Disposal of Unused Medicines in India

"Good Manufacturing Practices (GMP) and Requirements of Premises, Plant and Equipment for pharmaceutical products laid down in Schedule M of the Drugs and Cosmetics Rules, 1945 prescribe the requirements for disposal of waste including the rejected drugs. Details are as under:

1. The disposal of sewage and effluents (solid, liquid and gas) from the manufacturer shall be in conformity with the requirements of Environment Pollution Control Board.
2. All bio-medical waste shall be destroyed as per the provisions of the Bio-Medical Waste (Management and Handling) Rules, 1996.
3. Additional precautions shall be taken for the storage and disposal of rejected drugs. Records shall be maintained for all disposal of waste.
4. Provisions shall be made for the proper and safe storage of waste materials awaiting disposal. Hazardous, toxic substances and flammable materials shall be stored in suitably designed and segregated, enclosed areas in conformity with Central and State Legislations."

Segregation of discarded medicines from other wastes is equally important as their disposal. The waste category number five from the Bio-Medical Waste (Management and Handling) Rules, 1998 constitutes the outdated, contaminated and discarded medicines and cytotoxic drugs. The rules also insist that no untreated bio-medical waste shall be mixed with other wastes. The bio-medical waste shall be segregated into containers or bags at the point of generation prior to its storage, transportation, treatment and disposal. They are to be collected in yellow-colored, non-chlorinated plastic bags or containers and should be treated separately.

In India, following are the methods advised by the concerned government authorities for disposal of unused medicines at domestic and industrial level:

1. Medicine Take-Back Programs

Medicine take-back programs are the only secure and environmentally sound way to dispose of leftover and expired medicine. Wherever feasible returning to the manufacturer should be the first choice because the manufacturer is likely to have good disposal methods that allow recycling of components wherever possible . Expired cytotoxic drugs and items contaminated with cytotoxic drugs are to be returned back to the manufacturer or supplier for incineration at temperature >1200 0C or to common bio-medical waste treatment facility or hazardous waste treatment, storage and disposal facility for incineration at >12000C Or Encapsulation or Plasma Pyrolysis at >12000C. (According to Bio-Medical Waste Management and Handling Rules, 1998)

2. Waste immobilization: Encapsulation

In areas where medicine take back program is not available the following steps are practised at household level:

- Mix the medicines without crushing the tablets or capsules with unpalatable substances such as kitty litter, used coffee grounds etc.
- Place the mixture in a container such as a sealed plastic bag.
- Throw the container in your household trash.

In an industrial scale encapsulation involves immobilizing the pharmaceuticals in a solid block within a plastic or steel drum. They are filled to 75% capacity with solid and semi-solid pharmaceuticals, and the remaining space is filled by pouring in a medium such as cement or cement/lime mixture, plastic foam or bituminous sand. Once the drums are filled to 75% capacity, the mixture of lime, cement and water in the proportions 15:15:5 (by weight) is
added and the drum filled to capacity. Steel drums are then sealed secure and should be placed at the base of a landfill which is then covered with fresh municipal solid waste.

3. Flushing of Certain Medicines

There is a small number of medicines that may be especially harmful and, in some cases, fatal in a single dose if they are used by someone other than the person the medicine was prescribed for. For this reason, a few medicines have specific disposal instructions that

indicate they should be flushed down the sink or toilet when they are no longer needed and when they cannot be disposed of through a drug take-back program. There is a list of such drugs that need immediate disposal if not in use or else one can check the disposal instructions of the medicines at DailyMed.

4. Incineration of hazardous pharmaceutical waste

The incinerators should meet the operating and emission standards set by the environment control strategies of the National Environment Commission (NEC). The incinerators should have the following specifications:

Type	rotary kiln incinerators
Chambers	Two
Minimum Temperature	1100 degree Celsius
Capacity Range	Depending on the waste generated data

Wastes with high heavy-metal content (e.g. lead, cadmium, mercury) should not be incinerated as it will cause emission of toxic metals into the atmosphere. Hazardous pharmaceutical wastes, including wastes containing more than 1 % halogenated compounds, should be incinerated in rotary kiln incinerators with a minimum temperature of 1100 °C.