

	<b>ACCREDITATION DOCUMENT</b>	<b>F-06/02</b> <b>Issue Date: 18/08/2020</b> <b>Rev. No: 09</b> <b>LAB 073</b>
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**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 **17-07-2026**.

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**

**25-09-2023**

Date

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Director General



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**Testing Laboratory.**

**Accreditation Scope of Quality Control Laboratory, Brookes Pharma Private Limited.  
Karachi, Pakistan**

**Permanent laboratory premises**

<b>Materials/Products tested</b>	<b>Testing field (e.g. environmental testing or mechanical testing)</b>	<b>Types of test/ Properties measured</b>	<b>Reference to standardized method (e.g. ISO 14577-1:2003)/ Internal method reference</b>
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-2023 (Appendix XII C V-A433,434)  BP-2023 (Appendix XII B V-A413)  BP-2023 (V-A407)
Neo-Choline Injection	Analytical Testing	pH/ pH Value (4.5 – 6.5)	(QCA/STM/NE/122)  USP-2023 (General Chapter (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-2023 (General Chapter (791) Physical Tests)  USP-2023 (General Chapter (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/ Disintegration Time (Not more than 60min)	(QCA/STM/AL/116)  BP-2023 (Appendix XII C V-A433,434)  BP-2023 (Appendix XII B V-A413)  BP-2023 (V-A407)

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Nezocin Infusion	Analytical Testing	pH/ pH Value (4.5 – 5.5)	Internal: QCA/STM/NC/191 / USP-2023 (General Chapter (791) Physical Tests)
Gen-Levo I.V. Infusion	Analytical Testing	pH/ pH Value (4.5 – 6.0)	Internal: QCA/STM/GF/135 / USP-2023 (General Chapter (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-2023 (Appendix XII C V- A433,434)  USP-2023 (General Chapter (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-2023 (Appendix XII C V- A433,434)  USP-2023 (Official Monographs / Ciprofloxacin Tablets)  USP-2023 (General Chapter (701) / Physical Tests)
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)	(QCA/STM/GN/095)  BP-2023 (Appendix XII C V- A433,434)  USP-2023 (General Chapter (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-2023 (Appendix XII C V- A433,434)  USP-2023 (General Chapter (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/ Disintegration Time (Not more than 30min)	(QCA/STM/GV/137)  BP-2023 (Appendix XII C V- A433,434)  USP-2023 (General Chapter (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-2023 (Appendix XII C V- A433,434)  BP- 2023 (Appendix XII B V- A413)  USP-2023 (General Chapter (701) / Physical Tests)

**25-09-2023**

Date

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Director