

Stability Data for Eltroxin 100µg Tablets (Reformulation)

Batch / Lot Number	Test							
	Description	Levothyroxin-Na Content by HPLC (% LC)	Dissolution (%) 45 Min.	Drug Related Impurities by HPLC (as % of Levothyroxin -Na)				
				Total Impurities	Liothyronine Na	Tetraiodo-thyroacetic Acid	HDPPhDP	Unknown
Specification	see note 1	90,0 - 105,0	70%	NGT 6,0 see note 2	NGT 1,0	NGT 1,0	NGT 2,5	NGT 1,0
7C002 (00013695)	complies	99.0	93	1.9	0.2	0.6	0.4	complies
7F004 (00013865)	complies	98.5	98	1.5	0.2	0.5	0.4	complies
7F004 (00013867)	complies	98.5	96	1.8	0.2	0.6	0.5	complies
7H005 (00013976)	complies	97.5	93	1.3	0.2	0.4	0.3	complies
7L006 (00014079)	complies	98.2	97	1.0	0.1	0.3	0.2	complies
8A002 (00014190)	complies	99.8	96	1.0	0.1	0.3	0.3	complies
8A001 (00014191)	complies	100.3	98	1.0	0.1	0.3	0.3	complies
8A003 (00014323)	complies	99.4	96	0.7	0.3	0.2	0.2	complies
Complaint 7L006	complies	98.7	96	3.0	0.3	0.3	0.3	complies

ND = Not Detected

NGT = not greater than

Note:

1. White to off-white, round, biconvex tablets imprinted GS 21C on one face and 100 on the other
2. Total impurities exclude liothyronine sodium

Stability Data for Eltroxin 100µg Tablets (Reformulation)

Dissolution

Batch / Lot no.	7C002 (00013695)	7F004 (00013865)	7F004 (00013867)	7H005 (00013976)	7L006 (00014079)	8A002 (00014190)	8A001 (00014191)	8A003 (00014323)	Complaint 7L006
Result	complies Level 1	complies Level 1	complies Level 1	complies Level 1	complies Level 1	complies Level 1	complies Level 1	complies Level 1	complies Level 1
% Release Mean	93	98	96	93	97	96	98	96	96
% Release single tablet	1 96	1 97	1 98	1 91	1 94	1 95	1 98	1 95	1 95
	2 93	2 98	2 95	2 94	2 97	2 95	2 98	2 94	2 95
	3 92	3 97	3 95	3 92	3 99	3 96	3 100	3 99	3 97
	4 98	4 102	4 96	4 94	4 98	4 97	4 98	4 96	4 96
	5 82	5 97	5 95	5 92	5 96	5 96	5 95	5 92	5 96
	6 96	6 99	6 95	6 95	6 95	6 95	6 97	6 98	6 95

Stability Data for Eltroxin 50µg Tablets (Reformulation)

Batch / Lot Number	Test							
	Description	Levothyroxin-Na Content by HPLC (% LC)	Dissolution (%) 45 Min.	Drug Related Impurities by HPLC (as % of Levothyroxin -Na)				
				Total Impurities	Liothyronine Na	Tetraiodo-thyroacetic Acid	HDPHDP	Unknown
Specification	see note 1	90,0 - 105,0	70%	NGT 6,0 see note 2	NGT 1,0	NGT 1,0	NGT 2,5	NGT 1,0
7A003 (00013494)	complies	97.2	93	2.9	0.2	0.3	1.0	complies
7A003 (00013725)	complies	96.5	92	2.9	0.2	0.3	1.0	complies
7D004 (00013726)	complies	100.3	89	2.0	0.2	0.4	0.6	complies
7D005 (00013868)	complies	97.0	91	3.0	0.5	0.4	1.1	complies
7D007 (00013955)	complies	97.6	93	3.0	0.2	0.4	1.0	complies
7G008 (00013975)	complies	95.2	90	3.1	0.2	0.4	1.2	complies
7M009 (00014080)	complies	99.4	93	1.6	0.1	0.2	0.5	complies
7M002 (00014188)	complies	99.2	88	1.2	0.1	0.2	0.4	complies
8B001 (00014325)	complies	100.6	95	0.9	0.2	0.3	0.2	complies
8B002 (00014324)	complies	101.4	96	1.0	0.2	0.3	0.2	complies
7M002 (00014326)	complies	99.3	84	1.1	0.2	0.3	0.3	complies

ND = Not Detected

NGT = not greater than

Note:

1. White to off-white, round, biconvex tablets imprinted GS 11E on one face and 50 on the other
2. Total impurities exclude liothyronine sodium

