Hewlett-Packard
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Module 3 - Section 2.P.8.3 - Stability Data

Stability Study Summary
Bicalutamide 150 mg film-coated tablets

Version number:	SSS.NUS.BCM.tab150.002 (10.0)
Supersedes document of issue date:	SSS.NUS.BCM.tab150.002 (9.0), electronically controlled
Number of appendices:	Two
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Document length:	26 pages

Contents:

1 Introduction

In this Stability Study Summary, the data regarding Bicalutamide 150 mg tablets are presented. These data are gathered as a result of the execution of SDE.NUS.BCM.tab150.002.

Explanation of terms used in this Stability Study Summary:

Long term study:	25 °C / 60% RH
Intermediate study:	30 °C / 65% RH
Accelerated study:	40 °C / 75% RH
C:	Complies with specification
NC:	Does not comply with specification
--:	Not performed or no results available

2 Overview long term stability data

2.1 Long term stability study: 25 °C/60 % RH blister (PVC/PE/PVDC:Al)

In this part of the stability study summary, the results of Bicalutamide 150 mg tablets, packaged in a PVC/PE/PVDC:Al blister and stored at 25 °C/60 % RH are presented.

Product / strength:	Bicalutamide 150mg				Packaged lot number:				04D211EA											
Storage condition:	25°C/60% RH				Batch size:				50000 tablets											
Study start date:	14/05/2004				Packaging				30 tablets											
Packaging:	PVC/PE/PVDC/Alu				Closure:				NA											
Bulk batch number:	04D211E				Drug substance:				Bicalutamide											
Bulk Mfg. Date:	21/04/2004				Drug substance Mfg:				Synthon sro											
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				57621											
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**		**60**
Appearance:		C		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		77	83	82	84	81	83	77	83	78	83	80	85	82	85	74	83	75	84	74	78
Identification (HPLC),		C		C		C		C		C		C		C		C		C		C
Assay (HPLC) [mg/tab]:		146.4		144.2		147.3		151.6		147.0		147.2		146.5		143.8		145.6		144.3
- % of declared value		98		96		98		101		98		98		98		96		97		96
Impurities (HPLC):																				
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.06
- Total unidentified impurities		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.06
- Total impurities		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.07		0.06
Microbial contamination																				
- Total viable aerobic count																				
'- Aerobic bacteria:		C		---		C		---		C		---		C		C		C		C
'- Fungi:		C		---		C		---		C		---		C		C		C		C
- Escherichia coli:		---		---		C		---		C		---		C		C		C		C

Product / strength:	Bicalutamide 150mg				Packaged lot number:				04D26IEA											
Storage condition:	25°C/60% RH				Batch size:				50000 tablets											
Study start date:	19/05/2004				Packaging				30 tablets											
Packaging:	PVC/PE/PVDC/Al				Closure:				NA											
Bulk batch number:	04D26IE				Drug substance:				Bicalutamide											
Bulk Mfg. Date:	26/04/2004				Drug substance Mfg:				Synthon sro											
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				57630											
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**		**60**
Appearance:		C		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		80	85	86	89	77	83	83	86	64	78	76	80	74	81	82	85	81	85	75	78
Identification (HPLC):			C		C		C		C		C		C		C		C		C		C
Assay (HPLC) [mg/tab]:			146.0		145.7		147.2		152.2		147.6		150.1		144.1		146.1		148.2		143.1
- % of declared value			97		97		98		101		98		100		96		97		99		95
Impurities (HPLC):																					
- A/509			≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity			0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.07
- Total unidentified impurities			0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.07
- Total impurities			0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.08		0.07
Microbial contamination																					
- Total viable aerobic count																					
'- Aerobic bacteria:			C		---		C		---		C		---		C		C		C		C
'- Fungi:			C		---		C		---		C		---		C		C		C		C
- Escherichia coli:			---		---		C		---		C		---		C		C		C		C

