

02.09.2006

Welcome to the
world of
“Pharmaceutical
Packaging”

Packaging for Pharma Exports

Global Pharma market size 535 Billion USD in 2005

Sale through Pharmacies in 2003-2004 in Billion USD

USA	Europe	Japan	Latam	Others
163.15	76.6	52.8	12.08	13.31

Growth at the rate of 7.7%

Significance of Pharma packaging

1. Route of administration
2. Statutory compliance
3. Pharmacopoeial standards
4. Patent Protection
5. Dosage delivery
6. Customer convenience
7. Product protection upto shelf life

Requirements

- ❖ Regulated markets and Nearly regulated markets
- ❖ Generics & Branded formulations
- ❖ DMF
- ❖ MSDS
- ❖ Identification
- ❖ Declaration from Vendors for compliance
- ❖ Identical to Innovator product/pack

Drug Master File

A Drug Master File (DMF) is a submission to the Food & Drug Admn. (FDA) that may be used to provide confidential detailed information about facilities, processes, packaging & storing of one or more human drugs.

Types of DMF

Type I : Manufacturing site, operating procedures & personnel

Type II : Drug substance & drug substance intermediate

Type III : Packaging material

Type IV : Excipient, colourant, flavour & essence

Type V : FDA accepted reference information

Holder Obligation

A. Notice reqd. for changes in DMF

B. Listing of persons authorized to refer to a DMF

C. Annual update

ANDA

“Abbreviated New Drug Application” contains data for review & ultimate approval of a generic drug product. Once approved, an applicant may manufacture & market the generic drug product, provided all issues related to patent protection & exclusivity associated with the RLD (Reference Listed Drug) have been resolved in.

*Generic drug applications are termed “abbreviated” as they are generally not reqd. to include preclinical (animal) & clinical (human) data to establish safety & effectiveness.

Annual Updation

Change in primary container

Equivalency data

1. Material characterization
2. Stability data

Packaging Related Documents for ANDA

For Container/Closure System

- Container/Closure specification
- Test reports & procedures (GTP's & STP's)
- IR spectrums & DSC thermograms of std. & sample
- Manufacturer's test report (COA)
- Dimensional drawing of container & closure
- DMF authorization letter from manufacturers
- DMF authorization letter from resin supplier
- DMF authorization letter from colourant supplier
- DMF authorization letter from liner supplier

Specification for HDPE bottle as per USP

✓ Multiple internal reflectance

✓ Thermal analysis

✓ Light transmission

✓ Non-volatile residue

✓ Heavy metals

✓ Container permeation

Specs. for Absorbent cotton (filler) as per EP

- ✓ Identification
- ✓ Acidity/Alkalinity
- ✓ Foreign Fibers
- ✓ Fluorescence
- ✓ Neps
- ✓ Absorbancy
- ✓ Ether soluble substances
- ✓ Extractable colouring matter
- ✓ Surface active substances
- ✓ Water soluble substances
- ✓ Loss on drying
- ✓ Sulphated ash
- ✓ Weight per yard

Other requirements

- ❖ Resin grade
- ❖ Colourant grade
- ❖ Vendor name (DMF)
- ❖ Liner
- ❖ Innovator pack characterization for all primary pkg. materials

Patent Protection

- Pack outsert
- Usage of oxygen absorbent
- Pack design
- Child Resistant Closures

Labeling Requirements

- ❖ Country specific requirements
- ❖ Pharmacode
- ❖ Barcode
- ❖ Part peel labels
- ❖ NDC No.
- ❖ Blister pocket to have barcode, lot no. & expiry
- ❖ Braille script on carton

Constraints in Indian Pkg. Industry

- ❑ Few vendors with DMF

- ❑ GMP practices
 - Manufacturing
 - Documentation

- ❑ Quality Assurance
- ❑ Low investment in R&D

Implications

- Importation of materials
- Higher price
- Transportation cost
- Long lead time
- High inventory
- Less competitive in product pricing

Expectations

- cGMP standards
- Facility upgradation
- Infrastructure
- DMF approvals
- Alliancing/partenering on key components

Thank You