



**ACCREDITATION
DOCUMENT**

F-06/02
Issue Date: 10/08/15
Rev. No: 07
LAB 073

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 17025:2005**

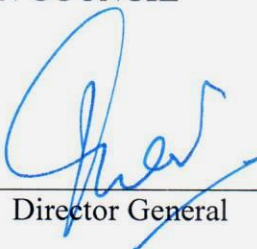
The accreditation requires regular surveillance, and is valid until **17-07-2017**

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.

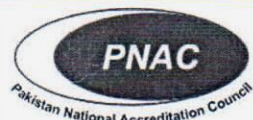
The organization however, itself is responsible for the results of performed measurements/tests.

PAKISTAN NATIONAL ACCREDITATION COUNCIL

14/10/2015
Date



Director General



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Testing Laboratory.

**Accreditation Scope of
Quality Control Laboratory
BROOKES PHARMA (PRIVATE) LIMITED. KARACHI, PAKISTAN.**

Permanent laboratory premises

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) Dissolution Test/ Dissolution (Not less than 80%) Disintegration Test/ Disintegration Time (Not more than 60min)	BP-2014 BP-2014 BP-2014
Neo-Choline Injection	Analytical Testing	pH/ pH Value (4.5 – 6.5)	BP-2014
Phloglin Injection (Label Claim 75mg/3ml)	Analytical Testing	Assay /API Content (90% - 105% of Label Claim) pH/ pH Value (8.0 – 9.0) Volume Variation/ Deliverable Volume (Not less than 3.0)	Internal: QC-STM-003P USP-2014 BP-2014
Arnil 75 Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (250.3 mg- 305.9 mg) Dissolution Test/ Dissolution (Not less than 80%) Disintegration Test/ Disintegration Time (Not more than 60min)	BP-2014 BP-2014 BP-2014

13-10-2015

Date

Director



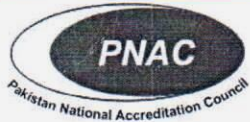
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Materials/Products tested	Testing field (e.g. environmental testing or mechanical testing)	Types of test/ Properties measured	Reference to standardized method (e.g. ISO 14577-1:2003)/ Internal method reference
Nezocin Infusion	Analytical Testing	pH/ 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

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Director