Product / strength:	Bicalutamide 150mg				Packaged lot number:				04D28IEA											
Storage condition:	25°C/60% RH				Batch size:				50000 tablets											
Study start date:	19/05/2004				Packaging				30 tablets											
Packaging:	PVC/PE/PVDC/Al				Closure:				NA											
Bulk batch number:	04D28IE				Drug substance:				Bicalutamide											
Bulk Mfg. Date:	28/04/2004				Drug substance Mfg:				Synthon sro											
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				57621 - 57630											
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**		**60**
Appearance:		C		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		73	80	74	81	70	75	79	85	68	75	77	81	73	79	80	83	71	82	81	82
Identification (HPLC):,			C		C		C		C		C		C		C		C		C		C
Assay (HPLC) [mg/tab]:			148.8		147.2		147.6		151.3		147.2		149.0		146.5		148.5		150.0		145.8
- % of declared value			99		98		98		101		98		99		98		99		100		97
Impurities (HPLC):																					
- A/509			≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity			0.07		0.06		0.07		0.06		0.06		0.07		0.06		0.08		0.06		0.06
- Total unidentified impurities			0.07		0.06		0.07		0.06		0.06		0.07		0.06		0.08		0.06		0.06
- Total impurities			0.07		0.06		0.07		0.06		0.06		0.07		0.06		0.08		0.06		0.06
Microbial contamination																					
- Total viable aerobic count																					
'- Aerobic bacteria:			C		---		C		---		C		---		C		C		C		C
'- Fungi:			C		---		C		---		C		---		C		C		C		C
- Escherichia coli:			---		---		C		---		C		---		C		C		C		C

Product / strength:	Bicalutamide 150mg				Packaged lot number:				05D29IEA											
Storage condition:	25°C/60% RH				Batch size:				50000 tablets											
Study start date:	22/07/2005				Packaging				30 tablets											
Packaging:	PVC/PE/PVDC/Alu				Closure:				NA											
Bulk batch number:	05D29IE				Drug substance:				Bicalutamide											
Bulk Mfg. Date:	29/04/2005				Drug substance Mfg:				CF Pharma Ltd											
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				85201											
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**		**60**
Appearance:		C		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		86	89	88	93	88	90	86	90	95	98	90	94	82	89	88	92	84	88	87	89
Identification (HPLC):		C		C		C		C		C		C		C		C		C		C
Assay (HPLC) [mg/tab]:		148.2		150.3		147.7		149.3		148.0		146.9		148.2		147.9		149.7		146.3
- % of declared value		99		100		98		100		99		98		99		99		100		98
Impurities (HPLC):																				
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		0.07		≤ 0.05		≤ 0.05
- Total unidentified impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		0.07		≤ 0.05		≤ 0.05
- Total impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		0.07		≤ 0.05		≤ 0.05
Microbial contamination																				
- Total viable aerobic count																				
'- Aerobic bacteria:		C		---		C		---		C		---		C		C		C		C
'- Fungi:		C		---		C		---		C		---		C		C		C		C
- Escherichia coli:		C		---		C		---		C		---		C		C		C		C

Product / strength:	Bicalutamide 150mg	Packaged lot number:	05E031EA
Storage condition:	25°C/60% RH	Batch size:	50000 tablets
Study start date:	22/07/2005	Packaging	30 tablets
Packaging:	PVC/PE/PVDC/Al	Closure:	NA
Bulk batch number:	05E031E	Drug substance:	Bicalutamide
Bulk Mfg. Date:	03/05/2005	Drug substance Mfg:	CF Pharma Ltd.
Bulk Mfg.site:	Synthon Hispania	Drug substance lot number:	85198

Tests \ Time in months	0			3			6			9			12			18			24			36			48			60	
Appearance:		C			C			C			C			C			C			C			C			C			C	
Seal integrity of the blister/container:		C			C			C			C			C			C			C			C			C			C	
Uniformity of dosage units		C			C			C			C			C			C			C			C			C			C	
Dissolution:	Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave		Min	Ave	
- in 30 minutes	90	93		92	94		90	96		89	91		90	97		92	97		84	90		85	93		87	88		96	98	
Identification (HPLC):		C			C			C			C			C			C			C			C			C			C	
Assay (HPLC) [mg/tab]:		148.1			147.0			147.4			147.8			146.6			147.3			147.5			146.7			149.0			147.9	
- % of declared value		99			98			98			99			98			98			98			98			99			99	
Impurities (HPLC):																														
- A/509		≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05	
- Largest unidentified impurity		≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05	
- Total unidentified impurities		≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05	
- Total impurities		≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05			≤ 0.05	
Microbial contamination																														
- Total viable aerobic count																														
'- Aerobic bacteria:		C			---			C			---			C			---			C			C			C			C	
'- Fungi:		C			---			C			---			C			---			C			C			C			C	
- Escherichia coli:		C			---			C			---			C			---			C			C			C			C	

