TGA eBS Registration Active

ARTG Entry:	48965	DITROPAN oxybutynin hydrochloride 5mg tablet bottle	
Sponsor:	24277	Sanofi-Aventis Australia Pty Ltd	
Therapeutic type:	Medicine Registered		
Entry start date:	30/05/1994		
Evaluation area:	Drug Safety Evaluation Branch	Code Stock:	No

- ▷ Sponsor
- ▷ Agent
- ▷ ExportNames
- ▷ Source history
- ▷ Variations
- ▷ Device information
- ▷ Conditions
- ▷ Comments
- ▷ Admin activity
- ▷ Financials
- ▷ Products
- ▶ Manufacturers
- ▷ Standards

Manufacturers Information

Current Manufacturers

Name	Id	Start date	Certificate / GMP Reference
s47 [redacted]		13/04/2017	MI-2010-LI-04988-3 [redacted]
		12/01/2012	MI-2015-CL-13165-1 [redacted]
		14/06/2022	MI-2016-CL-05446-1 [redacted]
		13/04/2017	MI-2013-LI-10546-1 [redacted]

Ceased Manufacturers

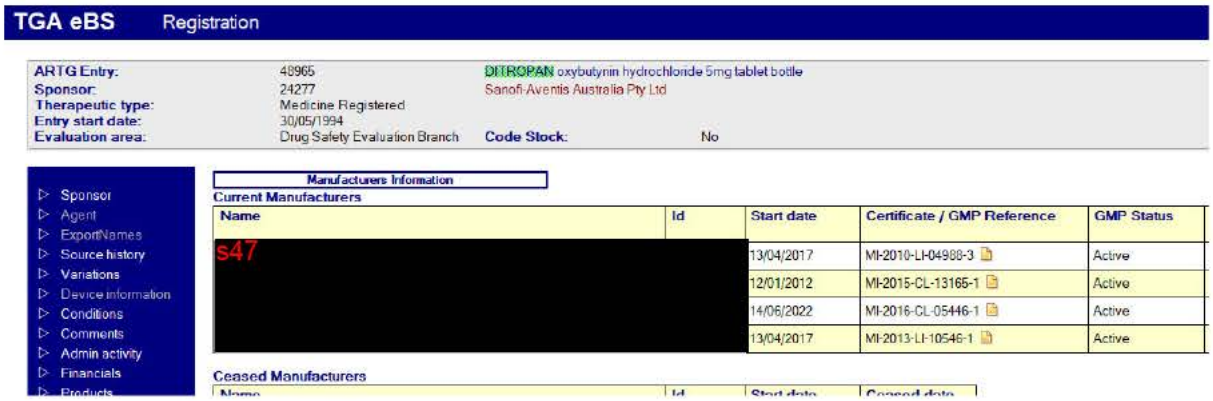
Name	Id	Start date	Ceased date
s47 [redacted]		09/05/94	23/05/94
		23/05/94	12/01/2012
		08/03/2002	30/05/2005
		08/03/2002	14/06/2022
		13/04/2017	14/06/2022
		07/06/2002	16/05/2016
		30/08/95	06/07/2007
		08/03/2002	04/08/2005

s47	08/03/2002	27/01/2011
	04/08/2005	27/01/2011
	30/04/2008	27/01/2011
	30/04/2008	27/01/2011
	27/01/2011	16/05/2016
	27/01/2011	14/06/2022
	27/01/2011	14/06/2022
	27/01/2011	14/06/2022
	13/04/2017	14/06/2022
	09/05/94	07/06/2002
	19/06/2006	16/05/2016
	06/07/2007	14/06/2022

Created on: 31/10/2008
Modified on: 12/10/2023

FOI 5064 ARTG snapshots and Compilation/Research Notes

Figure 1 ARTG snapshot of the sites of manufacture of DITROPAN as of 17 April 2024 - addresses and related steps of manufacture are copied below



TGA eBS Registration

ARTG Entry: 48965 DITROPAN oxybutynin hydrochloride 5mg tablet bottle
Sponsor: 24277 Sanofi-Aventis Australia Pty Ltd
Therapeutic type: Medicine Registered
Entry start date: 30/05/1994
Evaluation area: Drug Safety Evaluation Branch Code Stock: No

- Sponsor
- Agent
- ExportNames
- Source history
- Variations
- Device information
- Conditions
- Comments
- Admin activity
- Financials
- Products

