Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Desk Review of Finished Product Manufacturer

Part 1	**General information**	
Company information		
Name of manufacturing site	Hetero Labs (Unit III Jeedimetla - FPP)	
Corporate address of manufacturer	H. No: 7-2-A2, Industrial Estates, Sanathnagar, Hyderabad-500 018, Telangana, India.	
Inspected site		
Address of manufacturing site	Production Unit: Hetero Labs Ltd, Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055, India Central Warehouse: Plot-14 (Part), Survey No. 50, Phase-III, I.D.A. Jeedimetla, Hyderabad-500 055, Telangana State, India Finished Goods Warehouse: Plot-38, Survey No. 300 &306, Sri Venkateswara Co-operative Industrial Estate (S.V.C.I.E.), Ramireddy Nagar, Jeedimetla, Hyderabad-500 055, Telangana State, India	
Date of review	30 August 2018	
Production Block/Unit	Block-A, Block-B, Unit III	
Manufacturing license number (local)	7127/E(J)/TS/2017	
History of WHO inspections and compliance status		
Dates of inspection ; Conclusion of inspection	The inspection of Unit III block A and B was last performed by WHO PQT on June 9-12, 2015. This was the eighth inspection of this site. It was found compliant with only 1 major deficiency and 7 listed as "other".	
Brief summary of SRA/NRA inspection evidence considered (from most recent to last)		
US FDA Division of Inspectional Assessment	Dates of inspection:	19 - 23 March 2018
	Type of inspection:	Product specific pre-approval inspection and post-approval inspection.
	Block:	Unit III, A & B
	Type of Products covered:	Tablets and oral solutions
Spanish Agency for Medicines and Medical Devices, Medicines control department	Dates of inspection:	27th February – 3rd March 2017
	Type of inspection:	Routine
	Block:	Unit III, A & B
	Type of Products covered:	Tablets, capsules, oral liquids, granules
Summary of the last WHO inspection		
Brief summary of the manufacturing activities	Manufacturing of solid dosage forms – Tablets (uncoated and coated) – Capsules – Oral liquids Primary and secondary packaging	

	Storage Quality control No hormones or cytotoxic were manufactured in the unit. Besides the site of the manufacturing workshops there were the two outside warehouses belonging to the Unit III: – Central Warehouse for storage of excipients and packaging materials – FG - Warehouse for finished goods
General information about the company and manufacturing site	Hetero Labs Ltd, a division of Hetero group was established in 1993. Hetero Labs Limited Unit III was located about 45 km from Hyderabad international airport. There were two blocks (Block-A and Block-B) on the site with different multi-product formulation and packaging modules.
Focus of the inspection	The inspection focused on general principles of GMP and the production and control of prequalified products and products under assessment - tablets, capsules and oral solutions.
Areas inspected	Quality Assurance, Sanitization and hygiene, Qualification and validation, Complaints, Recalls, Supplier qualification, Personnel, Training, Personal hygiene, Premises, Equipment, Materials, Documentation, Production, Quality control
Restrictions	None encountered
Out of scope	Not applicable
WHO products covered by the last WHO inspection	USFDA ANDA 78-850 Lamivudine Tablet 300mg USFDA ANDA 78-957 a Stavudine Capsules, hard 15mg USFDA ANDA78-957 b Stavudine Capsules, hard 20mg USFDA ANDA 78-957 c Stavudine Capsules, hard 30mg USFDA ANDA78-957 d Stavudine Capsules, hard 40mg USFDA ANDA 79-124 Lamivudine/Zidovudine Tablet USFDA ANDA 91-560 Abacavir (sulfate) Tablet 300mg USFDA ANDA 22-459 Lamivudine/Tenofovir disoproxil (fumarate) Tablet 300mg/300mg HA155 Nevirapine Tablet 200mg HA275 Lamivudine/Nevirapine/Zidovudine Tablet, Film-coated 150mg/200mg/300mg HA399 Efavirenz Tablet, Film-coated 600mg HA448 Lamivudine/Tenofovir disoproxil (fumarate) Tablet 300mg/300mg HA457 Zidovudine Tablet, Film-coated 300mg HA486 Zidovudine Solution, Oral 10mg HA492 Lopinavir/Ritonavir Tablet, Film-coated 200mg/50mg HA493 Abacavir (sulfate) Solution, Oral 20mg/mL HA498 Emtricitabine/Tenofovir disoproxil (fumarate) Tablet, Film-coated 200mg/300mg HA508 Tenofovir disoproxil (fumarate) Tablet, Film-coated 300mg HA521 Lamivudine/Zidovudine Tablet, Film-coated 150mg/300mg

	HA549 Efavirenz/Lamivudine/Tenofovir disoproxil (fumarate) Tablet, Film-coated 600mg/300mg/300mg HA565 Ritonavir Tablet, Film-coated 100mg HA575 Abacavir (sulfate) Tablet, Film-coated 300mg HA719 Darunavir (ethanolate)/Ritonavir Tablet, Film-coated 400mg/50mg
Additional products	HA650 Lopinavir/Ritonavir Tablet, Film-coated 100mg/25mg HA682 Dolutegravir (Sodium) Tablet, Film-coated 50mg NDA 207315 USFDA Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 75mg/75mg **Under registration:** HA677 Lamivudine Solution, Oral 10mg/ml HA696 Dolutegravir (Sodium)/Lamivudine/Tenofovir disoproxil fumarate Tablet, Film-coated 50mg/300mg/300mg
Abbreviations	CAPA – corrective actions and preventive actions FPP – finished pharmaceutical product GMP – good manufacturing practice PQR – product quality review

Part 2	**Brief summary of the review and comments**

Brief summary of the Review and comments

1. **Manufacturing authorization granted by local authorities (number and list of activities under the license)**
   The manufacturing authorization No. 7127/E(J)/TS/2017 covered all of the activities declared to WHO.

2. **Foreign authorities inspection reports (general comments)**
   Altogether, the USFDA and Spanish Agency's inspection reports and accompanying documents were considered acceptable of GMP.

3. **Evaluation of Site Master File/Laboratory Information File (date, number/version)**
   SMF-FIII-08-13, dated 27 October 2017, was reviewed and considered acceptable.

4. **PQR(s) of the concerned product(s)**
   PQRs were selected on a risk basis for several products and reviewed. No issues of concern were found.

5. **Master batch manufacturing/packaging formula of the concerned product(s)**
   Provided and considered acceptable.

6. **Self-inspection or external audit dedicated to the company**
   The Company's statement was provided and considered acceptable.

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, ***Hetero Labs Ltd, Unit III, Survey No 51, Plot No 22-110 IDA, Jeedimetla, Hyderabad, Telangana, 500 055, 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.