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Microbial Analysis of Some Expired Drugs Collected from Local Market of Kalol, North Gujarat Region

Shah HR
Microbiology Department, Ananya Institute Of Science, K.I.R.C. Campus, Kalol

ABSTRACT

Different syrup samples of expired dates were collected from local available outlets of North Gujarat region. Around 30 samples of drugs were selected for microbial analysis. Sample includes cough syrup, ear drops, eye drops and antibiotic in liquid form etc. while drugs included paracetamol, ofloxacine, paradichlorobenze, cefpodoxime and Levocelirizine in liquid form. Each sample was inoculated in Nutrient broth at 37°C for 24-48 hours. Same samples were also inoculated for fungal growth in Sabouraud dextrose broth at 28°C for 3-4 days. Samples and all different colonies were studied using morphological and biochemical characteristics. Result concluded presence of Bacterial sp. including *Staphlococcus aureus, S.epidermis,Pseudomonas sp,Bacillus sp., Enterococcus sp.,Microbacterium sp* etc. whereas Fungal sp. include *Aspergillus niger,Mucor sp.,Aspergillus sp., Neurospora sp. etc.*

Keywords*:* Expired drugs, Bacterial and fungal species, Morphological and biochemical characteristics.

*Corresponding Author Email: 311hiral@gmail.com
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INTRODUCTION

Interaction or presence of micro organisms in any products depends on many parameters overall production, packaging, storage etc. Beside all these parameters even material used in manufacturing and container material quality also directly or indirectly affect microbial quality in pharma products. Contaminant presence may differ in quality and quantity which also includes pathogens.

Majority material used in preparation of pharmaceutical products support microbial growth as depending on the nutritive properties and moisture content of the products (Ogbonna and Akueshi,1984)[1]Most pharmaceutical products are susceptible to microbial contamination, which may cause their spoilage by changing their chemical, physical or aesthetic nature .Contamination tends to arise during manufacture rather than during use and can be prevented by controlling personnel, environment, raw materials and formulation (Booth,2002)[2]

The objective of this study is to understand and identify the micro organisms associated with expired drugs.

MATERIALS AND METHOD

Sample collection

Different drugs in liquid form (syrups) were obtained from different medical outlets located in north Gujarat regions. Around15 outlets were selected for sample collection and 30 samples were taken for detail studies. Drugs selected on bases of their frequent use by patients of all age groups such as Paracetamol, Cefpodoxime, Amoxicillin, Cefixime and Levocelirizine etc.

Sample preparation

Samples were marked with code number D1 to D30. 2ml of sample was added to 8ml N. saline amd mixed properly. One Nsaline 10ml kept as negative control., from each sample test tube a loopful was streaked on nutrient agar plate, Mac Conkey agar and Sabouraud agar plate to study colonial characteristic. Plates were incubated at 37°C for 24-48 hours for Bacteria and at Room temperature (28°C) for 3-4 days. Different isolated colonies were labeled as BH1 to BH20 and Fungal colonies (growth) FH1 TO FH09. All isolated organisms were cultivated in Nutrient broth and Sabouraud broth for further studies All labeled isolates were used to understand biochemical properties and for identification.

Morphological and biochemical characterization

Pure culture suspension was prepared from all isolated colonies labeled from BH1 to BH20 and FH1 to FH09. For Bacterial isolates by performing different staining like gram staining, spore

staining, capsule-staining etc., basic information were collected.(Alderson,2004)[3] After confirmation of pure isolate, subculturing was done for biochemical tests to understand metabolic patterns as well as for identification up to genus or species level. Whereas, the fungi were identified using a combination of colonial characteristics and microscopy. The fungal species were identified by standard procedure described. (Robert and Ellen, 1998)[4]

RESULTS AND DISCUSSION

When all labeled isolates were observed microscopically and their biochemical reactions were studied many different bacterial sp. and fungal sp were identified. Those microbes were present most frequently as contaminates in drug samples**.** Study of isolated organism by gram staining and biochemical test indicated presence of various types of bacterial species. Certain bacterial species were found saprophytic and nonpathogenic while few were Suspected pathogens or pathogens.(Shown in table 1) and also fungal growth was studied using colonial and morphological characteristics (shown in table 2)

Table 1: Bacterial isolates from selected expired drugs

Bacterial isolate	Drug sample	Characteristics
Staphylococcus aureus	Cefpodoxime, Cefixime Amoxicillin	Saprophytic,pathogen,
Enterococcus sp	Paracetamol, Cefpodoxime Levocelirizine	Suspected pathogens
Bacillus sp,B.subitils	Amoxicillin	Saprophytic bacteria
Staphylococcus epidermidis	Amoxicillin, Paracetamol,	pathogenic
Enterobacter cloacae	Paracetamol	Suspected pathogen
Micrococcus sp	Paracetamol	suspected pathogen

Table:2 Fungal isolates from selected expired drugs

Drug	Colonial properties	Fungi
Cefpodoxime	White powdery	*Mucor sp.*
	Grayish black powdery	*Aspergillus niger*
	Light pink colonies	*Neurospora sp*
Amoxicillin	Black powdery growth	*Aspergillus niger*
	Light green powdery	*Aspergillus flavus*
	White margin light green growth	*Aspergillus fumigatus*
	White- grey powdery	*Aspergillus sp*
Paracetamol	Black powdery growth	*Aspergillus niger*
	Green velvety	*Penicillum sp*
	Cottony white growth	Mucor sp.
Levocelirizine	Grey powdery growth	*Aspergillus sp*
	Bluish green powdery growth	*Penicillum sp.*
	Blackish grey powdery growtj	*Alternaria sp*
	Light green powdery	*Aspergillus flavus*

Above results indicated the presence of different kinds of contaminants in the selected samples which includes pathogenic bacterial and fungal species also. Main potential pathogenic fungi such as Neurospora sp, Fusarium sp., *Aspergillus flavus*, *Aspergillus niger* and *Aspergillus fumigates* fungal specieswere identified. Among bacterial species such as *Staphylococcus aureus, Enterococcus sp* and *Micrococcus sp (*Lyudmila.,et al 2006)[5]were found high number. Even in less number many different catagories of fungal and bacterial species were observed like *Penicillum sp. Candida sp, Actinomycetes sp, Bacillus cereus, Pseudomonas aeruginosa and clostridium sp etc.* Even small number of organism presence is also not advisable to neglect.

CONCLUSION

Presence of fungal and bacterial species in such liquid drugs is big question mark for quality of manufacturing pharma companies. This type of contaminants concluded drawback in selection and handling of raw material, operating and packaging error. Smallest mistake in GMP can create big effects. The present study agreed with Obuekwe and Ogbimi work in 1998A best quality control and compliance of techniques under aseptically preparation and packaging of the product as well as personal hygiene is essential. Best hygiene conditions must follow during production processof the product. (shani.,1981)[6]This primary work is done to understand importance microbial analysis of manufacturing dates and expiry dates of any drugs although it sealed packed.

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