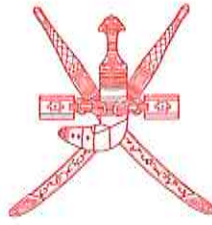


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدل
والرقابة الدوائية
مسقط

Circular No. 125/ 2020

14 -11-1441 H

06 -07-2020

TO

ALL LOCAL AGENTS & LOCAL PHARMACEUTICAL MANUFACTURERS

After Compliments,

**Sub: Application form for Biowavers based on Biopharmaceutics
Classification System (BCS)**

In our constant endeavour to assist speedy registration of pharmaceutical companies and products in Oman by identifying and clarifying the regulatory requirements in a consistent manner with scientific foundations and in line with regulations enforced by other regulatory bodies around the world, this is to inform you that we have developed an application form for Biowavers based on Biopharmaceutics Classification System (BCS).

Accordingly, applicants are requested to use this form in case they want to request a waiver of in-vivo bioavailability (BA) and/or bioequivalence (BE) study requirement for registration and/or post approval changes applications of immediate-release (IR) solid oral dosage forms. Guidelines on BCS based biowaivers are listed in the application form under the section of references. The form should be placed in Module 5 (M5) of the eCTD registration form along with supportive studies. You will also find the form uploaded in our website.

Yours faithfully,

Dr. Mohammed Hamdan Al Rubaie
Director General



Cc: DDC
DQCL