

ITEM: Foldable IOL Sterile Lens & Preloaded Foldable IOL Sterile Lens						
Tender no:20/MPPHSCL/Foldable IOL Sterile Lens/2015 dated 27-02-2015						
Evaluation Report						
Schedule No. 1 –						
Sr No	Description of Item	Technical Specification	Quantity	Bidder:M/s Emco Tech Equipments Pvt Ltd,Bhopal (Alcon)	Bidder:M/s Abbott Medical Optics Pvt Ltd,Gurgaon (Abbott)	Bidder:M/s Lab Medica Systems Pvt Ltd,Ahmedabad (Hoya)
1	Lens Material -	Foldable Hydrophobic Acrylic Aspherical,Single Piece,Square edge		Yes	Yes	Yes
2	Positioning Holes	None		Yes	Yes	Yes
3	Optic Configuration	6 mm, Biconvex, Round Preference will be given to square edge & 100% usable area of optics, Aspherical		Yes	Yes	Yes
4	A constants	116-120		Yes	Yes	Yes
5	Powers	+18 to 22 D		Yes	Yes	Yes
6	Sterilisation	ETO		Yes	Yes	Yes
7	Other requirement	US FDA Approved		Yes	Yes	Yes
	Types of lenses required with above specifications:					
7.1		Foldable IOL sterile lens +18D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
		Foldable IOL sterile lens +18.5 D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
7.2		Foldable IOL sterile lens +19D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
		Foldable IOL sterile lens +19.5 D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
7.3		Foldable IOL sterile lens +20D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
		Foldable IOL sterile lens +20.5 D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
7.4		Foldable IOL sterile lens +21D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
		Foldable IOL sterile lens +21.5 D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
7.5		Foldable IOL sterile lens +22D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
		Foldable IOL sterile lens +22.5 D (USFDA approved, detailed specification as above)	500	Yes	Yes	Yes
	Dioptic power	+18 d +19D+20D to+22 D (in 0.50 D Steps)				
	Sterilisation	ETO				

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	ACIOL	3% of total IOL,+18 D kelvin Mutiflex type equal quantities of +18 D to +20D				
	Basic requirement	US FDA certified,IOL must be quality certified from US-FDA regulation,such certificate should be available with the bidder on or before the date of bid-opening				
	Marking	The packing of each Iol to be marked with Govt of MP supply ,not for Sale		Yes	Yes	Yes
		The PC & AC IOL to be packed and dispatched to each consignee in equal proportion of size and Dioptic Power as specified below:				
	Lens	Dioptic Power		Yes	Yes	Yes
	PCIOL	+18.0,18.5		Yes	Yes	Yes
	PCIOL	+19.0,19.5		Yes	Yes	Yes
	PCIOL	+20.0,20.5		Yes	Yes	Yes
	PCIOL	+21.0,21.5		Yes	Yes	Yes
	PCIOL	+22.0,22.5		Yes	Yes	Yes
		Note:requirement of 1000 lens may be broken into 500+500 quantity for 0.50 dioptic Steps ,increment in power				
Schedule No. 2 – Specification of Preloaded Foldable IOL Sterile Lens						
Sr No	Description of Item	Technical Specification	Quantity	Yes	Not Quoted	Yes
1	Lens Material -	Fully Preloaded Foldable Hydrophobic Acrylic Aspherical,Single Piece,Square edge 360 Degree(Disposable Single use injector and easy to read lable slider with barcode)		Yes	Not Quoted	Yes
2	Positioning Holes	None		Yes	Not Quoted	Yes
3	Optic Configuration	6 mm, Biconvex, Round Preference will be given to square edge & 100% usable area of optics, Aspherical		Yes	Not Quoted	Yes
4	A constants	116-120		Yes	Not Quoted	Yes
5	Powers	+18 to 22 D		Yes	Not Quoted	Yes
6	Sterilisation	ETO		Yes	Not Quoted	Yes
7	Other requirement	US FDA Approved		Yes	Not Quoted	Yes
	Types of lenses required with above specifications:					
7.1		Preloaded Foldable IOL sterile lens +18D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes

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		Preloaded Foldable IOL sterile lens +18.5 D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
7.2		Preloaded Foldable IOL sterile lens +19D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
		Preloaded Foldable IOL sterile lens +19.5 D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
7.3		Preloaded Foldable IOL sterile lens +20D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
		Preloaded Foldable IOL sterile lens +20.5 D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
7.4		Preloaded Foldable IOL sterile lens +21D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
		Preloaded Foldable IOL sterile lens +21.5 D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
7.5		Preloaded Foldable IOL sterile lens +22D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
		Preloaded Foldable IOL sterile lens +22.5 D (USFDA approved, detailed specification as above)	500	Yes	Not Quoted	Yes
	Dioptric power	+18 d +19D+20D to+22 D (in 0.50 D Steps)				
	Sterilisation	ETO				
	ACIOL	3% of total IOL,+18 Dkelvin Mutiflex type equal quantities of +18 D to +20D				
	Basic requirement	US FDA certified,IOL must be quality certified from US-FDA regulation,such certificate should be available with the bidder on or before the date of bid-opening				
	Marking	The packing of each IOL to be marked with Govt of MP supply ,not for Sale		Yes	Not Quoted	Yes
		The PC & AC IOL to be packed and dispatched to each consignee in equal proportion of size and Dioptric Power as specified below:				
	Lens	Dioptric Power				
	PCIOL	+18.0,18.5		Yes	Not Quoted	Yes

