

USP – IPC 8TH ANNUAL SCIENTIFIC MEETING
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DRUG SUBSTANCES ADULTERANTS

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Issues For Discussion

- Case Studies
- Implications
- Measures To Be Taken

J.J. Hospital Glycerin Tragedy

- Glycerin adulterated with di-ethyleneglycol
- 14 Persons lost life
- Enquiry by high court judge
- Lead to many changes in fda working
- Glycerin monograph had no test for detection of di-ethyleneglycol

HAITI Tragedy

- 89 persons died
- Paracetamol syrup
- Vehicle propylene glycol adulterated with di-ethyleneglycol
- Pharmacopoeia had identification test by tlc which cannot detect less than 5% of di-ethyleneglycol

Framycetin

- Framycetin Description
- Identification

Neomycin

- Description
- Identification

Metakelfin Tablets

- Sulphamethoxypyridazine
(Approved ingredient)
- Sulphamethoxypyridazine
(Ingredient used)
- All tests except ir identification was different
- Difference in the structure about position of the double bond

Metakelfin Contd...

- Approved ingredient was not available in India
- However formulation was being exported
- Case detected and investigated in coordination with CDSCO
- Conviction
- 3years RI

Comsat Forte Tablets

- Tmp – Sulpha tablet
- Adulterated with Glibenclamide
- Ingredient mix up during manufacturing process
- Effective steps taken by the manufacturer for withdrawal of the drug
- After recall , death reported, due to use of physician's sample

Sildenafil Citrate In Ayurvedic Capsules

- Ayurvedic capsules/drugs are never tested for any allopathic drug leave apart Sildenafil citrate
- For detection information/intelligence and investigations are the important tools
- Sildenafil citrate is contraindicated in heart patients
- Ayurvedic drugs doesn't have side effects - normal feeling

Raw Material Transportation

- Tampering of raw material drums
- Replacement of part quantity with DCP/Starch, etc.
- Adulteration
- Replacement of seal

Food Articles

- Similar examples about food articles
- Edible oil adulteration with Argimone oil
- Adulteration of milk with Melamine (China)
- Detection of Melamine in chocolates
- Nickel/heavy metals in chocolates

Food Articles Contd...

- Pesticides/pesticides residue in soft drinks/packaged drinking water
- Adulteration of Methanol in Alcohol which causes death or loss of eye sight

Measures

- Control on source and availability of raw material
- Active Ingredients
- Additives
- Robust R.M. standards and testing
- Robust packaging development

Measures Contd...

- Development of pharmacopoeal monographs
- Development and availability of analytical methods and materials including reference standards, columns, etc.
- Test for related substances (inclusion of poisonous/dangerous natural adulterants)

Measures Contd...

- Drug distribution records
- GMP with a view on contamination, cross contamination, sabotage
- Effective withdrawal and recall system
- Pharmaco vigilance and adverse effects reporting system
- Development/up gradation of the government/public testing/private laboratories

Measures Contd...

- Coordination between manufacturers, enforcement agencies and all the stake holders
- Development of strong drug control administration
- Development consumer alert systems, etc.

THANK YOU