KEMWELL

Certificate of Analysis

Batch/Lot No	Manufacturing date	Expiration date	Released for sale
5074801	2010-08-20	2015-07	2010-10-11
Product			Retest date
Sulfasalazine with Povidone			2013-07-31

DESCRIPTION

Sulfasalazine with Povidone contains about 3 % povidone.

Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

TESTS	LIMITS	RESULTS		METHODS
Before coating				
Identification by infrared absorption	Spectrum matches reference spectrum	Not performed	1)	Ph.Eur. 2.2.24
Identification by UV-visible absorption	Spectrum matches reference spectrum	Passed test		USP
Sulphated ash	Max 0.5%	0.0		Ph Eur. 2.2.14
Chloride	Max 0.014%	Not performed	2)	Ph.Eur. 2.4.4
Sulphate	Max 0.04%	Not performed	2)	Ph.Eur. 2.4.13
Heavy metals	Max 0.001%	Not performed	2)	Ph.Eur. 2.4.8
Related substances				
- in total	Max 4 %	Passed test		Ph. Eur.
- largest single	Max 1 %	Passed test		Ph. Eur.
Sulfapyridine	Max 0.5%	<0.5		Ph.Eur
Salicylic acid	Max 0.5%	<0.5		Ph.Eur
Assay, sulfasalazine	97.0 - 101.5 %	99.1		Ph. Eur
After coating				
Identification of povidone by infrared absorption	Spectrum matches reference spectrum	Not performed	3)	06215
Loss on drying	Max 5.0 %	2.8		Ph Eur 2.2.32
Formic acid	Max 0.3 %	0.1		02371
Assay, Sulfasalazine	94.0 - 98.5 %	96.8		06266

1) Testing is performed on the Drug Product
2) Testing is performed on every 20th batch
3) Compliance is assured by performing the test on povidone

We hereby confirm that this batch has been manufactured in accordance with current GMP Guidelines and is in accordance with the registration file.

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Phone: +46 18 164 000

Quality Assurance

26 April 2011
Date

Thailand

KEMWELL

Certificate of Analysis

Batch/Lot No	Manufacturing date	Expiration date	Released for sale
5074828	2010-09-07	2015-08	2010-10-13
Product			Retest date
Sulfasalazine with Povidone			2013-04-30

DESCRIPTION

Sulfasalazine with Povidone contains about 3 % povidone.

Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

TESTS	LIMITS	RESULTS		METHODS
Before coating				
Identification by infrared absorption	Spectrum matches reference spectrum	Not performed	1)	Ph.Eur. 2.2.24
Identification by UV-visible absorption	Spectrum matches reference spectrum	Passed test		USP
Sulphated ash	Max 0.5%	0.0		Ph Eur. 2.2.14
Chloride	Max 0.014%	Not performed	2)	Ph.Eur. 2.4.4
Sulphate	Max 0.04%	Not performed	2)	Ph.Eur. 2.4.13
Heavy metals	Max 0.001%	Not performed	2)	Ph.Eur. 2.4.8
Related substances				
- in total	Max 4 %	Passed test		Ph. Eur.
- largest single	Max 1 %	Passed test		Ph. Eur.
Sulfapyridine	Max 0.5%	<0.5		Ph.Eur
Salicylic acid	Max 0.5%	<0.5		Ph.Eur
Assay, sulfasalazine	97.0 - 101.5 %	98.6		Ph. Eur
After coating				
Identification of povidone by infrared absorption	Spectrum matches reference spectrum	Not performed	3)	06215
Loss on drying	Max 5.0 %	2.8		Ph Eur 2.2.32
Formic acid	Max 0.3 %	0.1		02371
Assay, Sulfasalazine	94.0 - 98.5 %	96.0		06266

1) Testing is performed on the Drug Product
2) Testing is performed on every 20th batch
3) Compliance is assured by performing the test on povidone

We hereby confirm that this batch has been manufactured in accordance with current GMP Guidelines and is in accordance with the registration file.

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Quality Assurance

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Date

Thailand

KEMWELL

Certificate of Analysis

Batch/Lot No	Manufacturing date	Expiration date	Released for sale
5074827	2010-09-06	2015-08	2010-10-13
Product			Retest date
Sulfasalazine with Povidone			2013-08-31

DESCRIPTION

Sulfasalazine with Povidone contains about 3 % povidone.

Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

TESTS	LIMITS	RESULTS		METHODS
Before coating				
Identification by infrared absorption	Spectrum matches reference spectrum	Not performed	1)	Ph.Eur. 2.2.24
Identification by UV-visible absorption	Spectrum matches reference spectrum	Passed test		USP
Sulphated ash	Max 0.5%	0.0		Ph Eur. 2.2.14
Chloride	Max 0.014%	Not performed	2)	Ph.Eur. 2.4.4
Sulphate	Max 0.04%	Not performed	2)	Ph.Eur. 2.4.13
Heavy metals	Max 0.001%	Not performed	2)	Ph.Eur. 2.4.8
Related substances				
- in total	Max 4 %	Passed test		Ph. Eur.
- largest single	Max 1 %	Passed test		Ph. Eur.
Sulfapyridine	Max 0.5%	<0.5		Ph.Eur
Salicylic acid	Max 0.5%	<0.5		Ph.Eur
Assay, sulfasalazine	97.0 - 101.5 %	99.1		Ph. Eur
After coating				
Identification of povidone by infrared absorption	Spectrum matches reference spectrum	Not performed	3)	06215
Loss on drying	Max 5.0 %	2.6		Ph Eur 2.2.32
Formic acid	Max 0.3 %	0.1		02371
Assay, Sulfasalazine	94.0 - 98.5 %	95.5		06266

1) Testing is performed on the Drug Product
2) Testing is performed on every 20th batch
3) Compliance is assured by performing the test on povidone

We hereby confirm that this batch has been manufactured in accordance with current GMP Guidelines and is in accordance with the registration file.

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