Manufacturers Information

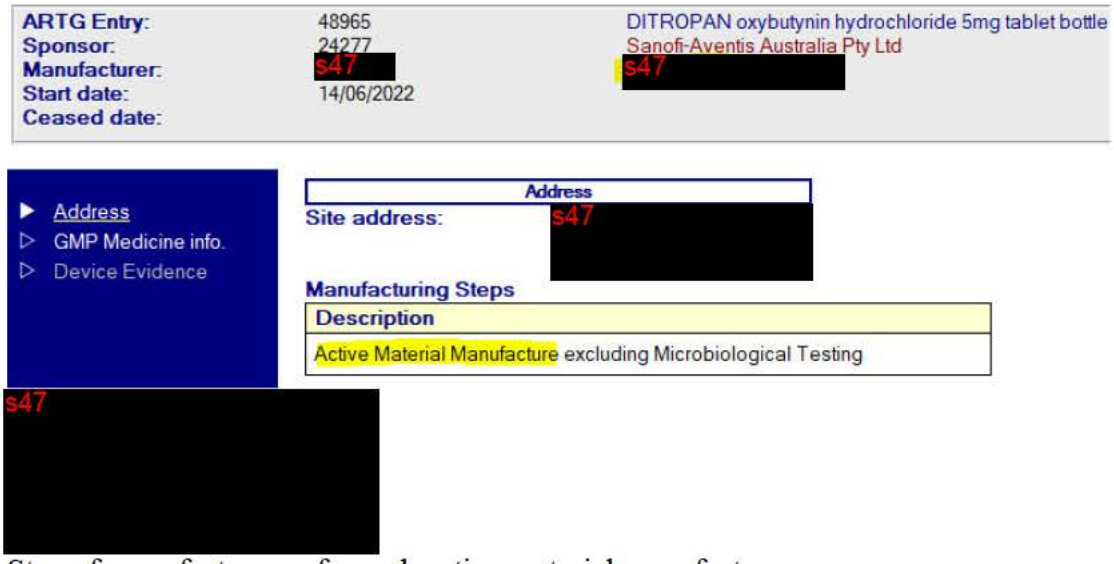
Current Manufacturers

Name	Id	Start date	Certificate / GMP Reference	GMP Status
s47		13/04/2017	MI-2010-LI-04988-3	Active
		12/01/2012	MI-2015-CL-13165-1	Active
		14/06/2022	MI-2016-CL-05446-1	Active
		13/04/2017	MI-2013-LI-10546-1	Active

Ceased Manufacturers

Name	Id	Start date	Ceased date

Site of manufacture of API



ARTG Entry: 48965 DITROPAN oxybutynin hydrochloride 5mg tablet bottle
Sponsor: 24277 Sanofi-Aventis Australia Pty Ltd
Manufacturer: s47 s47
Start date: 14/06/2022
Ceased date:

- Address
- GMP Medicine info.
- Device Evidence

Address

Site address: s47

Manufacturing Steps

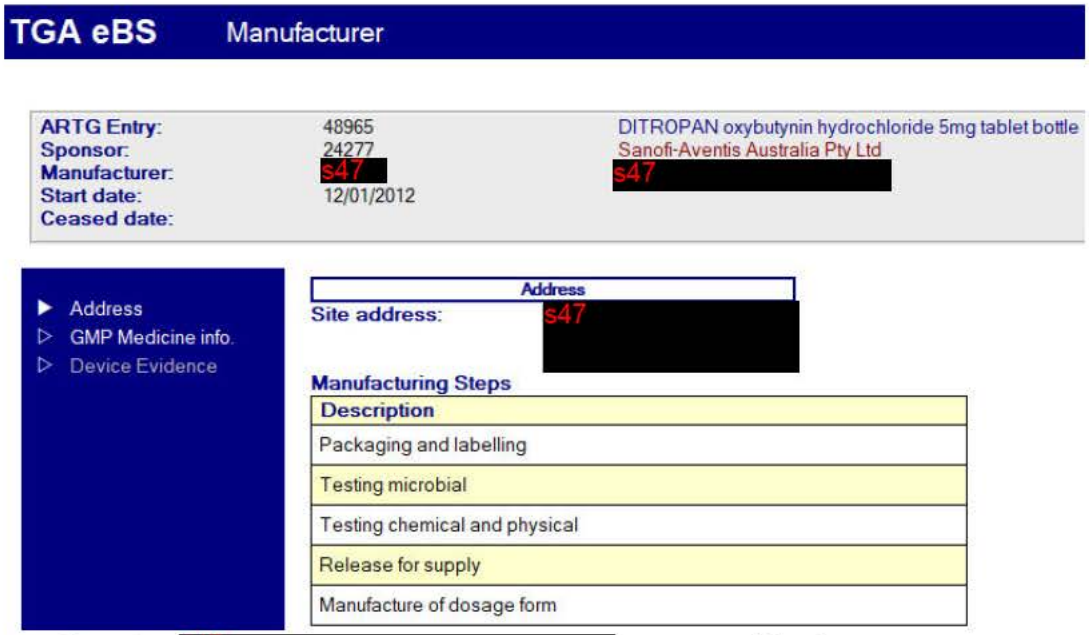
Description
Active Material Manufacture excluding Microbiological Testing

s47

Step of manufacture performed: active material manufacture

s47 referenced as existing site of manufacture of DITROPAN during in 9D(3) application 2006/819 (see f.9 of D21-3469286). s47 changed name to s47 as per Notification PM-2022-02443-1-3 lodged 10/6/22 (D22-5572161) and acknowledged 14/6/2022 (D22-5576966). Initial listing of s47 appears *circa* 1995.

