

Batch/Lot No 5089410	Manufacturing date 2019-02-12	Expiration date 2024-01	
Product <b>Sulfasalazine with Povidone</b>		Country/Customer Chile	

## DESCRIPTION

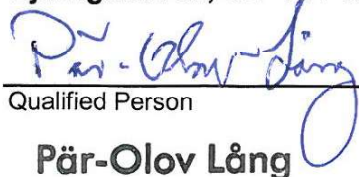
Sulfasalazine with Povidone contains about 3% povidone. Bright yellow to light brownish-yellow, odourless, moderately coarse powder.

TESTS	LIMITS	RESULTS	METHODS
<b><u>Sulfasalazine</u></b>			
Identification by infrared absorption	Spectrum matches reference spectrum	1)	Ph Eur
Identification by UV-visible absorption	To pass test	1)	USP
Loss on drying	Max 1.0%	2)	Ph Eur
Formic acid	Max 0.3%	2)	06703
Sulphated ash	Max 0.5%	NMT 0.1	Ph Eur
Chloride	Max 140 ppm	3)	Ph Eur
Sulphate	Max 400 ppm	3)	Ph Eur
Heavy metals	Max 10 ppm	3)	Ph Eur
Sulfapyridine	Max 0.5%	Complies	Ph Eur
Salicylic acid	Max 0.5%	Complies	Ph Eur
<b><u>Total impurities/Degradation impurities</u></b>			
- In total	Max 4%	2.5	Ph.Eur
- Single	Max 1% each	0.7	Ph Eur
Assay, sulfasalazine	97.0 - 101.5 % (calculated on the dried basis)	99.2	Ph.Eur
<b><u>Sulfasalazine with povidone</u></b>			
Identification by infrared absorption	Spectrum matches reference spectrum	1)	Ph. Eur monograph on Sulfasalazine
Identification of sulfasalazine by UV-visible absorption	To pass test	1)	USP monograph on Sulfasalazine
Identification of povidone by infrared absorption	Spectrum matches reference spectrum	1)	06215
Loss on drying	Max 5 %	3.1	Ph Eur 2.2.32
Formic acid	Max 0.3 %	0.2	02371
Assay, sulfasalazine	94.0 - 98.5 % (calculated on the dried basis)	96.7	06266

- 1) Compliance for all batches is assured through strict adherence to established GMP rules throughout the manufacturing procedure
- 2) Complies when tested. Testing is performed on Sulfasalazine with povidone
- 3) Testing is performed on every 20th batch.

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

**Recipharm Uppsala AB**  
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 Qualified Person  
**Pär-Olov Lång**

2019-05-21  
 Date