

REGULATION OF DIAGNOSTIC KITS/REAGENTS IN INDIA

BY

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



REGULATORY REQUIREMENT (MANUFACTURE OR IMPORT)

MANUFACTURE

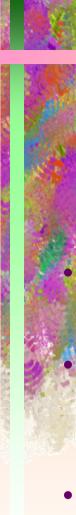
- CRITICAL & NON CRITICAL KITS
- HIV, HbSAg,HCV & BLOOD GROUPING REAGENTS-CRITICAL KITS
- SUBMISSION OF MANUFACTURING FACILITY, PRODUCT DOSSIER



- 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



- 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



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



- 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



- 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.