Accreditation No: LAB 073

Awarded to

Quality Control Laboratory
BROOKES PHARMA (PRIVATE) LIMITED.
KARACHI, PAKISTAN.

The scope of accreditation is in accordance with the standard specifications outlined in the following page(s) of this document. The accredited scope shall be visible and legible in areas such as customer service, sample-receiving section etc and shall not mislead its users.

The accreditation was first time granted on **18-07-2014** by Pakistan National Accreditation Council.

The laboratory complies with the requirements of **ISO/IEC 17025:2017.**

The accreditation requires regular surveillance, and is valid until **17-07-2020**

The decision of accreditation made by Pakistan National Accreditation Council implies that the organization has been found to fulfill the requirements for accreditation within the scope.

The organization however, itself is responsible for the results of performed measurements/tests.

PAKISTAN NATIONAL ACCREDITATION COUNCIL

31-12-2019

Date

Director General

Testing Laboratory.

Accreditation Scope of BROOKES PHARMA (PRIVATE) LIMITED.
KARACHI, PAKISTAN.

Permanent laboratory premises [X]

Materials/Products tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured	Reference to standardized method (e.g. ISO 14577-1:2003)/ Internal method reference
Arnil 50 Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (178.5 mg- 241.5 mg)	BP-2014
		Dissolution Test/ Dissolution (Not less than 80%)	BP-2014
		Disintegration Test/ Disintegration Time (Not more than 60min)	BP-2014
Neo-Choline Injection	Analytical Testing	pH/ pH Value (4.5 – 6.5)	BP-2014
Phlogin Injection (Label Claim 75mg/3ml)	Analytical Testing	Assay /API Content (90% - 105% of Label Claim)	Internal: QC-STM-003P
		pH/ pH Value (8.0 – 9.0)	USP-2014
		Volume Variation/ Deliverable Volume (Not less than 3.0)	BP-2014
Arnil 75 Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (250.3 mg- 305.9 mg)	BP-2014
		Dissolution Test/ Dissolution (Not less than 80%)	BP-2014
		Disintegration Test/ Disintegration Time (Not more than 60min)	BP-2014

31-12-2019
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Director

Nezocin Infusion	Analytical Testing	pH/ pH Value (4.5 – 5.5)	Internal: QC-SOP-010N / USP-2014
Gen-Levo I.V Infusion	Analytical Testing	pH/ pH Value (4.5 – 6.0)	Internal: QC-STM-008G/USP-2014
Quinox 200 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (357.8 mg- 437.3 mg) Disintegration Test/ Disintegration Time (Not more than 30min)	BP-2014 / USP-2014 BP-2014/USP-2014
Gen - Cipro 250 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (463.5 mg - 566.5 mg) Dissolution Test/ Dissolution (Not less than 80%) Disintegration Test/ Disintegration Time (Not more than 30min)	BP-2014 / USP-2014 BP-2014 BP-2014/USP-2014
Gen - Cipro 500 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (727.7 mg - 889.4 mg) Disintegration Test/ Disintegration Time (Not more than 30min)	BP-2014 / USP-2014 BP-2014/USP-2014
Gen-Levo 250 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (374.0 mg – 457.2 mg) Disintegration Test/ Disintegration Time (Not more than 30min)	BP-2014 / USP-2014 BP-2014/USP-2014

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Gen-Levo 500 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (748.1mg – 914.3 mg) Disintegration Test/ Disintegration Time (Not more than 30min)	BP-2014 / USP-2014 BP-2014/USP-2014
Nezocin Tablets 600 mg	Analytical Testing	Uniformity of Weight/ Weight variation (834.3mg – 1019.7 mg) Dissolution Test/ Dissolution (Not less than 75%) Disintegration Test/ Disintegration Time (Not more than 30min)	Internal: QC-STM-012N/BP-2014 Internal: QC-STM-012N/BP-2014 Internal: QC-STM-012N/ BP-2014

31-12-2019
Date

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Director