This form, when completed, will be classified as '**For official use only**'.
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OTC medicine evaluation

Analytical validation summary

Analytical method number:	
Assay/identification (circle) of:	
Method type (eg. HPLC, GC, IR):	

Performance parameter	Results				Page no.	Met acceptance criteria Y/N
Accuracy **Typically determined at three concentrations over the range.**	**Concentration determined at (% of nominal)**	**Percentage recovery**	**RSD**			
Precision	**Variable assessed (e.g. analyst, equipment)**	**Number of replicates**	**Mean**	**RSD**		
Intermediate						
Repeatability	N/A N/A					

Performance parameter	Results			Page no.	Met acceptance criteria Y/N
Linearity/range	**Concentration determined at (% of nominal)**	**%, %, %, %, %, %**			
	Correlation coefficient r^2				
	y-intercept (%)				
Specificity **Chromatograms to support the specificity of the method must be provided. Include the page numbers of the relevant supporting chromatograms.**		**Peaks interfering with the analyte (Y/N)**			
	Placebo/excipients				
	Other actives (state)				
	Related substances (state)				
	Other (state)				
Specificity Forced degradation **Forced degradation studies may not be necessary for active assays where known degradants have been used to establish specificity.** **Include the page numbers of the relevant supporting chromatograms.**		Y/N	If yes, state any relevant details (e.g. % decrease in recovery, stressing conditions)		
	Decreased recovery of the analyte after stressing.				
	New peaks formed.				
	Any interfering peaks.				
	Peak purity acceptable.				
Detection limit (LOD)					

Performance parameter	Results	Page no.	Met acceptance criteria Y/N
Quantitation limit (LOQ)			
Other (e.g. robustness, solution stability)			

Name			
Signature		Date	