

Prequalification Team Inspection services
WHO PUBLIC INSPECTIONREPORT
(WHOPIR)
Desk review of Finished Product Manufacturer

Part 1		General information	
Company information			
Name of manufacturing site		Macleods (Village Theda), Unit VI (Baddi, also called Nalagarh)	
Corporate address of manufacturer		Head Office: 304-Atlanta Arcade, Marol-Church Road, Andheri (East), Mumbai - 400059, Maharashtra, India R&D: G-2 Mahakali Caves Road, Shanti Nagar, Andheri (East), Mumbai 400 093, Maharashtra, India	
Inspected site			
Address of manufacturing site		Block No. N2, Village Theda, P.O. LodhiMajra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India	
Production Block		N2	
Manufacturing license number (local)		MNB/07/594 and MB/07/593 issued by Health and family welfare department Himachal Pradesh, issued 07.07.2007 (first issuance), subsequently renewed on 07/07/2012 , 07/07/2017 , valid upto06/07/2022 for the manufacture of tablets, capsules. Liquid orals and sachet (pellets & granules).	
Date of review		27 August 2018	
History of WHO inspections and compliance status			
Dates of inspection ; Conclusion of inspection		• March 2009 - GMP compliant • January 2011 - GMP compliant(biowaiver inspection) • March 2012 - GMP compliant • July 2014 - GMP compliant	
Brief summary of SRA/NRA inspection evidence considered (from most recent to last)			
US FDA Division of Inspectional Assessment	Dates of inspection:	11/13/2017-11/17/2017, 11/20/2017-11/24/2017, for a total of 10 days on site.	
	Type of inspection:	Routine	
	Block:	N2	
	Type of Products covered:	Tablets, capsules, oral liquids, granules	
UK MHRA	Dates of inspection:	24/04/2017-28/04/2017	
	Type of inspection:	Routine	
	Block:	N2	
	Type of Products covered:	Tablets and Hard Gelatine Capsules	
US FDA Division of Inspectional Assessment	Dates of inspection:	01/18/2016 – 01/20/2016	
	Type of inspection:	Routine	
	Block:	N2	
	Type of Products covered:	Tablets, capsules, oral liquids, granules	
Summary of the last WHO inspection			

Brief summary of the manufacturing activities	Manufacture, packaging, quality control and distribution of tablets, capsules, liquid orals and sachet (pellets & granules)
General information about the company and manufacturing site	Macleods Pharmaceuticals Ltd (referred to as “Macleods” in the rest of this text) has been manufacturing pharmaceuticals since 1996 and has 12 finished product manufacturing facilities in India, as well as one facility for active pharmaceutical ingredients. It is supported by its R&D and in-house bioequivalence centers in Mumbai. Sites participating in WHO Prequalification include: • Daman- Solid oral dosage forms • Nalagarh, Himachal Pradesh - Solid and Liquid oral dosage forms • Palghar, Maharashtra - Solid and Liquid oral dosage forms • Sarigam, Gujarat -API manufacturing facility R&D and Clinical bioequivalence centers (G-2, Mahakali Caves Road, Shanti Nagar, Andheri (East), Mumbai 400 093, Maharashtra, India AND R & D-II, Plot no. 95, Road no. 16, Opp Suncity Hotel, MIDC, Andheri (East), Mumbai, Maharashtra, 400 093, India The company, has in total, approximately 10,000 employees. The Nalagarh site was started in 2007. The site has 3 independent manufacturing facilities designated as Block N1 (Small tablet and soft gelatin block), Block N2 (General block), Block N3 (Cephalosporin block). Only Block N2 was being used for the above-listed WHO products. Only Block N2 was covered by this inspection.
Focus of the inspection	The inspection focused on the production and control of prequalified solid oral dosage forms products. The inspection covered all the sections of the WHO GMP text, including premises, equipment, documentation, materials, validation, sanitation and hygiene, production, quality control and utilities. The inspection covered quality assurance, sanitization and hygiene, qualification and validation, complaints, recalls, self-inspection, personnel, training, personal hygiene, premises, equipment, materials, documentation, production and quality control.
Areas inspected	N2
Restrictions	N/Ap
Out of scope	Blocks N1 and N3
WHO product numbers covered by the Last WHO inspection	HA424 Lamivudine Tablet, Film-coated 150mg HA459 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg HA506Efavirenz Tablet, Film-coated 600mg HA513 Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg HA514 Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 300mg/300mg HA516Tenofovir disoproxil fumarate Tablet, Film-coated 300mg HA523 Lamivudine Solution, Oral 10mg/mL

