

ANNEXURE - II

**Annexure to the Biological drug manufacturing licence No. 290 of
M/S INCEPTA Pharmaceuticals Ltd., Dhamrai Unit, Dhaka, Bangladesh.**

DAR No.	Product Name	Composition	Specification	Qty./ml (in mg)
366-002-039		<u>Active Ingredient (s)</u>		
	Medogen Injection (1 ml in Vial per pack)	Medroxyprogesterone Acetate (Sterile, Micronized)	BP/Ph.Eur.	150.0000
		<u>Excipients</u>		
		Methylparaben	BP/Ph.Eur.	1.3700
		Propylparaben	BP/Ph.Eur.	0.1500
		Sodium Chloride (Injectable Grade)	BP/Ph.Eur.	8.6800
		Polyethylene Glycol 3350	BP/Ph.Eur.	28.9000
		Polysorbate 80 (Tween 80)	BP/Ph.Eur.	2.4100
		Sodium Hydroxide	BP/Ph.Eur.	qs to adjust pH
		Hydrochloric Acid 37%	BP/Ph.Eur.	qs to adjust pH
		Water For Injection (WFI)	BP/Ph.Eur.	qs to 1ml
		Nitrogen Gas	BP/Ph.Eur.	q.s.

* Fill Volume will be 1.22 ml per vial to ensure withdrawal
fill volume 1 ml

Inclusion Date : 04-04-2012

Valid up to : 03-04-2027



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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