

## 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	Specifi- cation	Qty./Tablet ( in mg )
116-865-032	<b>Barcavir 1 Tablet</b> (10, 20, 30, 50 tablets in blister/strip pack)	<b><u>Active Ingredient (s)</u></b>		
		Entecavir Monohydrate	INN/In-house (eqv. to Entecavir 1.00 mg)	1.0650
		<b><u>Excipients:</u></b>		
		Lactose Monohydrate (Fine)	BP/Ph. Eur.	31.5210
		Microcrystalline Cellulose (102)	BP/Ph. Eur.	60.0000
		Povidone (K 30)	USP-NF	4.0000
		Crospovidone (Type B)	USP-NF	10.0000
		Sodium Lauryl Sulfate/Sodium Laurilsulfate	BP/Ph. Eur.	0.4000
		Pigment Blend PB-1166 Pink	In-house	0.0140
		Colloidal Silicon Dioxide (200)	USP-NF	2.0000
		Magnesium Stearate	BP/Ph. Eur.	1.0000
		<b><u>Coating Materials</u></b>		
		Hypromellose 15 cps (Hydroxypropyl Methylcellulose 15 cps)	BP/Ph. Eur.	1.3000
		Hypromellose 5 cps (Hydroxypropyl Methylcellulose 5 cps)	BP/Ph. Eur.	1.9500
		Titanium Dioxide	BP/Ph. Eur.	0.4000
		Macrogol 6000/Polyethylene Glycol 6000	BP/Ph. Eur.	0.6500
		Purified Talc /Talc	BP/Ph. Eur.	0.6500
		Pigment Blend PB-1166 Pink	In-house	0.1000
		Polysorbate 80	BP/Ph. Eur.	0.0500
		Methanol*	BP/Ph. Eur.	22.4000
		Dichloromethane/Methylene Chloride*	BP/Ph. Eur.	33.6000

\* Does not appear in the final product.

Inclusion Date : 01-08-2011

Valid up to : 31-07-2026



**Major General Mohammad Yousuf**

Director General

Directorate General of Drug Administration  
&

Licensing Authority (Drugs)

Govt. of the People's Republic of Bangladesh

13 SEP 2022

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