	HA526 Zidovudine Solution, Oral 10mg/mL HA573 Lopinavir/Ritonavir Tablet, Film-coated 100mg/25mg HA611 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/300mg/300mg TB154 Cycloserine Capsules, hard 250mg TB156 Para-aminosalicylate (sodium) Granules, Gastro-resistant 60g/100g TB218 Ofloxacin Tablet, Film-coated 200mg TB230 Moxifloxacin (hydrochloride) Tablet, Film-coated 400mg TB277 Levofloxacin Tablet, Film-coated 250mg TB278 Levofloxacin Tablet, Film-coated 500mg TB279 Levofloxacin Tablet, Film-coated 750mg TB297 Linezolid Tablet, Film-coated 600mg TB326 Levofloxacin Tablet, Dispersible 100mg TB342 Moxifloxacin (hydrochloride) Tablet, Dispersible 100mg IN014 Oseltamivir (phosphate) Capsules, hard 30mg IN015 Oseltamivir (phosphate) Capsules, hard 45mg IN016 Oseltamivir (phosphate) Capsules, hard 75mg NT004 Praziquantel Tablet, Film-coated 600mg DI005 Zinc sulfate Tablet, Dispersible 20mg
Additional products to be covered by the desk review (if any)	TB179 Isoniazid Tablet 300mg TB307 Pyrazinamide Tablet, Dispersible 150mg HA562 Efavirenz/Emtricitabine/Tenofovir disoproxil fumarate Tablet, Film-coated 600mg/200mg/300mg HA574 Lopinavir/Ritonavir Tablet, Film-coated 200mg/50mg HA713 Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg HA714 Efavirenz/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 400mg/300mg/300mg

Abbreviations	BMR	batch manufacturing record	
	BPR	batch packaging record	
	CAPA	corrective actions and preventive actions	
	FPP	finished pharmaceutical product	
	GMP	good manufacturing practice	
	NRA	national regulatory agency	
	OQ	operational qualification	
	PQ	performance qualification	
	PQR	product quality review	
	SRA	Stringent regulatory authority	

Part 2	Brief summary of the review and comments (where applicable)
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Brief summary of the Review and comments

1. Manufacturing authorization granted by local authorities (number and list of activities under the license)

Licence MNB/07/594 and MNB/07/593 from the State Drugs Controller, valid until 06.07.2022, was provided.

2. Foreign authorities inspection reports (general comments)

Overall, the outcomes of the inspections were all acceptable and are considered relevant to WHO products.

3. Evaluation of Site Master File/Laboratory Information File (date, number/version)

Site Master File No. MPC/N2/SMF/33, effective 02/18, was reviewed and considered acceptable.

4. PQR(s) of the concerned product(s)

The review of the PQRs revealed no issues of concern. The PQR IN016 was selected as an example for review.

5. Master batch manufacturing/packaging formula of the concerned product(s)

The review of the BPRs revealed no issues of concern. The BPRs for DI005 were selected as an example for review.

6. Self-inspection or external audit dedicated to the company

Corporate QA last inspected Block N2 between 1-3 February 2018.

Part 3	Conclusion
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Based on the previous WHO inspections and on the GMP evidence received and reviewed, it is considered that a desk review is acceptable in lieu of a WHO Inspection. The site, ***Macleods (Village Theda) Block No. N2, Village Theda, P.O. Lodhi Majra, Tehsil Baddi, District Solan, Himachal Pradesh, 174 101, India*** is considered to be operating at an acceptable level of compliance with WHO good manufacturing Practices for pharmaceutical products.

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.