



November 02, 2022

**NATIONAL PHARMACEUTICAL REGULATORY AGENCY
MINISTRY OF HEALTH MALAYSIA
DRUG CONTROL AUTHORITY (DCA)**

DECLARATION

To whom it may concern:

We, **UNISON LABORATORIES CO., LTD.**, manufacturer and exporter of **OTAGIL 20 Tablet (Rosuvastatin calcium eq. to Rosuvastatin 20 mg)** under Thai FDA Registration No. **1A 28/62 (NG)**, and with export brand name **“OTAGIL 20 mg Tablet”**, hereby declare that **“OTAGIL 20 Tablet”** in the dossier is identical to **“OTAGIL 20 mg Tablet”** and **“OTAGIL 20 mg Film coated Tablet”** being proposed for registration and marketing in Malaysia in all aspects and that only the product name is different.

For your kind information and understanding.

Sincerely yours,



Ms. MA. ANASTACIA F. RIVERO
Manager
International Regulatory Affairs

IRA Memo 22-092 (D)_Nov 2022 (RA)

PART I - Section E14.