
	<b>GILES CHEMICAL ~ PREMIER MAGNESIA</b>		
	<b>Company Form</b>		
	Title: <b>Out-of-Specification Report</b>	Number: <b>Q13-PR-100-F025b</b>	
	Owner: <b>Deborah Durbin</b>	Revision: <b>0</b>	
	Effective Date: <b>05/15/13</b>	Page: <b>1 of 3</b>	

## OUT-OF-SPECIFICATION REPORT



<b>OOS Report Number:</b>
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### Phase Ia – Laboratory Investigation

<b>Analyst Name:</b>		<b>Date:</b>		
<b>Material Description:</b> <i>(raw material, in-process, final product, stability, other and Lot #, if applicable)</i>				
<b>Specification:</b>	<b>OOS Result:</b>	<b>SOP #:</b>		
<b>Checklist:</b>		<b>Yes</b>	<b>No</b>	<b>N/A</b>
1. Error in calculations or write/transfer error?				
2. Is there any dilution error?				
3. Were the appropriate and valid standards and reagents used? ( incl. expiry date, storage)				
4. Was method followed? Analyst properly trained on method?				
5. Instruments meet established performance specifications and properly calibrated?				
6. Correct glassware (volumetric flasks, pipettes) used?				
7. Power failure?				
8. Spillage/contamination in standard/sample? Proper sample handling?				
9. Sample representative of lot? Sample correctly taken and prepared?				
10. Sample properly stored?				
11. Other: _____?				
12. Same result when same analyst repeats test?				
13. Same result when different analyst repeats test?				
14. Same result after testing hypothesis?				

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### Phase Ib – Laboratory Investigation Conclusion



<b>OOS due to confirmed Laboratory Error?</b> <input type="checkbox"/> <b>YES</b> <i>If yes, explain corrective action taken:</i>  <input type="checkbox"/> <b>NO</b> <i>If no, proceed to Phase II or file a Supplier Complaint, if applicable. SCAR #: _____</i>		
<b>Is this a repeat error?</b> <input type="checkbox"/> <b>YES</b> <i>If yes, how many times? _____</i> <input type="checkbox"/> <b>NO</b>	<b>Repeated test result after CA:</b>  	<b>QA Release?</b> <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>

### Phase IIa – Full-scale OOS Investigation

<b>1. Statement of the reason of the investigation:</b>
<b>2. Summary of aspects of production process that may have caused the problem:</b>
<b>3. Results of documentation review, with assignment of actual or probable cause:</b>
<b>4. Results of review to determine if problem has occurred previously:</b>
<b>5. Description of corrective actions taken:</b>

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### Phase IIb – Full-scale OOS Investigation Conclusion

<b>Confirmed OOS?</b> <input type="checkbox"/> <b>YES</b> <i>If yes, proceed to close investigation.</i> <input type="checkbox"/> <b>NO</b> <i>If no, begin a CAPA investigation. CAPA # _____</i>
<b>Describe root cause(s) of confirmed OOS:</b>         
<b>Disposition of OOS material(s):</b>     
<b>Is a FDA field-alert report required to be issued?</b> <input type="checkbox"/> <b>YES</b> <input type="checkbox"/> <b>NO</b>

Approval Signatures <i>(all applicable parties)</i>				
	Name	Title	Signature	Date
Quality				
Production				
Operations				

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