REGULATION OF DIAGNOSTIC KITS/REAGENTS IN INDIA

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DEFINITIONS – SECTION 3(b) (i) & (iv) OF DRUGS & COSMETICS ACT 1940

REGULATORY REQUIREMENT (MANUFACTURE OR IMPORT)

MANUFACTURE

- CRITICAL & NON CRITICAL KITS
- HIV, HbSAg,HCV & BLOOD GROUPING REAGENTS-CRITICAL KITS
- SUBMISSION OF MANUFACTURING FACILITY, PRODUCT DOSSIER

CONTD.

- ISSUE OF TEST MANUFACTURING LICENCE
- EVALUATION AT NATIONAL LABORATORY

  JOINT GMP INSPECTION BY STATES & CENTRAL DRUGS CONTROL OFFICIALS ALONGWITH THE EXPERTS
- ISSUE OF LICENCE
- FIRST FIVE BATCHES SEND FOR TESTING TO NATIONAL LAB TO VARIFY THE CONSISTENCY OF QUALITY

CONTD.

- OTHER NON CRITICAL DIAGNOSTIC REAGENTS-LICENCE ISSUED WITHOUT EVALUATION
- FORM NO. 25 OR 28-LICENCE ISSUED
- SALE OF DIAGNOSTIC-REGULATED

IMPORT

- REGISTRATION OF FOREIGN MANUFACTURER
- ONLY CRITICAL KITS LIKE HIV, HbSAg, HCV & BLOOD GROUPING REAGENTS- REGISTRATION
- NON CRITICAL KITS OTHER THAN ABOVE REQUIRE A SIMPLE FORM 10 LICENCE

CONTD.

- **REGISTRATION**
  - SUBMISSION IN FORM- 40
  - SUBMISSION OF INFORMATION - SCHEDULE D(I) & D(II)
  - PRODUCT DOSSIER

- **TESTING**

  CRITICAL KITS MANUFACTURED INDEGINOUSLY/ OR IMPORTED EVALUATED AT NIB, NOIDA

DCC GUIDELINES

- FOR MANUACTURE OF DIAGNOSTIC KITS / REAGENTS
- TESTING
- NATIONAL INSTITUTE OF BIOLOGICALS-APPELLATE AUTHORITY UNDER RULE 3 A OF DRUGS & COSMETICS ACT/RULES, 1945

CONTD.

- FUNCTIONS OF NIB AT NOIDA IN RESPECT OF BLOOD GROUPING REAGENTS & DIAGNOSTIC KITS FOR HUMEN IMMUNODEFICIENCY VIRUS, HEPATITIS B SURFACE ANTIGEN & HEPATITIS C VIRUS & THE FUNCTIONS OF THE DIRECTO OF THE SAID LAB SHALL BE EXCERSIED BY THE DIRECTOR OF THE ABOVE LAB

- IN-VITRO DIAGNOSTIC DEVICES FOR HIV, HCV- NOTIFIED AS DEVICE VIDE GSR 601 (E) DATED 27.8.2002

CONTD.

- INVITRO BLOOD GROUPING SERA & IN-VITRO DIAGNOSTIC DEVICES FOR HIV, HCV INSERTED IN SCHEDULE C I OF THE DRUGS & COSMETICS RULES VIDE GSR 600(E) DATED 27.8.2002

- SCHEDULE M-III OF DRUGS & COSMETICS RULES- MEDICAL DEVICES REQUIREMENTS HAVE TO PRESCRIBED REUIREMENTS FOR INVITRO DIAGNOSTIC DEVICES ALSO.