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Drug Substances used in the Manufacture of Phenylephrine HCl Ophthalmic Solution, USP Drug Products					
Drug substance				Drug product	
Control No.	S(+)- isomer ⁽¹⁾	R(-)- isomer ⁽¹⁾	Reference	Used to manufacture Lot#	Strength
CH07110017	0.05%	99.95%	376/70	11323	10%
CH07110018	0.01%	99.99%	376/70	11577/11578/11581	2.5% and 10% (11581)
CH02110026	0.03%	99.97%	376/70	11302	2.5%
CH07120084	ND ⁽²⁾	100.0%	376/70	13126	2.5%
CH04130021	0.83%	99.17%	376/198	13142	10%

(1) Average of two injections

(2) Not detected

NOTE: S(+)-isomer concentration was determined by HPLC using a Chiralpak 4.6x250mm, 5µm column at 270nm as per Altaire test method TMQC-247.

Prepared by: PL 4/30/15	Reviewed by: [Signature] 4/30/15	Approved by: [Signature] 4/30/15
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