Site of manufacture of final dosage form, FP testing site, packaging site.

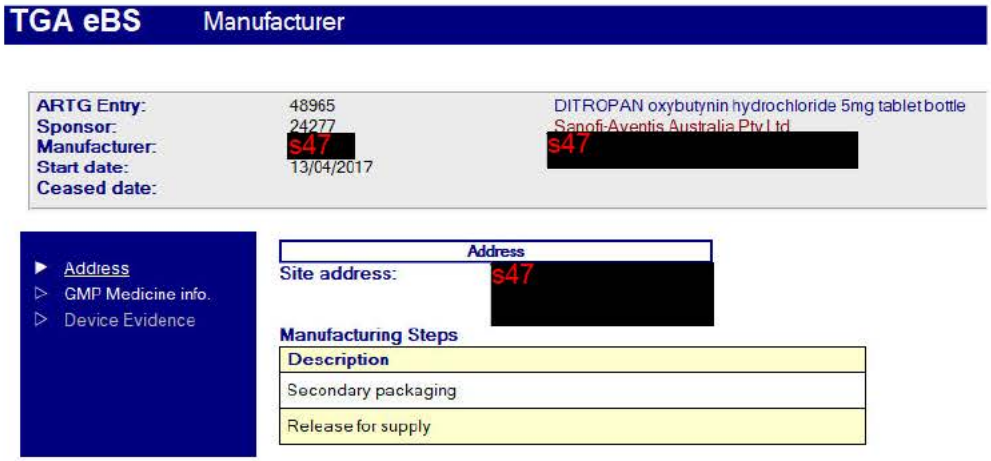


Confirmed as s47 as per Notification PM-2022-02443-1-3 above. s47 started on this ARTG entry in 2012, but first included under different company name – see PM-2011-03764-3-3 (R11/553680) for reference to the same address under the name s47. Company name change occurred between 2011 and 2012 (name change documentation not found).

s47

Steps of manufacture performed (within scope of FOI): manufacture of dosage form, FP testing, packaging

Packaging sites 2 and 3

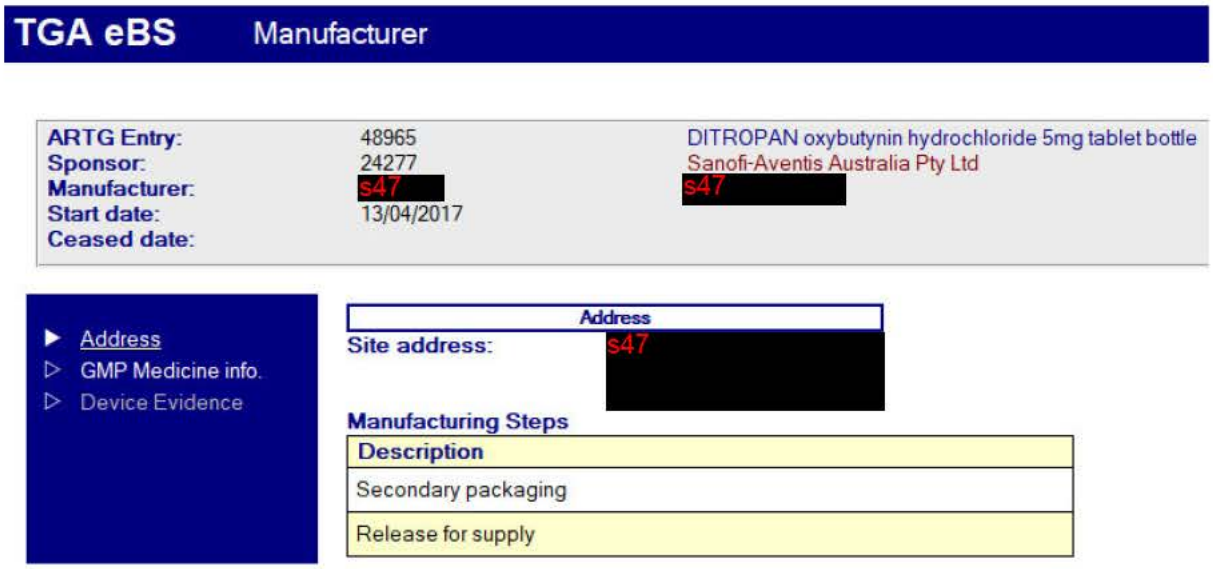


Confirmed as s47 and s47 in SAR PM-2017-00888-1-3 (zip file D17-202531 module 1). Other sites were included in this SAR but were subsequently removed in Notification PM-2022-02443-1-3.

