

	RAW MATERIAL SPECIFICATION		Page No.	1 of 2
	Quality Control Department			
Name of Raw Material	FD&C BLUE 2			
Specification No.	RM/SPEC/IH/096-01	Supersedes No.:	NA	
Reference	IH	Effective Date	20/12/2023	
Ref. Annexure No.	A/SOP/QC/030/02	Review Month	NOV'2028	

GENERAL INFORMATION

Pharmacopeial reference : In House

Special requirement of pack : Material should be packed in LDPE bag in HDPE/ Fiber drum.

Approved vendor : Please refer current approved vendor list.

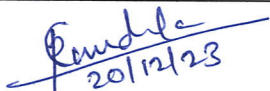
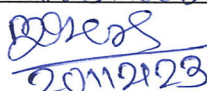
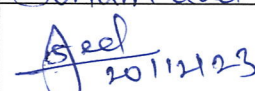
Handling hazards : Refer Material Safety Data Sheet

Quantity to be sampled

Analysis Sample	Control sample
30 g	60 g

Retest Period : 12 Months

Storage : Store in an ambient temperature and dry place.

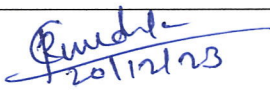
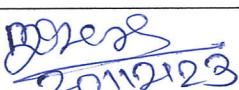
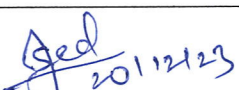
	PREPARED BY	REVIEWED BY	APPROVED BY
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Sign/Date	 20/12/23	 20/12/23	 20/12/23
Designation	SO. Executive	SO. Executive	Sr. manager
Department	Quality control	Quality Control	Quality Assurance

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Name of Raw Material	FD&C BLUE 2		
Specification No.	RM/SPEC/IH/096-01		

Sr. No.	TEST	SPECIFICATIONS	REFERENCE
01.	Description #	Dark Blue powder	In House
02.	Solubility #	Soluble in water	In House
03.	Water insoluble matter	NMT 0.2 %	In House
04.	Volatile matter at 135° C	NMT 15.0 %	In House
05.	Pure Dye Content #	85.0 % - 100.0 %	In House
# : Re-evaluation tests			

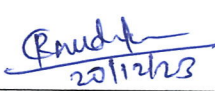
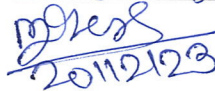
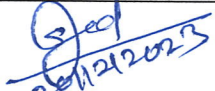
REVISION HISTORY FOR SPECIFICATION:

Revision No.	Revision Description	Effective Date
01	New Document prepared as per Approved Change control CC/PD/23/019	20/12/2023

	PREPARED BY	REVIEWED BY	APPROVED BY
Sign/Date	 20/12/23	 20/12/23	 20/12/23

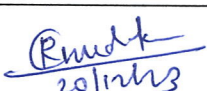
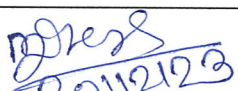
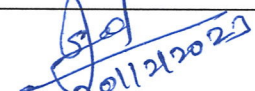
	RAW MATERIAL STANDARD TEST PROCEDURE (STP)		Page No.	1 of 3
	Quality Control Department			
Name of Material	FD&C BLUE 2			
STP No.	RM/STP/IH/096-01			
Reference	IH	Supersedes No.	01	
Ref. SPEC No.	RM/SPEC/IH/096-01	Effective Date	20/12/2023	
Ref. Annexure No.	A/SOP/QC/030/06	Review Month	Nov 2028	

01.	Description: Take about 2 to 3 g of test sample and transferred into a clean and dry petri dish. Spread it uniformly by spatula; observe its color. Specification: Dark blue powder.	Instrument: Balance
02.	Solubility: Soluble in water: Weigh about 1.0 g of test sample and transfer into a clean and dry test tube, add 30 ml of water. Shake well and observe the solubility. Specification: Soluble in water.	Instrument: Balance
03.	Water Insoluble Matter: Weigh a glass sintered glass crucible, Put 2 g of test sample in to 600 ml beaker, dissolve in hot temperature is 80° C - 90° C deionized water and allow the solution to cool room temperature. Filter the solution through the sintered crucible, wash with deionized water until the washings are colorless. Dry the crucible at 135° C for 3 hours, allow to cool in a desiccator for 30 minutes and weigh. Calculate the % Water Insoluble Matter as per following formula, $\% \text{ Water Insoluble Matter} = \frac{(M_2 - M_1)}{M} \times 100$	Instrument: Balance, Oven

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Department	Quality control	Quality Control	quality assurance

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	Where, M_1 = Empty weight of sintered glass crucible. M_2 = Weight of sintered glass crucible after drying M = Weight of Sample Specifications : Not more than 0.2 %	
04.	Volatile Matter at 135° C: Instrument: Balance, Oven Take 1.5 g of sample in a glass stoppered weighing bottle. Heat for 2 hours in an oven at 135° C $\pm$ 2 ° C, cool in a desiccator and weigh until constant weight. Calculate the Volatile matter as per following formula, $\text{Volatile Matter at 135° C} = \frac{(W_2 - W_4)}{(W_2 - W_1)} \times 100$ Where, W_1 = Weight of the empty weighing bottle (g) W_2 = Weight of the weighing bottle with test sample before drying (g) W_3 = Weight of the weighing bottle with residue after drying (g) W_4 = Weight of the weighing bottle with residue after drying (g) (Constant weight) Specifications : NMT 15.0 %	
05.	Pure Dye Content : Instrument: Balance, UV spectrophotometer Ammonium Acetate: Weigh the 3.3915 g ammonium acetate (Molecular weight is 77.08 gm/mole) in 1 liter volumetric flask add deionized water sonicate to dissolve completely. Make upto the mark with deionized water and shake well. Procedure: Weigh the dry sample accurately 90-110 mg and transfer into a 1 liter volumetric flask and dissolve in deionized water sonicate to dissolve completely and dilute upto mark with deionized water. Pipette out 10 ml of this solution and dilute to 100 ml with 0.044 N ammonium acetate solution as a Buffer to make a final concentration for 0.9 – 1.1 mg/100	

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Sign/Date			

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ml. Determine the maximum absorbance (ABS) of this solution with distilled water as blank, in a glass cell with 10 mm light path by scanning visible range 400-750 nm Or photometric at 610 ± 4 nm. $E(1\%/1\text{cm}) = 480$, a = absorptivity 0.0478

$$A \times 1L \times 100 \text{ mL} \times 100$$

% Pure Dye content = -----

$$a \times b \times \text{Wt.} \times 10 \text{ mL}$$

Where,

a = absorptivity (L/(mg.cm))

b = cell path length (cm)

A = absorbance of diluted solution at λ max corrected for absorbance of blank

1L = volume of concentrated solution

100 ml = volume of diluted solution

10 ml = volume of aliquot of concentrated solution

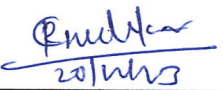
Wt = weight of sample (mg)

100 = factor for conversion to percent

Specifications : 85.0 % - 100.0 %

REVISION HISTORY FOR STANDARD TEST PROCEDURE:

Revision No.	Revision Description	Effective Date
01	New Document prepared as per Approved Change control CC/QC/23/019	20/12/2023

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