

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	Barcavir 1 Tablet	<u>Active Ingredient (s)</u>		
	(10, 20, 30, 50 tablets in blister/strip pack)	Entecavir Monohydrate	INN/In-house (Eq. to Entecavir 1.00 mg)	1.0650

Excipients:

Lactose Monohydrate (Fine)	BP/Ph. Eur.	31.5210
Microcrystalline Cellulose (Avicel 102)	BP/Ph. Eur.	60.0000
Povidone (Povidone K 30)	USP-NF	4.0000
Crospovidone (Kollidon CL)	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 (Aerosil 200)	USP-NF	2.0000
Magnesium Stearate	BP/Ph. Eur.	1.0000

Coating Materials

Hypromellose 15 cps	BP/Ph. Eur.	1.3000
(Hydroxypropyl Methylcellulose 15 cps)		
Hypromellose 5 cps	BP/Ph. Eur.	1.9500
(Hydroxypropyl Methylcellulose 5 cps)		
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	1.0000
Polysorbate 80 (Tween 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 : 31-07-2021



Major General Md Mustafizur Rahman

Director General

Directorate General of Drug Administration

&

Licensing Authority (Drugs)

Govt. of the People's Republic of Bangladesh

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