

**Methadose Dispersible Tablets, 40 mg**  
**3.2.P.5.1 Specifications****ANDA 074184****Mallinckrodt™**Mallinckrodt Inc.  
172 Railroad Avenue  
PO Box P  
Hobart, NY 13788-0416**Specification Report**Tele: 607 538-2000  
Fax: 607 538-2500

Product: Methadose™ Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP) 40 mg CII

Active/Theo Label Claim: Methadone Hydrochloride, 40 mg

Lot Number: METHDISP40SPECDC03J

Residual Solvents Statement: Compliant with USP <467> Residual Solvents Option 1.

Comments:

Part Number: MT03

Sample ID: 200240928

Sample Source: POOLED SAMPLE

**Physical Tests:**

Description: 0.8125" round convex quadrisection white to off-white tablet debossed with "METHADOSE 40".

Component	Specification	Units
Description	Matches	Pass/Fail
Disintegration	NMT 15 minutes	Pass/Fail
Dispersion	NMT 2 minutes	Pass/Fail
Identification - By TLC or NIR	Presence of Methadone HCl	Pass/Fail
Identification - HPLC Retention Time	RT Ratio 1.00 ± 0.02	Pass/Fail

**Assay:****Active 01: Methadone Hydrochloride**

Component	Specification	Units
Label Claim	100.0% ± 7%	%

**Uniformity of Dosage:**

Current USP

**Active 01: Methadone Hydrochloride****Level: 1**

Component	Specification	Units
Acceptance Value - L1	NMT 15.0	NONE
Label Claim	Report Value	%
Standard Deviation	Report Value	NONE

**Level: 2**

Component	Specification	Units
Acceptance Value - L2	NMT 15.0	NONE
Label Claim	Report Value	%
Standard Deviation	Report Value	NONE
MAX	NMT 123.1%	%
MIN	NLT 76.2%	%

Report Generated By: Stephanie Oisen

Report Generated: Thursday, December 17, 2015 04:01 PM

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**3.2.P.5.1 Specifications**

ANDA 074184

**Specification Report**

Product: Methadose™ Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP) 40 mg CII  
Lot Number: METHDISP40SPEC03J

**Dissolution:**

Current USP

Apparatus: 2

RPM: 50

Time/Medium: 500 mL water, 45 minutes

Q: 75%

**Active 01: Methadone Hydrochloride****Stage: 1**

Component	Specification	Units
Label Claim	(Each NLT Q+5%)	%

**Stage: 2**

Component	Specification	Units
Label Claim	= or > Q (None LT Q-15%)	%

**Stage: 3**

Component	Specification	Units
Label Claim	= or > Q (NMT two LT Q-15% and None LT Q-25%)	%

**M88 MOISTURE (KARL FISCHER)**

Component	Specification	Units
Moisture (Karl Fischer)	NMT 10%	%

Specification Approved By: \_\_\_\_\_ Date: \_\_\_\_\_

Specification Approved By: \_\_\_\_\_ Date: \_\_\_\_\_

**Methadose Dispersible Tablets, 40 mg**  
**3.2.P.5.1 Specifications****ANDA 074184****Mallinckrodt™**Mallinckrodt Inc.  
172 Railroad Avenue  
PO Box P  
Hobart, NY 13788-0416Tele: 607 538-2000  
Fax: 607 538-2500**Stability Specification Report**

Product: Methadose™ Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP) 40 mg CII

Active/Theo Label Claim: Methadone Hydrochloride, 40 mg

Lot Number: METHDISP40SPECD03J

Residual Solvents Statement: Compliant with USP <467> Residual Solvents Option 1.

Comments: .

Part Number: MT03

Sample ID: 200240931

Sample Source: STABILITY

**Physical Tests:**

Description: 0.8125" round convex quadrisection white to off-white tablet debossed with "METHADOSE 40".

Component	Specification	Units
Description	Matches	Pass/Fail
Disintegration	NMT 15 minutes	Pass/Fail
Dispersion	NMT 2 minutes	Pass/Fail
Organoleptic	No unusual odor/No physical defects	Pass/Fail

**Assay:****Active 01: Methadone Hydrochloride**

Component	Specification	Units
Label Claim	100.0% ± 7%	%

**Methadose Dispersible Tablets, 40 mg**  
**3.2.P.5.1 Specifications**

ANDA 074184

**Stability Specification Report**

Product: Methadose™ Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP) 40 mg CII

Lot Number: METHDISP40SPEC03J

**Dissolution:**

Current USP

Apparatus: 2

RPM: 50

Time/Medium: 500 mL water, 45 minutes

Q: 75%

**Active 01: Methadone Hydrochloride****Stage: 1**

Component	Specification	Units
Label Claim	(Each NLT Q+5%)	%

**Stage: 2**

Component	Specification	Units
Label Claim	= or > Q (None LT Q-15%)	%

**Stage: 3**

Component	Specification	Units
Label Claim	= or > Q (NMT two LT Q-15% and None LT Q-25%)	%

**M88 MOISTURE (KARL FISCHER)**

Component	Specification	Units
Moisture (Karl Fischer)	NMT 10%	%

Specification Approved By: \_\_\_\_\_ Date: \_\_\_\_\_

Specification Approved By: \_\_\_\_\_ Date: \_\_\_\_\_