

The world-class pharmaceutical manufacturing facility of
Eskayef Bangladesh Limited at Tongi

achieves

APPROVAL

from

UK MHRA

(Medicines and Healthcare products Regulatory Agency of the United Kingdom)

MHRA

Safeguarding public health
 Certificate No: UK GMP 33631 Insp GMP 33631/544560-0001

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1
 Issued following an inspection in accordance with Art. 111(5) of Directive 2001/83/EC

The competent authority of the United Kingdom confirms the following:

The manufacturer: **ESKAYEF BANGLADESH LIMITED**
 Site address: **400 SQUIBB ROAD
 TONGI INDUSTRIAL AREA
 TONGI
 GAZIPUR
 BANGLADESH**

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2)(3)(2)(19)(3)(44)(3)* of Regulation (EC) 726/2004 transposed in the following national legislation: *Regulation 3(a) of the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations (SI 2005/2789) and Section 19(3) of the Medicines Act 1968 as amended*

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on 23-26/09/2008, it is considered that it complies with the Good Manufacturing Practice requirements referred to The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

The authenticity of this certificate may be verified with the issuing authority.

Medicines and Healthcare products Regulatory Agency
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An executive agency of the Department of Health

UK MHRA approval

ensures high standards of safety and quality
 for Eskayef products

opens European & other highly regulated markets
 for Eskayef products

depicts the Total Quality Management approach
 of Eskayef



SK+F
Eskayef Bangladesh Limited

Excellence through quality
www.skfbd.com