

QUALITY ASSURANCE DIVISION

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The Division is responsible for research and quality assurance of vaccines, biological products and diagnostic test devices at each and every step of production processes and quality control testing to ensure that products are consistently produced and controlled to the quality standards. Under the Vaccine Research Centre, Quality Assurance Division is involved in quality management system of: production, in-process quality control, quality assurance and distribution of plasma-derived hepatitis B vaccine (DMR-HB vaccine). The small scale production of plasma-derived hepatitis B vaccine was carried out in collaboration with Technology Development Division and Quality Control Division under the Vaccine Research Centre.

RESEARCH PROJECTS

1. COMMUNICABLE DISEASES

1.1. VIRAL HEPATITIS

1.1.1. Laboratory scale production of Hepatitis B vaccine (2016)

The laboratory scale production of plasma-derived hepatitis B vaccine was carried out in collaboration with Technology Development Division and Quality Control Division. During the year under report, 495 units of blood with HBsAg positivity were collected from various hospitals in Yangon areas and 7.04 litres of HBsAg positive plasma were separated and kept at -20°C. A total of 4 times to 2 times for formulation of purified bulk of lot no 01/14 and 01/16, followed by vialing, labeling and packaging were performed. To date, 5,562 of 5-ml vials (55,620 child doses) were produced and 4,558 of 5-ml vials (45,580 child doses) were provided to the Vaccine & Diagnostic Clinic, DMR.

1.2. CHIKUNGUNYA VIRUS

1.2.1 Molecular detection of chikungunya virus among inpatients with clinically suspected acute viral infection in medical units at Yangon General Hospital(2016)

(Collaboration with Quality Control Division)

2. ACADEMIC AND TECHNOLOGY DEVELOPMENT

2.1 Evaluation of Wound Healing Activity of Gelatin-Chitosan-Eclipta Alba Leaves (Kyeik-hman)(ကြိတ်ခဲးနီ) Composite Film

Biomaterials are natural polymers and are biodegradable. The two polymers of Chitosan and gelatin have wound healing properties individually. The gelatin and combination of chitosan - gelatin may show improvement in wound healing property. In this study, gelatin was extracted from Fish skins of Ngaphe (*Notopterusnotopterus*) which was prepared by simple method using sodium chloride.

The purity of gelatin was checked by Sodium Dodecyl Sulfate-Polyacrylamide gel electrophoresis. The viscosity of gelatin (1% solution) is 3.3cp. The Fourier transform infrared (FTIR) spectroscopy obtained in this study and the amide band of gelatin was found at a wavenumber of 3495 and 3419.90 cm^{-1} . The peak of amide I and amide II of gelatin were found at 1658.84 and 1535.39 cm^{-1} . Amide III band of gelatin was detected at 1242.20 cm^{-1} . The gelatin - polyvinyl alcohol-chitosan composite films(GPC), gelatin- polyvinyl alcohol-chitosan – *Eclipta Alba* films(GPCE), were prepared to test to ascertain the applicability of prepared combination for wound healing activity on rats. The films were prepared by (1) casting proportions 1:40 of chitosan (SIGMA)(1%), gelatin (10%) solution (composite films) with 0.2ml. Polyvinyl alcohol as plasticizer (GPC), (2)(GPC) and 20% of *Eclipta Alba* liquid was put in beaker and stirred for 1 hour, after vacuum filtration for removal of entrapped air bubbles on the plastic tray and air dry at room temperature(GPCE composite films). No treatment group, negative control group was not applied any treatment on the wound of rats.

Application mode of all treatment composite film was topically, once per day for 20 days was done. The wound area of each animal was measured on the 1st, 3rd, 7th, 14th, 17th and 20th days post. Specimens of skin from healed wounds from each rat were taken at the 20th day of treatment and were fixed in 10% buffered formalin solution for histopathological studies. Specimens of the healed skin were made at a thickness of 5 μ and, were stained with haematoxylin and eosin (H & E), and assessed for histopathological changes.

The results showed that the treatment with GPC was the best and showed well wound healing in skin of rat was observed. The presence of complete epithelialization in epidermis layer and normal appearance of granulation tissues in the dermis were observed. Slightly delayed wound healing process of rat's skin in GPCE group. Wound healing was not good in skin of the rats of negative control group. Normal epithelial healing process is slightly delayed in epidermis. The present study clearly demonstrated that gelatin- polyvinyl alcohol-chitosan composite film (GPC) and gelatin- polyvinyl alcohol-chitosan *Eclipta Alba* composite film (GPCE) can be used in the management of wounds and burns.

SERVICES PROVIDED

1. VACCINE PRODUCTION

1.1. Enhancing laboratory safety in vaccine production area; to ensure clean environment and quality water (2016)

According to the Good Manufacturing Practice (GMP) as recommended by the World Health Organization the vaccine production area requires an appropriate air room system in order to minimize the risks of particulate and microbial contamination of products or materials being handled. QA Division is also involved in control and monitoring of clean environment (48 tests), quality water and cleaning and calibration of equipment in vaccine production areas.

1.2 Monitoring of clean environment in the laboratories of DMR(2016)

The Strengthening of Quality Assurance system needs to be established to promote apparent improvement in laboratories and vaccine production areas. The training programme is divided into theoretical sessions and practical sessions. The programme begins with introductory sessions on the Quality Assessment Programme and an introduction to standard operation procedures and monitoring of clean environment in the laboratories and vaccine production areas.