

ANNEXURE - II

**Annexure to the Biological drug manufacturing licence No.108 of
M/S INCEPTA Pharmaceuticals Ltd., Savar, Dhaka, Bangladesh.**


DAR No.	Product Name	Composition	Speci- fication	Qty./tablet (in mg)
116-1061-032		<u>Active Ingredient (s)</u>		
	Twinvir Tablet (6, 12, 28, 42, 84 tablets in blister/ strip/bottle/ Plastic Container)	Ledipasvir (Premix) [Ledipasvir-Co-Povidone (1:1)]	INN/In-house (eqv. to Ledipasvir 90mg)	180.0000
		Sofosbuvir	INN/In-house	400.0000
		<u>Excipients</u>		
		Lactose (Fine) (Lactose Monohydrate)	BP/Ph. Eur.	180.0000
		Microcrystalline Cellulose (Avicel 101)	BP/Ph. Eur.	356.0000
		Croscarmellose Sodium	BP/Ph. Eur.	60.0000
		Colloidal Silicon Dioxide (Aerosil 200)	USP-NF	6.0000
		Magnesium Stearate	BP/Ph. Eur.	18.0000
		<u>Coating Materials</u>		
		Opadry II 85G58977 White	In House	27.0000
		Iron Oxide Yellow	In House	0.0513
		Purified Water*	BP/Ph. Eur.	150.0000

* Does not appear in the final product.

Inclusion Date : 10-08-2015

Valid Up to : 09-08-2025




Major General Md Mahbubur Rahman
Director General
Directorate General of Drug Administration
&
Licensing Authority (Drugs)
Govt. of the People's Republic of Bangladesh

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