World Health Organization

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Prequalification Team Inspection services
WHO Public Inspection Report
(WHOPIR)
Desk Assessment of FPP Manufacturer

Part 1	**General information**		
Company information			
Name of manufacturing site	Macleods Pharmaceuticals Limited		
Corporate address of manufacturing site	Macleods Pharmaceuticals Ltd G-2 Mahakali Caves Road Shanti Nagar, Andheri (E) Mumbai 400 093		
Site submitted to Desk Assessment			
Address of manufacturing site	Unit 2, Plot No. 25-27, Survey No. 366, Premier Industrial Estate Daman 396 210 India		
Unit/block / workshop number	Unit 2- Phase II, Phase III		
Manufacturing license number (local)	*DD/375 and DD/376*		
History of WHO inspections and compliance status			
Dates of inspection(s) ; Conclusion of inspection	2004	10 to 12 May	Satisfactory
	2005	21 to 23 March	Satisfactory
	2007	18 to 20 June	Satisfactory
	2010	14 to 19 Feb	Satisfactory
	2011	30 May to 3 June	Satisfactory
	2012	4 to 11 June	Satisfactory
	2014	20 to 23 May	Satisfactory
Brief summary of GMP inspection evidence considered			
US FDA	Dates of inspection:	22 – 29 May 2017	
	Type of inspection:	Routine	
	Block:	Plot No. 25-27, Survey No. 366, Premier Industrial Estate Daman 396 210 India	
	Type of Products	Tablets and hard gelatin capsules	
Government of Upper Franconia (Germany)	Dates of inspection:	13 – 15 June 2017	
	Type of inspection:	Routine and Follow up	
	Block:	Unit 2 (Building 2 and Building 6)	
	Type of Products covered:	Tablets and hard gelatin capsules	
Summary of the last WHO inspection			
Brief summary of the site's activities	Production and control of finished pharmaceutical products		
Focus of the inspection	The inspection focused on the production of solid oral dosage forms		

Areas inspected	Building no 2 (Phase II - SSF Area Granulation I, Non-RIFA Area: granulation area, Tablet Inspection Room no 2 and Packing Hall.), Building No 6 (Phase III - granulation-I Capsule Filling. , coating-I and Primary Packing-II), quality control (Cold Chamber and instrument Lab)
Out of scope and restrictions	N/A
WHO product numbers covered by the Last WHO inspection	HA424 Lamivudine tablets 150mg HA459 Lamivudine/Zidovudine tablets 150/300mg HA514 Lamivudine/Tenofovir Disoproxil fumarate tablets 300/300mg HA561 Emcitabine/ Tenofovir Disoproxil fumarate tablets 200/300mg HA513 Lamivudine /Nevirapine/Zidovudine 150/200/300 mg Tablets HA516 Tenofovir Disoproxil Fumarate Tablets 300 mg HA 562 Efavirenz/Emtricitabine/Tenofovir Disoproxil Fumarate, Film-coated, 600 mg / 200 mg /300 mg MA091 Artemether/Lumefantrine tablets 20/120mg TB133 Ethionamide tablets USP 250mg TB134 Ethambutol tablets BP 400mg TB154 Cycloserine capsules USP 250mg TB156 Para-aminosalicylate sodium granules TB158 Rifampicin/Isoniazid tablets 150/75mg TB159 Pyrazinamide tablets USP 400mg TB168 Rifampicin/Isoniazid/Pyrazinamide/Ethambutol tanlets 150/75/400/275mg TB178 Isoniazid tablets BP 100mg TB179 Isoniazid tablets BP 300mg TB183 Rifampicin/Isoniazid/Ethambutol tablets 150/75/275 TB226 Ethambutol tablets BP 100mg TB230 Moxifloxacin tablets 400mg TB231 Rifampicin/Isoniazid tablets 300/150mg TB243 Pyrazinamide tablets BP 500mg TB259 Rifampicin capsules BP 150mg TB302 Rifampicin/Isoniazid dispersible tablets 75/50mg TB333 Ethionamide dispersible tablets 125mg
Additional WHO products to be covered by the desk assessment (if any)	Approved Products: TB 303 Terizidone Capsules 250 mg TB 309 Isoniazid/Pyrazinamide/Rifampicin Tablet, Dispersible 50mg/150mg/75mg TB 330 Cycloserine Capsules 125 mg TB 332 Rifampicin Capsules 300 mg TB 334 Ethambutol Dispersible Tablets 100 mg Products under assessment: MA125 Artesunate / Amodiaquine 25 / 67.5 mgN/A MA126 Artesunate / Amodiaquine 50 / 135 mg MA 127 Artesunate / Amodiaqiune 100 / 270 mg

Abbreviations	BMR	batch manufacturing record	
	BPR	batch packaging record	
	CAPA	corrective actions and preventive actions	
	FPP	finished pharmaceutical product	
	GCP	good clinical practices	
	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**

1. **Manufacturing authorization granted by local authorities (number and list of activities under the license)**
   DD/375 and DD/376
2. **Foreign authorities inspection reports (general comments)**
   US FDA22 – 29 May 2017. CAPA were submitted and were found appropriate.
   Government of Upper Franconia (Germany)13 – 15 June 2017. CAPA were submitted and were found adequate as a result a GMP certificate *(DE_BY_05_GMP_2017_1039*) *was issued on 02.10.2017*
3. **Site Master File/ (date, number/version)**
   MPL/SMF/E/2017 25.10.2017
4. **PQR(s) of the concerned product(s)**
   The company provided laborious PQRs for 22 products
5. **Self-inspection or external audit dedicated to the company**
   A confirmation was provided. The Kachigam facilities are audited twice a year by a site auditing team and by a corporate body. According to the confirmation appropriate CAPA are followed up and implemented.
   Apart from USFDA and German authorities' inspections the site was also inspected in 2017 by CDSCO, India. The scope included among others WHO prequalified products

Part 3	**Conclusion**

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 Unit 2, Plot No. 25-27, Survey No. 366, Premier Industrial Estate Daman 396 210 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.