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	PCIOL	+19.0,19.5		Yes	Not Quoted	Yes
	PCIOL	+20.0,20.5		Yes	Not Quoted	Yes
	PCIOL	+21.0,21.5		Yes	Not Quoted	Yes
	PCIOL	+22.0,22.5		Yes	Not Quoted	Yes
		Note:requirement of 1000 lens may be broken into 500+500 quantity for 0.50 dioptic Steps ,increment in power				
		Brand		AcrySof® IQ NATURAL Single Piece Intraocular Lens (Model SB 30AL),preloaded in AcrySert®C delivery system	Tecnis-1piece Acrylic Posterior Chamber IOL - Intraocular Lens	Isert
		MODEL		USFDA(equivalent to SN 60 AT) True Noterised Copy of original USFDA (June 24,2003)on file at Alcon Laboratories Inc,State of Texas,USA	(Model Number :ZCB00)	(Model:iSert 250)Foldable IOL Sterile Lens,(Model : iSert 251)-Fully pre- Loaded Foldable IOL
		Checklist		Yes	Yes	
		EMD		Yes	Yes	Yes
		Validity 180 days of BG		Yes	Yes	Yes
		Tender form Section X		Yes	Yes	Yes
		Power of Attorney		Yes-Mr Sudhir Singh	Yes-Mr Biren Patel,Director
		Clause by Clause Compliance		Yes	Yes	Yes
		Tennical deviations if any		No	No	No
		Cataloge/brochure		Yes	Yes	Yes
		Valid USFDA certificate		USFDA Certificate of Foreign Government dated25-02-2014	USFDA Certificate of Foreign Government dated4-11-2013, 16-10-2013	USFDA Certificate of Foreign Government dated4-09-2013
		Order and End user certificates		Yes	Yes	Yes
		120 days validity from opening		Yes	Yes	Yes
		Income Tax Statement		Yes	Yes	Yes
		Full Add of Banker		Yes	Yes	Yes
		Payment terms agreed		Yes	Yes	Yes
		Delivery Period Agreed		Yes	Yes	Yes
		Conditions in GCC Clause 15accepted		Yes	Yes	Yes
		Certificte of Incorporation		Yes	Yes	Yes

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		Accepted terms and conditions of TE document		Yes	Yes	Yes
		Document establishing eligibility criteria-Section IX1.Indian Manufacturer or Indian Subsidiary of foreign manufacturer		Yes	Yes	Yes
		In last 3 yrs supplied 100% of similar items		Yes	Yes	Yes
		Sec IX -Qualification Criteria Performance Statement		Yes	Yes	Yes
		Annual report 3 yrs		Yes	Yes	Yes
		Bidder Information and Production Capacity Section VIII		Yes	Yes	Yes
		Monthly Single shift Production capacity:-				
		Normal		30 single shift	1 piece: 33552 units/month normal 3 pieceOL:131040 units/month	80000 per month
		Max		60 single shift		100000 per month
		Turnover		Approx INR 520 crores (Alcon)	INR 256.72 crores	INR 500crores
		QMS				
		BIS/ISO		DIN EN ISO9001,DIN EN ISO 13485	ISO 13485:2003 standard	ISO 13485:2003 standard
		Compliance to USFDA 21 CFR		Yes	Yes	Yes
					CE Marking of Conformity reissued 1-11-2012	
		Expertise			Over 5 years	Over 25 years
		Type test				Biological Test
		Health Authority Registration		USFDA	USFDA	USFDA & FDCA
		Manufacturing Process			AMO PROCEDURE,BOM,PO,INSPECTION PROCEDURES,DHR QUALITY INSPECTION	Lathe cut,Tumble polish & Pad polish
		DEMO Meeting specifications-OK/NOT OK		OK	OK	NOT OK
		Comments-Responsive/Non responsive-Schedule I Foldable -IOL		QUOTED-Responsive	QUOTED-Responsive	QUOTED- Non responsive
		Comments-Responsive/Non responsive-Schedule II Preloaded Foldable IOL		QUOTED-Responsive	NOT QUOTED	QUOTED-Non responsive

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		Remarks (if any)				Haptic is made up of 2 material Acrylic and PMMA .Hence lens is not a single piece
	Prepared by					
	dt					
	Signature of Tech Committee members					