Accreditation No: LAB 073

Awarded to

Quality Control Laboratory
Brookes Pharma Private Limited
58-59, Sector No. 15, Korangi Industrial Area
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 **17-07-2023.**

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

11-03-2021
Date

Sd
Director General

Testing Laboratory.

Accreditation Scope of Quality Control Laboratory, 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) Dissolution Test/ Dissolution (Not less than 80%) Disintegration Test/ Disintegration Time (Not more than 60min)	(QCA/STM/AR/117) BP-2020 (Appendix XII C V-A408,V-409) BP-2020 (Appendix XII B V-A393, V-A397) BP-2020 (General Monographs III-77)
Neo-Choline Injection	Analytical Testing	pH/ pH Value (4.5 – 6.5)	(QCA/STM/NE/122) USP-2020 (USP-43 7022-7025 (791) / Physical Tests)
Phlogin 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 ml)	Internal: QCA/STM/PL/119 USP-2020 (USP-43 7022-7025 (791) / Physical Tests) USP-2020 (USP-43 6934 (697) / Physical Tests)
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 (Not more than 60min)	(QCA/STM/AL/116) BP-2020 (Appendix XII C V-A408,V-409) BP-2020 (Appendix XII B V-A393, V-A397) BP-2020 (General Monographs III-77)

11-03-2021
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Director

	Analytical Testing	pH/ pH Value (4.5 – 5.5)	Internal: QCA/STM/NC/191 / USP-2020 (USP-43 7022-7025 (791) / Physical Tests)
Gen-Levo I.V. Infusion	Analytical Testing	pH/ pH Value (4.5 – 6.0)	Internal: QCA/STM/GF/135 / USP-2020 (USP-43 7022-7025 (791) / Physical Tests)
Quinox 200 mg Tablets	Analytical Testing	Uniformity of Weight variation (357.8 mg- 437.3 mg) Disintegration Test / Disintegration Time (Not more than 30min)	(QCA/STM/QN/140) BP-2020 (Appendix XII C V-A408,V-409) USP-2020 (USP-43 6940-6943 (701) / Physical Tests)
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)	(QCA/STM/GE/094) BP-2020 (Appendix XII C V-A408,V-409) USP-2020 (USP-43 Official Monographs / Ciprofloxacin Tablets 1015) USP-2020 (USP-43 6940-6943 (701) / Physical Tests)
Gen - Cipro 500 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (727.7 mg - 889.4 mg) Disintegration Test (Not more than 30min)	(QCA/STM/GN/095) BP-2020 (Appendix XII C V-A408,V-409) USP-2020 (USP-43 6940-6943 (701) / Physical Tests)
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)	(QCA/STM/GL/136) BP-2020 (Appendix XII C V-A408,V-409) USP-2020 (USP-43 6940-6943 (701) / Physical Tests)

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Gen-Levo 500 mg Tablets	Analytical Testing	Uniformity of Weight/ Weight variation (748.1mg – 914.3 mg) Disintegration Test (Not more than 30min)	(QCA/STM/GV/137) BP-2020 (Appendix XII C V-A408,V-409) USP-2020 (USP-43 6940-6943 (701) / Physical Tests)
Nezocin Tablets 600mg	Analytical Testing	Uniformity of Weight variation (834.3mg – 1019.7 mg) Dissolution Test/ Dissolution (Not less than 75%) Disintegration Test/ Disintegration Time (Not more than 30min)	Internal: QCA/STM/NL/155 / BP-2020 (Appendix XII C V-A408,V-409) Internal: QCA/STM/NL/155 / BP-2020 (Appendix XII B V-A390,V-A393) Internal: QCA/STM/NL/155 / BP-2020 (General Monographs III-77)

11-03-2021
Date

Sd
Director