QUALITY ASSURANCE DIVISION

Research Officer	…	Dr. Myat Khwar Phyu Pe MBBS(UM1)
Research Assistant (3)	…	Daw Myo Myo Aye BSc(Chemistry)(YU)
Research Assistant (4)	…	U Kyaw Kyaw Khaing BA(History)(YU)
	…	Daw Nay Yee Tun BCom(YIEco)
Laboratory Attendant	…	Daw Swe Swe Zin BSc(Physics)(YU)

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 (2015)

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, 405 units of blood with HBsAg positivity were collected from various hospitals in Yangon areas and 16.2 liters of HBsAg positive plasma were separated and kept at -20^{o}C. A total of 6 times for formulation of purified bulk of lot no. 01/12and 01/14, followed by vialing, labeling and packaging were performed. To date, 4,009 of 5-ml vials (40,090child doses) were produced and 4,320 of 5-ml vials (43,200 child doses) were provided to the Vaccine & Diagnostic Clinic, DMR.

2. ACADEMIC AND TECHNOLOGY DEVELOPMENT

2.1. Evaluation of Wound Healing Activity of Gelatin Film from the skin of Bronze Featherback (Ngaphe)

Skin wound healing is one of the body's natural processes of regenerating dermal and epidermal tissue. The ability of the skin to repair itself after a minor wound is remarkable, but when the damage is severe or occurs in large amounts of skin area, proper and immediate coverage of wound surface with an adequate dressing is needed to protect the wound and accelerate wound healing. Ultimately the immediate wound coverage, temporary or permanent, is one of the principal goals of wound management. For this films made with biomaterials are becoming popular due to many advantages. 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 wave number of 3495 and 3419.90cm^{-1}.The peak of amide I and amide II of gelatin were found at1658.84 and 1535.39cm^{-1}.Amide III band of gelatin was detected at 1242.20cm^{-1}. The gelatin –polyvinyl alcohol film (GP), gelatin –polyvinyl alcohol- drug(GPD), gelatin-polyvinyl alcohol-chitosan composite films(GPC), gelatin-polyvinyl alcohol-chitosan – drug films(GPCD), were prepared to test to ascertain the applicability of prepared combination for wound healing activity on rats. Specimens of skin from healed wounds from each rat were taken at the 18^{th} 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 5µ and, were stained with hematoxylin and eosin (H & E), and assessed for histopathological changes. The results showed that the treatment with GPC was the best and showed regular wound healing process of rat's skin. Incomplete epithelialization in epidermis, dermis and cutaneous layers inno treatment group and slightly delayed wound healing of rat's skin in Std. drug treatment group. The GPCD group showed bad outcome of wound healing a loss of epithelialization and loss of hair follicles and sebaceous glands in dermis. The present study clearly demonstrated that gelatin- polyvinyl alcohol-chitosan composite film can be used in the management of wounds and burns.

SERVICES PROVIDED

1. VACCINE PRODUCTION

1.1. Production and In-process quality assessment of the DMR plasma- derived hepatitis B vaccine (2015)

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, A total of 6 time for formulation of purified bulk of lot no. 01/12and 01/14, followed by vialing, labeling and packaging were performed and purification process of lot 10/14In-process was checked by In-Process quality control tests(IPC). All batches of vaccine passed the specifications of Quality Control tests recommended by WHO. To date, 4,009 of 5-ml vials (40,090 child doses) were produced and 4,320 of 5-ml vials (43,200 child doses) were provided to the Vaccine & Diagnostic Clinic, DMR.

1.2. Enhancing laboratory safety in vaccine production area; to ensure clean environment and quality water (2015)

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. 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). Quality Assurance Division also provided the Standard Operating Procedures (42 nos.) for laboratory safety in vaccine production area and Production Process for Sterile preparation in clean room, training for Personnel Hygiene. 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.

1.3. Monitoring of clean environment in the laboratories of DMR (2015)

The Strengthening of Quality Assurance system needs to be established to promote apparent improvement in laboratories and vaccine production areas. The QA Division is trying to prepare a fulfill/GLP standards laboratory in Vaccine Research Center and developing strategies, systems and structures to achieve the Good Laboratory Practice(GLP).QA team can provide the following services as part of the activities of the QA Division; 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.