Item 5 UNSCETDG/29/INF 59

LIMITED QUANTITIES

Exemption for small quantities of
Pharmaceutical research and
Development samples

Comments on ST/SG/AC.10/C.3/2006/49

Transmitted by the Dangerous Goods Advisory Council (DGAC)
and the Association of Hazmat Shippers (AHS)

Comments on ST/SG/AC.3/2006/49

Materials

- Thousands of research compounds per month.
- Unique, one-of-a-kind compounds.
- Valuable, sometimes irreplaceable compounds.
- Searching for pharmacological activity.
- Minute, (µl) quantities
  - < demonstrate potential activity
  - < progress to development stage
  - < reach clinical study phase
  - < reach the consumer *(patient)*

Classification

- Significant numbers of research materials are shipped between corporate laboratories and contract/third-parties.
- Very little *(or no)* information "known".
- Minute quantities make hazard testing impractical.
- Analogous (default) classification, based on "*shipper's knowledge".*

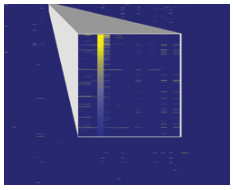
Shipper's Knowledge

- Risk assessment:
  - 1,547 compounds progressed to development
  - 1,306 (84.4%) not meeting 6.1 criteria
  - 241 (15.6%) classed PG III or II
  - 3 (0.19%) determined to be PG I
- Other indicators: Comparators, analogy, therapeutic study area; (e.g., oncology, CNS, respiratory, etc).

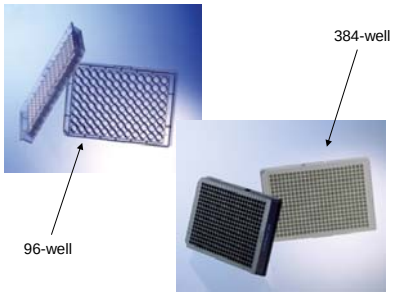
HTS Process

- Automated, high through-put screening
- Screen thousands of molecules

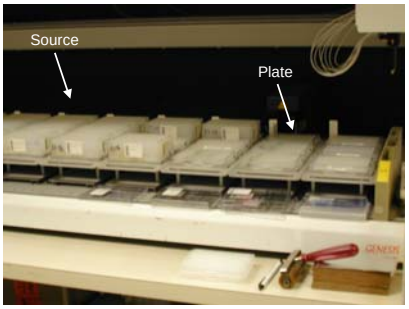
The heat map displays the percent inhibition of compounds (rows) against targets (columns). The activity of each compound is displayed by varying the color from blue (inactive) to yellow (very active). Promising series of compounds are easily identifiable by examining the patterns of activity against the entire panel.



Sterile Plates

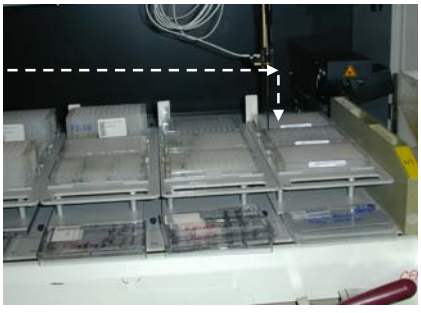


Process layout

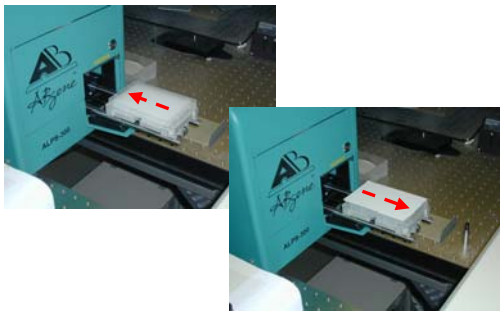


Aspirate from source

Dispense to plate



Sealing



Multiple levels of protection

- Primary packaging (plate).
- Heat sealed.
- Safety lid.
- Secondary container (zip-lock bag).
- Additional container (dry ice).
- Additional container (outer).

Risk Formula

X = Probability toxic material in µl quantity poses unreasonable hazard in transport. ($.01^2$)

Y = Probability that material properly packaged as previously depicted would spill/leak under conditions normally incident to transport. ($.01^2$)

Z = Probability that material is PG I. (0.19)

X	Y	Z	Risk
(0.01) x	(0.01) x	(0.0019)	= 0.00000019

(< 2 in ten million)