the sample S_{11} & S_{12} of S_I group. In case of S_H group S_{15} & S_{16} showed that their was too much variation in R*f* values. For the of medicine of S_I group sample S_{18} & S_{19} have no fluorescence but their Rf value is too less as compare to S_{18} & S_{19}.

The present work is concerned with the application of TLC technique and U.V examination of all the Sample medicines depending on the color, Rf value and U. V light. After the examination of all the twenty one samples of patent and generic medicines analyzed by visual, TLC,U.V examination of samples - **S_A, S_B, S_D, S_E** and **S_J** were found to differ with the Rf value of just by ± 0.05 considering the error in examination or considered as genuine medicines **(Sammnal, 2003).** Medicine of S_G group only found to have the same R*f* value considering genuine.

3. Result and Discussion

Table: Result of different sample after examination at various parameters

Groups.	Samples of patent and generic medicine of same group	Rf values of developed spot	Visible Light	Examination under UV light	
				Short light (254nm)	Long light (365nm)
S_A	S_1 Calpol (P) S_2 Paracetamol (G)	0.26	Colorless	S.P.S*	No Fluorescence
		0.30	Colorless	S.P.S	No Fluorescence
S_B.	S_3 Zupar (P) S_4 Pyremol IB (G)	0.23 0.95	Colorless	D.P.S	No Fluorescence
		0.23 0.93	Colorless	D.P.S	No Fluorescence
S_C.	S_5 Calpol (P) S_6 Pacemol (G)	0.76	Colorless	S.P.S	No Fluorescence
		0.73 0.76	Colorless	D.P.S	No Fluorescence
S_D.	S_7 Levoflox (P) S_8 Levolkem (G)	0.94	Colorless	S.P.S	Fluorescence
		0.92	Colorless	S.P.S	Fluorescence
S_E.	S_9 Aciloc (P) S_{10} Ranetidine (G)	0.65	Green	S.P.S	Fluorescence
		0.62	Orange	S.P.S	No Fluorescence
S_F.	S_{11} Zenflox OX (P) S_{12} Onoff OX (G)	0.8	Light reddish	S.P.S	Fluorescence
		0.7 0.4 0.2	Light reddish	T.P.S***	Fluorescence
S_G.	S_{13} Lecoff (P) S_{14} Mahalevo (G)	0.5	Colorless	S.P.S	Fluorescence
		0.5	Colorless	S.P.S	Fluorescence
S_H.	S_{15} Onflox 200 (P) S_{16} Oflokem 20 (G)	0.66 0.38	Colorless	D.P.S**	Fluorescence
		0.69 .44	Colorless	D.P.S	Fluorescence
S_I.	S_{17} Zifi 200 (P) S_{18} Alcef 200 (G_1) S_{19} FixxDT 200(G_2)	0.75	Colorless	No separation	Fluorescence
		0.98	Yellow	S.P.S	No Fluorescence
		0.95	Yellow	S.P.S	No Fluorescence
S_J.	S_{20} Shelcol 500 (P) S_{21} Cipcal 500 (G)	0.27	Blue	No separation	Fluorescence
		0.25	Colorless	No separation	Fluorescence

***SPS= Single Purple Spot, **DPS = Double Purple Spot, ***TPS = Triple Purple Spot**

S_C, S_F, S_H, S_I were considered as a fake or suspected medicine due to excess of adulterants or other composition viz., calcium which may or may not be harmful and also due to wide difference in their Rf value, color examination between patent and generic medicine.

4. Summary and Conclusion

Twenty different generic and patent medicines were examined by TLC (Thin Layer Chromatography) method with U.V light detection has been established for qualitative analysis of two types of medicines i.e., patent and generic in pharmaceutical preparations. Silica gel plate with fluorescence indicator F_{254} were used with different solvents in different ratios as mobile phase. U.V chamber was carried out for better visualizations at three different conditions i.e., visible light, short light (254nm) and long light (365 nm) and thus the Rf (Retention factor) of each patent and suspected generic medicines were calculated respectively for the purpose to check the purity and whether the particular drug consists of proper active ingredients, excess, less or wrong ingredients.

The proposed TLC method was used successfully for qualitative analysis, of generic and patent medicine through their Rf value, visual and U.V light examination. TLC method is a simple, sensitive,

rapid, inexpensive and reliable method for such qualitative examination of ingredient of drugs. However, possible additional and more sophisticated instruments like HPLC, Raman Spectroscopy etc can be applied for confirmatory result.

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