2.2 Long term stability study: 25 °C/60 % RH Bulk packaging

In this part of the stability study summary the results of Bicalutamide 150 mg tablets, packaged in bulk container, stored at 25 °C/60 % RH are presented.

Product / strength:	Bicalutamide 150mg						Packaged lot number:						04D21IE	
Storage condition:	25°C/60% RH						Batch size:						50000 tablets	
Study start date:	14/05/2004						Packaging						NA	
Packaging:	Bulk						Closure:						NA	
Bulk batch number:	04D21IE						Drug substance:						Bicalutamide	
Bulk Mfg. Date:	21/04/2004						Drug substance Mfg:						Synthon s r o	
Bulk Mfg.site:	Synthon Hispania						Drug substance lot number:						57621	
Tests	**Time in months**	**0**		**6**			**12**		**24**			**36**		
Appearance:		C		C			C		C			C		
Uniformity of dosage units		C		C			C		C			C		
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave			
- in 30 minutes		77	83	79	83	82	85	78	85	81	84			
Identification (HPLC):		C		C		C		C		C				
Assay (HPLC) [mg/tab]:		146.4		148.2		146.0		144.2		144.5				
- % of declared value		98		99		97		96		96				
Impurities (HPLC):														
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05				
- Largest unidentified impurity		0.07		0.06		0.07		0.07		0.07				
- Total unidentified impurities		0.07		0.06		0.07		0.07		0.07				
- Total impurities		0.07		0.06		0.07		0.07		0.07				
Microbial contamination														
- Total viable aerobic count														
'- Aerobic bacteria:		C		C		C		C		C				
'- Fungi:		C		C		C		C		C				
- Escherichia coli:		---		C		C		C		C				

3 Overview intermediate stability data

3.1 Intermediate stability study: 30 °C/65 % RH blister (PVC/PE/PVDC:Al)

In this part of the stability study summary, the results of Bicalutamide 150 mg tablets, packaged in a PVC/PE/PVDC:Al blister, stored at 30 °C/65 % RH are presented.

Product / strength:	**Bicalutamide 150mg**				Packaged lot number:				**04D21IEA**									
Storage condition:	**30°C/65% RH**				Batch size:				**50000 tablets**									
Study start date:	**14/05/2004**				Packaging				**30 tablets**									
Packaging:	**PVC/PE/PVDC/Alu**				Closure:				**NA**									
Bulk batch number:	**04D21IE**				Drug substance:				**Bicalutamide**									
Bulk Mfg. Date:	**21/04/2004**				Drug substance Mfg:				**Synthon sro**									
Bulk Mfg.site:	**Synthon Hispania**				Drug substance lot number:				**57621**									
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**
Appearance:		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		77	83	78	82	80	83	78	85	81	85	85	87	80	85	83	86	81	85
Identification (HPLC):,		C		C		C		C		C		C		C		C		C	
Assay (HPLC) [mg/tab]:		146.4		144.8		150.2		149.0		147.9		147.9		146.6		142.9		145.7	
- % of declared value		98		97		100		99		99		99		98		95		97	
Impurities (HPLC):																			
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Largest unidentified impurity		0.07		0.07		0.06		0.07		0.07		0.07		0.07		0.07		≤ 0.05	
- Total unidentified impurities		0.07		0.07		0.06		0.07		0.07		0.07		0.07		0.07		0.07	
- Total impurities		0.07		0.07		0.06		0.07		0.07		0.07		0.07		0.07		0.07	
Microbial contamination																			
- Total viable aerobic count																			
'- Aerobic bacteria:		C		---		C		---		C		---		C		C		C	
'- Fungi:		C		---		C		---		C		---		C		C		C	
- Escherichia coli:		---		---		C		---		C		---		C		C		C	