s47

s47 [redacted]

Step of manufacture performed (within scope of FOI): packaging



s47 [redacted]

Step of manufacture performed (within scope of FOI): packaging

s22

Document 3

Drug product site of manufacture - cessation of a site or deletion of a manufacturing step (CE)			
Action	Currently on the register	Proposed variation	ARTG ID
Add		s47 Active Material Manufacture excluding Microbiological Testing s47	48965
Update	s47 Manufacture of dosage form, Packaging and labelling, Release for supply, Quality Control s47	s47 Manufacture of dosage form, Packaging and labelling, Release for supply, Testing chemical and physical, Testing microbial s47	48965
Remove	s47 Release for supply, Secondary packaging s47		48965
Remove	s47 Release for supply, Secondary packaging s47		48965
Remove	s47 Release for supply, Secondary packaging s47		48965
Remove	s47 Secondary packaging s47		48965
Remove	s47 Packaging and labelling, Release for supply s47		48965
Remove	s47 Release for supply, Secondary packaging s47		48965
Remove	All manufacturers with invalid GMP included in the entry were automatically removed. Invalid GMP includes: expired clearances, cancelled licenses and those with no GMP reference.		48965

Supporting Information

Supporting documentation is to be sent separately

Fee(s)

SubmissionId	Variation group	Legislative basis	Fee Item	Fee $	Will a new ARTG Id be generated as a result of this submission?
PM-2022-02443-1	Notification	9D(2C)	2AD(a)	$840	No

Warning Message(s)

Unknown is an invalid container closure. It is being used in the following goods: 48965. Please update data within 'Container and Shelf Life' when you are next submitting a variation affecting that section.

Active material manufacture is not recorded for the following goods: 48965. Update 'Manufacturers' if relevant.

s22

Document 3

Client ID	Licence Number	Manufacturer Name and full site address	Steps of manufacture	Addition of cessation?
s47	s47		Secondary packaging Release for supply	Addition
s47			Secondary packaging Release for supply	Addition
s47			Secondary packaging (for AUST R 48965	Addition
s22			s22	
s47	s47		Secondary packaging Release for supply	Addition
s22				

Details of changes to Australian manufactures

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

In reply please quote:
File No: 2009/001618
Submission No: PM-2011-03764-3-3

The Managing Director
Sanofi-Aventis Australia Pty Ltd
Locked Bag 2227
NORTH RYDE BC NSW 1670

ATTENTION: Carolyn O'Connor

Dear Sir/Madam

I refer to your application dated 15 November 2011 to change the registered details of the following products under the provisions of the Therapeutic Goods Act 1989 ("the Act"):

s22 [redacted]

- 48965 - DITROPAN oxybutynin hydrochloride 5mg tablet bottle

Pursuant to subsection 9D(3) of the Act, this proposed variation is approved.

Specifically:

- s47 [redacted] is no longer a site of API manufacture.

s22 [redacted]

- s47 [redacted] is an additional site of finished product manufacture. Steps: manufacture of dosage form, packaging and labelling, quality control, release for supply. The manufacturing details are as described in your application.

s22 [redacted]

s22 [redacted]

s22

Document 5

s22

Document 5

s22

Document 5

Pages 1-214 and 216-225 redacted under s22 (irrelevant information) of the *Freedom of Information Act, 1982.*

Pin extra pages here

Part 5 - Manufacturer Details

Principal Manufacturer Details

Note: *Attach a copy of this section for each additional manufacturer.*

(max 100 characters)

30 Principal manufacturer's business name s47 [redacted]

31 Principal manufacturer's licence number *(if applicable)*

Office Use Only
Site code

32 Principal manufacturer's enterprise Identification code s47 [redacted]

Alternative principal manufacturer's

Note: *Attach a copy of this section for each additional manufacturer.*

(max 100 characters)

33 Alternative principal manufacturer's business name s47 [redacted]

34 Alternative principal manufacturer's licence number *(if applicable)*

Office Use Only
Site code

35 Alternative principal manufacturer's identification code s47 [redacted]

Sub-manufacturers

Note: *Attach a copy of this section for each additional sub-manufacturer.*

36 Sub-manufacturer's business name s47 [redacted]

37 Sub-manufacturer's licence licence number *(if applicable)* s47 [redacted]

Office Use Only
Site code

38 Sub-manufacturer's enterprise identification code

39 Step in manufacture Active material manufacture