



Bangladesh Accreditation Board (BAB)

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Certificate of Accreditation

This is to certify that

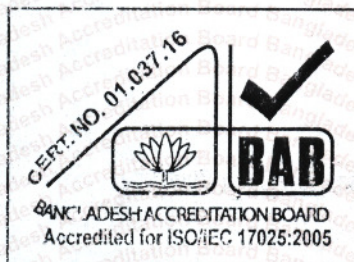
Quality Control Laboratory

Potent Product Facility (PPF), Renata Limited

Plot#01, Milk Vita Road, Section-07, Mirpur, Dhaka-1216

has been granted accreditation in respect of the scope of accreditation described in the attached document, subject to the terms and conditions governing the relevant Conformity Assessment Body (CAB) accreditation

This Testing Laboratory having met the requirements of ISO/IEC 17025:2005 and the BAB, is accredited for Pharmaceutical Testing as described in the associated Scope of Accreditation.



Certificate Number: 01.037.16

Issued on : 31 August 2016

Accreditation Date : 31 August 2016

Valid until : 30 August 2019

Director General

Bangladesh Accreditation Board (BAB)

This certificate has been issued under the authority of Bangladesh Accreditation Act, 2006 and must be returned on request; reproduction must follow guidelines in place at date of issue. For the specific scopes to which this accreditation applies, please refer to the directory of accredited CABs at <http://www.bab.org.bd/directory-of-accredited-cabs>

SCOPE OF ACCREDITATION

(For Testing Laboratory)

CAB Name & Address: Quality Control Laboratory
Potent Product Facility (PPF), Renata Limited.
Plot# 01, Milk Vita Road, Section-07, Mirpur, Dhaka-1216

Accreditation Standard: ISO/IEC 17025:2005
Certificate Number: 01.037.16
Last Amended on: NA
Amendment no: NA

Accreditation Date: 31 August 2016
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Valid until: 30 August 2019

S.N.	Products/ Materials/ Items of test	Type of tests performed	Specifications/ Standard test methods/Techniques used	Range of testing/Limit of detection
Field: Microbiology				
01.	Emcon Tablet (0.75mg Levonorgestrel BP/Ph.Eur.)	Total Bacterial Count	BP 2016, (Appendix-XVIB)/ Ph. Eur. 8.0 (Section-2.6.12 and 2.6.13)	≥10 CFU/g
		Total Yeast and Mould count		≥10 CFU/g
		<i>Escherichia coli</i>		Absent /Present
				≥10 CFU/g
02	Emcon1Tablet (1.5mg Levonorgestrel BP/ Ph.Eur.)	Total Bacterial Count	BP 2016, (Appendix-XVIB)/ Ph. Eur. 8.0 (Section-2.6.12 and 2.6.13)	≥10 CFU/g
		Total Yeast and Mould count		≥10 CFU/g
		<i>Escherichia coli</i>		Absent /Present
				≥10 CFU/g
03	Desolon Tablet (0.15mg Desogestrel BP/ Ph.Eur. & 0.03mg Ethinylestradiol BP/ Ph.Eur.)	Total Bacterial Count	BP 2016, (Appendix-XVIB)/ Ph. Eur. 8.0 (Section-2.6.12 and 2.6.13)	≥10 CFU/g
		Total Yeast and Mould count		≥10 CFU/g
		<i>Escherichia coli</i>		Absent /Present
				≥10 CFU/g
04	Bredicon Tablet (0.075 mg Desogestrel BP/ Ph.Eur.)	Total Bacterial Count	BP 2016, (Appendix-XVIB)/ Ph. Eur. 8.0 (Section-2.6.12 and 2.6.13)	≥10 CFU/g
		Total Yeast and Mould count		≥10 CFU/g
		<i>Escherichia coli</i>		Absent /Present
				≥10 CFU/g

END


Quality Manager