Product / strength:	**Bicalutamide 150mg**				Packaged lot number:				**04D26IEA**									
Storage condition:	**30ºC/65% RH**				Batch size:				**50000 tablets**									
Study start date:	**19/05/2004**				Packaging				**30 tablets**									
Packaging:	**PVC/PE/PVDC/Al**				Closure:				**NA**									
Bulk batch number:	**04D26IE**				Drug substance:				**Bicalutamide**									
Bulk Mfg. Date:	**26/04/2004**				Drug substance Mfg:				**Sytnhon sro**									
Bulk Mfg.site:	**Synthon Hispania**				Drug substance lot number:				**57630**									
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**
Appearance:		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		80	85	83	88	72	80	83	86	70	78	81	84	67	81	80	83	78	85
Identification (HPLC):,			C		C		C		C		C		C		C		C		C
Assay (HPLC) [mg/tab]:			146.0		143.7		147.8		149.0		148.5		147.3		147.2		147.4		147.5
- % of declared value			97		96		99		99		99		98		98		98		98
Impurities (HPLC):																			
- A/509			≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity			0.08		0.07		0.08		0.07		0.08		0.08		0.08		0.08		0.07
- Total unidentified impurities			0.08		0.07		0.08		0.07		0.08		0.08		0.08		0.08		0.07
- Total impurities			0.08		0.07		0.08		0.07		0.08		0.08		0.08		0.08		0.07
Microbial contamination																			
- Total viable aerobic count																			
'- Aerobic bacteria:			C		---		C		---		C		---		C		C		C
'- Fungi:			C		---		C		---		C		---		C		C		C
- Escherichia coli:			---		---		C		---		C		---		C		C		C

Product / strength:	Bicalutamide 150mg				Packaged lot number:				04D28IEA									
Storage condition:	30ºC/65% RH				Batch size:				50000 tablets									
Study start date:	19/05/2004				Packaging				30 tablets									
Packaging:	PVC/PE/PVDC/Al				Closure:				NA									
Bulk batch number:	04D28IE				Drug substance:				Bicalutamide									
Bulk Mfg. Date:	28/04/2004				Drug substance Mfg:				Synthon sro									
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				57621 - 57630									
Tests	**Time in months**	**0**		**3**		**6**		**9**		**12**		**18**		**24**		**36**		**48**
Appearance:		C		C		C		C		C		C		C		C		C
Seal integrity of the blister/container:		C		C		C		C		C		C		C		C		C
Uniformity of dosage units		C		C		C		C		C		C		C		C		C
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		73	80	80	82	65	75	80	85	68	76	81	83	72	81	83	85	74	83
Identification (HPLC):,		C		C		C		C		C		C		C		C		C	
Assay (HPLC) [mg/tab]:		148.8		150.5		147.8		151.5		147.6		151.6		147.1		145.8		151.0	
- % of declared value		99		100		99		101		98		101		98		97		101	
Impurities (HPLC):																			
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Largest unidentified impurity		0.07		0.06		0.07		0.06		0.07		0.07		0.06		0.07		0.06	
- Total unidentified impurities		0.07		0.06		0.07		0.06		0.07		0.07		0.06		0.07		0.06	
- Total impurities		0.07		0.06		0.07		0.06		0.07		0.07		0.06		0.07		0.06	
Microbial contamination																			
- Total viable aerobic count																			
'- Aerobic bacteria:		C		---		C		---		C		---		C		C		C	
'- Fungi:		C		---		C		---		C		---		C		C		C	
- Escherichia coli:		---		---		C		---		C		---		C		C		C	

