

Certificate of Analysis

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

DESCRIPTION

Sulfasalazine with Povidone contains about 3 % povidone.

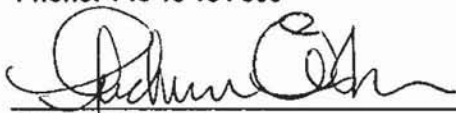
Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

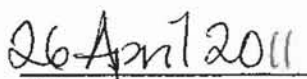
TESTS	LIMITS	RESULTS	METHODS
<u>Before coating</u>			
Identification by infrared absorption	Spectrum matches reference spectrum	Not performed 1)	Ph.Eur. 2.2.24
Identification by UV-visible absorption	Spectrum matches reference spectrum	Passed test	USP
Sulphated ash	Max 0.5%	0.0	Ph Eur. 2.2.14
Chloride	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
<u>After coating</u>			
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.

Kemwell AB
Björkgatan 30
SE-751 82 Uppsala, Sweden
Phone: +46 18 164 000


Quality Assurance


Date

Thailand

Certificate of Analysis

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

DESCRIPTION

Sulfasalazine with Povidone contains about 3 % povidone.

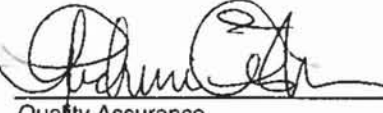
Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

TESTS	LIMITS	RESULTS	METHODS
<u>Before coating</u>			
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
<u>After coating</u>			
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

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3) Compliance is assured by performing the test on povidone

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Quality Assurance

26 April 2011
Date

Thailand

Certificate of Analysis

Batch/Lot No 5074827	Manufacturing date 2010-09-06	Expiration date 2015-08	Released for sale 2010-10-13
Product Sulfasalazine with Povidone			Retest date 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
<u>Before coating</u>			
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
<u>After coating</u>			
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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