Trade Name: -					
Chemical Name: **Titanium dioxide**					
CAS No.:[13463-67-7]					
Raw material/ Excipient ■	Starting material/ Intermediate □	API product □	Semi-finished product □	Finished product□	
Method of analysis:	USP ■	BP □	EP □	JP □	In House □
Handling and storage:					

Chemical specification				
No.	**Item**	**Standard-Specification**	**Ref.**	**Recommendation**
1	**Appearance**	White or almost white powder.	USP43	
2	**Solubility**	Practically insoluble in water. It does not dissolve in dilute mineral acids but dissolves slowly in hot concentrated sulfuric acid.	USP43	
3	**Identification**	A: When strongly heated, it becomes pale yellow, the colour disappears on cooling. B: An orange-red colour appears. C: To 5 mL of solution S2 add 0.5g of zinc R in granules. After 45 min, the mixture has a violet-blue colour.	USP43	
4	**Appearance of solution**	Solution S2 is not more opalescent than reference Suspension II and is colourless.	USP43	
5	**Acidity or alkalinity**	Not more than 1.0 mL of 0.01 M hydrochloric acid or 0.01 M sodium hydroxide is required to change the colour of the indicator.	USP43	
6	**Water soluble substances**	Maximum 25 mg	USP43	
7	**Antimony**	Maximum 100 ppm	USP43	
8	**Arsenic**	Maximum 5 ppm	USP43	
9	**Barium**	After 30 min, any opalescence in the solution is not more intense than that in a mixture of 10 mL of solution S1 and 1 mL of distilled water R.	USP43	

Written by	Reviewed by		Approved by	
QC Supervisor	QC Manager	R&D Manager	QA Manager	Qualified Person
Ms. Ashrafi	Dr. Dini		Eng. Nazarpour	Dr. Ramin

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10	**Iron**	Maximum 200 ppm	USP43	
11	**Assay**	98.0% to 100.5%	USP43	

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