Product / strength:	Bicalutamide 150mg				Packaged lot number:				05D29IEA				
Storage condition:	30°C/65% RH				Batch size:				50000 tablets				
Study start date:	22/07/2005				Packaging				30 tablets				
Packaging:	PVC/PE/PVDC/Alu				Closure:				NA				
Bulk batch number:	05D29IE				Drug substance:				Bicalutamide				
Bulk Mfg. Date:	29/04/2005				Drug substance Mfg:				CF Pharma Ltd				
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				85201				
Tests **Time in months**	**0**		**3**		**6**		**9**		**12**	**18**		**24**	**36**
Appearance:	C		C		C		C		C	C		C	C
Seal integrity of the blister/container:	C		C		C		C		C	C		C	C
Uniformity of dosage units	C		C		C		C		C	C		C	C
Dissolution:	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min Ave	Min	Ave	Min	Ave
- in 30 minutes	86	89	87	90	90	91	80	86	90 96	88	95	84 88	89 93
Identification (HPLC);,	C		C		C		C		C	C		C	C
Assay (HPLC) [mg/tab]:	148.2		150.5		148.8		150.5		145.4	150.1		150.7	151.4
- % of declared value	99		100		99		100		97	100		100	101
Impurities (HPLC):													
- A/509	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05		≤ 0.05	≤ 0.05
- Largest unidentified impurity	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05		≤ 0.05	0.06
- Total unidentified impurities	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05		≤ 0.05	0.06
- Total impurities	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05		≤ 0.05	0.06
Microbial contamination													
- Total viable aerobic count													
'- Aerobic bacteria:	C		---		C		---		C	---		C	C
'- Fungi:	C		---		C		---		C	---		C	C
- Escherichia coli:	C		---		C		---		C	---		C	C

Product / strength:	Bicalutamide 150mg	Packaged lot number:	05E03IEA
Storage condition:	30°C/65% RH	Batch size:	50000 tablets
Study start date:	22/07/2005	Packaging	30 tablets
Packaging:	PVC/PE/PVDC/Al	Closure:	NA
Bulk batch number:	05E03IE	Drug substance:	Bicalutamide
Bulk Mfg. Date:	03/05/2005	Drug substance Mfg:	CF Pharma Ltd.
Bulk Mfg.site:	Synthon Hispania	Drug substance lot number:	85198

Tests \ Time in months	0		3		6		9		12		18		24		36
Appearance:		C		C		C		C		C		C		C	C
Seal integrity of the blister/container:		C		C		C		C		C		C		C	C
Uniformity of dosage units		C		C		C		C		C		C		C	C
Dissolution:	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min Ave
- in 30 minutes	90	93	90	93	90	95	90	93	94	96	92	97	85	92	88 94
Identification (HPLC):		C		C		C		C		C		C		C	C
Assay (HPLC) [mg/tab]:		148.1		149.1		149.4		148.8		148.5		149.7		148.5	149.5
- % of declared value		99		99		100		99		99		100		99	100
Impurities (HPLC):															
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05
- Largest unidentified impurity		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05
- Total unidentified impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05
- Total impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	≤ 0.05
Microbial contamination															
- Total viable aerobic count															
'- Aerobic bacteria:		C		---		C		---		C		---		C	C
'- Fungi:		C		---		C		---		C		---		C	C
- Escherichia coli:		C		---		C		---		C		---		C	C

3.2 Intermediate stability study: 30 °C/65 % RH Bulk packaging

In this part of the stability study summary, the results of Bicalutamide 150 mg tablets, packaged in a bulk container stored at 30 °C/65 % RH are presented.

Product / strength:	Bicalutamide 150mg				Packaged lot number:				04D21IE			
Storage condition:	30°C/65% RH				Batch size:				50000 tablets			
Study start date:	14/05/2004				Packaging				NA			
Packaging:	Bulk				Closure:				NA			
Bulk batch number:	04D21IE				Drug substance:				Bicalutamide			
Bulk Mfg. Date:	21/04/2004				Drug substance Mfg:				Synthon sro			
Bulk Mfg.site:	Synthon Hispania				Drug substance lot number:				57621			
Tests **Time in months**	**0**		**6**		**12**		**24**		**36**			
Appearance:	C		C		C		C		C			
Uniformity of dosage units	C		C		C		C		C			
Dissolution:	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave		
- in 30 minutes	77	83	80	85	82	85	76	84	80	86		
Identification (HPLC):.	C		C		C		C		C			
Assay (HPLC) [mg/tab]:	146.4		147.4		146.7		145.5		148.5			
- % of declared value	98		98		98		97		99			
Impurities (HPLC):												
- A/509	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05			
- Largest unidentified impurity	0.07		0.07		0.07		0.07		0.07			
- Total unidentified impurities	0.07		0.07		0.07		0.07		0.07			
- Total impurities	0.07		0.07		0.07		0.07		0.07			
Microbial contamination												
- Total viable aerobic count												
'- Aerobic bacteria:	C		C		C		C		C			
'- Fungi:	C		C		C		C		C			
- Escherichia coli:	---		C		C		C		C			

4 Overview accelerated stability data

4.1 Accelerated stability study: 40 °C/75 % RH blister (PVC/PE/PVDC:Al)

In this part of the stability study summary, the results of Bicalutamide 150 mg tablets, packaged in a PVC/PE/PVDC:Al blister, stored at 40 °C/75 % RH are presented.

Product / strength:	**Bicalutamide 150mg**					Packaged lot number:					**04D21IEA**				
Storage condition:	**40°C/75% RH**					Batch size:					**50000 tablets**				
Study start date:	**14/05/2004**					Packaging					**30 tablets**				
Packaging:	**PVC/PE/PVDC/Alu**					Closure:					**NA**				
Bulk batch number:	**04D21IE**					Drug substance:					**Bicalutamide**				
Bulk Mfg. Date:	**21/04/2004**					Drug substance Mfg:					**Synthon sro**				
Bulk Mfg.site:	**Synthon Hispania**					Drug substance lot number:					**57621**				
Tests	**Time in months**	**0**		**1**		**2**		**3**		**6**		**12**			
Appearance:		C		C		C		C		C		C			
Seal integrity of the blister/container:		C		C		C		C		C		C			
Uniformity of dosage units		C		C		C		C		C		C			
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave		
- in 30 minutes		77	83	80	85	82	85	78	86	81	84	81	84		
Identification (HPLC),			C		C		C		C		C		C		
Assay (HPLC) [mg/tab]:			146.4		147.6		143.6		145.5		147.3		149.0		
- % of declared value			98		98		96		97		98		99		
Impurities (HPLC):															
- A/509			≤ 0.05		≤ 0.05		0.06		≤ 0.05		≤ 0.05		≤ 0.05		
- Largest unidentified impurity			0.07		0.07		0.09		0.07		0.06		0.07		
- Total unidentified impurities			0.07		0.07		0.09		0.07		0.06		0.07		
- Total impurities			0.07		0.07		0.15		0.07		0.06		0.07		

Product / strength:	**Bicalutamide 150mg**			Packaged lot number:			**04D26IEA**				
Storage condition:	**40°C/75% RH**			Batch size:			**50000 tablets**				
Study start date:	**19/05/2004**			Packaging			**30 tablets**				
Packaging:	**PVC/PE/PVDC/Al**			Closure:			**NA**				
Bulk batch number:	**04D26IE**			Drug substance:			**Bicalutamide**				
Bulk Mfg. Date:	**26/04/2004**			Drug substance Mfg:			**Synthon sro**				
Bulk Mfg.site:	**Synthon Hispania**			Drug substance lot number:			**57621 - 57630**				
Tests	**Time in months**	**0**		**1**	**2**		**3**	**6**		**12**	
Appearance:		C		C	C		C	C(*)		C	
Seal integrity of the blister/container:		C		C	C		C	C		C	
Uniformity of dosage units		C		C	C		C	C		C	
Dissolution:		Min	Ave	Min	Min	Ave	Min	Ave	Min	Min	Ave
- in 30 minutes		80	85	82	82	85	82	87	82	84	75	82
Identification (HPLC):,			C			C		C		C		C
Assay (HPLC) [mg/tab]:		146.0		145.8		147.1		145.7		145.5		149.3
- % of declared value		97		97		98		97		97		100
Impurities (HPLC):												
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity		0.08		0.08		0.08		0.08		0.09		0.08
- Total unidentified impurities		0.08		0.08		0.08		0.08		0.09		0.08
- Total impurities		0.08		0.08		0.08		0.08		0.09		0.08

(*): A tiny crack was observed on one edge of the tablet. This was not reproduced at t=12 months.

Product / strength:	**Bicalutamide 150mg**				Packaged lot number:				**04D28IEA**			
Storage condition:	**40°C/75% RH**				Batch size:				**50000 tablets**			
Study start date:	**19/05/2004**				Packaging				**60 tablets**			
Packaging:	**PVC/PE/PVDC/Al**				Closure:				**NA**			
Bulk batch number:	**04D28IE**				Drug substance:				**Bicalutamide**			
Bulk Mfg. Date:	**28/04/2004**				Drug substance Mfg:				**Synthon s r o**			
Bulk Mfg.site:	**Synthon Hispania**				Drug substance lot number:				**57630**			
Tests	**Time in months**	**0**		**1**	**2**		**3**		**6**		**12**	
Appearance:		C		C	C		C		C		C	
Seal integrity of the blister/container:		C		C	C		C		C		C	
Uniformity of dosage units		C		C	C		C		C		C	
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		73	80	80	84	75	82	75	80	78	82	64	75
Identification (HPLC):			C		C		C		C		C		C
Assay (HPLC) [mg/tab]:			148.8		149.0		146.1		146.1		150.0		146.8
- % of declared value			99		99		97		97		100		98
Impurities (HPLC):													
- A/509			≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05
- Largest unidentified impurity			0.07		0.07		0.06		0.08		0.07		0.06
- Total unidentified impurities			0.07		0.07		0.06		0.14		0.13		0.06
- Total impurities			0.07		0.07		0.06		0.14		0.13		0.06

Product / strength:	**Bicalutamide 150mg**				Packaged lot number:				**05D291EA**			
Storage condition:	**40°C/75% RH**				Batch size:				**50000 tablets**			
Study start date:	**22/07/2005**				Packaging				**30 tablets**			
Packaging:	**PVC/PE/PVDC/Alu**				Closure:				**NA**			
Bulk batch number:	**05D29IE**				Drug substance:				**Bicalutamide**			
Bulk Mfg. Date:	**29/04/2005**				Drug substance Mfg:				**CF Pharma Ltd**			
Bulk Mfg.site:	**Synthon Hispania**				Drug substance lot number:				**85201**			
Tests / **Time in months**	**0**		**1**		**2**		**3**		**6**		**12**	
Appearance:	C		C		C		C		C		C	
Seal integrity of the blister/container:	C		C		C		C		C		C	
Uniformity of dosage units	C		C		C		C		C		C	
Dissolution:	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes	86	89	86	89	86	90	88	90	81	87	87	94
Identification (HPLC):,	C		C		C		C		C		C	
Assay (HPLC) [mg/tab]:	148.2		148.8		149.8		148.8		149.9		148.4	
- % of declared value	99		99		100		99		100		99	
Impurities (HPLC):												
- A/509	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Largest unidentified impurity	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Total unidentified impurities	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Total impurities	≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	

Product / strength:	**Bicalutamide 150mg**				Packaged lot number:				**05E03IEA**				
Storage condition:	**40°C/75% RH**				Batch size:				**50000 tablets**				
Study start date:	**22/07/2005**				Packaging				**30 tablets**				
Packaging:	**PVC/PE/PVDC/Al**				Closure:				**NA**				
Bulk batch number:	**05E03IE**				Drug substance:				**Bicalutamide**				
Bulk Mfg. Date:	**03/05/2005**				Drug substance Mfg:				**CF Pharma Ltd.**				
Bulk Mfg.site:	**Synthon Hispania**				Drug substance lot number:				**85198**				
Tests	**Time in months**	**0**		**1**		**2**		**3**		**6**		**12**	
Appearance:		C		C		C		C		C		C	
Seal integrity of the blister/container:		C		C		C		C		C		C	
Uniformity of dosage units		C		C		C		C		C		C	
Dissolution:		Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave	Min	Ave
- in 30 minutes		90	93	86	90	89	92	92	95	84	87	93	95
Identification (HPLC).,			C		C		C		C		C		C
Assay (HPLC) [mg/tab]:		148.1		147.8		148.2		147.5		150.6		148.7	
- % of declared value		99		99		99		98		100		99	
Impurities (HPLC):													
- A/509		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Largest unidentified impurity		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Total unidentified impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	
- Total impurities		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05		≤ 0.05	